EXTRAORDINARY
GOVERNMENT OF FIJI GAZETTE SUPPLEMENT

No. 37 SUNDAY, 1st AUGUST 2021

[LEGAL NOTICE NO. 73]

MEDICINAL PRODUCTS ACT 2011

Medicinal Products (Classification Scheme) Regulations 2021

IN exercise of the powers conferred on me by sections 26 and 52 of the Medicinal Products Act 2011, I hereby make these Regulations—

Short title and commencement

1.—(1) These Regulations may be cited as the Medicinal Products (Classification Scheme) Regulations 2021.

(2) These Regulations come into force on the date of publication in the Gazette.

Interpretation

2. In these Regulations, unless the context otherwise requires—

"complementary medicine" is a medicinal product containing ingredients such as herbs, vitamins and minerals, nutritional or dietary supplements, homoeopathic medicines and aromatherapy products claiming to be for therapeutic use and consisting wholly or principally of one or more designated active ingredients, each of which has a clearly established identity and a traditional use;

"designated active ingredient" means an active ingredient, or a kind of active ingredient, listed below—

(a) a choline salt;

(b) a homoeopathic preparation;

(c) a lipid, including an essential fatty acid or phospholipid;

(d) a microorganism, whole or extracted, except a vaccine;

(e) a mineral including a mineral salt and a naturally occurring mineral;

(f) a mucopolysaccharide;

(g) a substance produced by or obtained from bees, including royal jelly, bee pollen and propolis;

(h) a sugar, polysaccharide or carbohydrate;

(i) a vitamin or provitamin;

(j) an amino acid;

(k) an essential oil;

(l) charcoal;

(m) non-human animal material (or a synthetically produced substitute for material of that kind) including dried material, bone and cartilage, fats and oils and other extracts or concentrates; or

(n) plant or herbal material (or a synthetically produced substitute for material of that kind), including plant fibres, enzymes, algae, fungi, cellulose and derivatives of cellulose and chlorophyll;

"medical professional" refers to a registered medical practitioner, nurse practitioner, dentist or veterinary surgeon; and

"nutritional or dietary supplement" is a manufactured product in a pill, capsule, tablet or liquid form intended to supplement the diet when taken by mouth.

General sale medicines

3.—(1) The medicines listed in Schedule 1 are classified as general sale medicines.

(2) General sale medicines are medicines which may be sold at any shop without supervision from a pharmacist or a medical professional.

(3) General sale medicines must be—

(a) clearly labelled with dosage instructions or directions for use in the English language; and

(b) stored in accordance with the manufacturer's storage requirements.

Pharmacy medicines

4.—(1) The medicines listed in Schedule 2 are classified as pharmacy medicines.

(2) Pharmacy medicines are medicines, the sale of which may require professional advice from a pharmacist and which should be available from a pharmacy or where a pharmacy service is not available, from a licensed person.

(3) Pharmacy medicines must be—

(a) clearly labelled with dosage instructions or directions for use in the English language;

(b) labelled to indicate that it is only to be made available from a pharmacy; and

(c) stored in accordance with the manufacturer's storage requirements.

Pharmacist only medicines

5.—(1) The medicines listed in Schedule 3 are classified as pharmacist only medicines.

(2) Pharmacist only medicines are medicines—

(a) available for sale from pharmacies without a prescription from a medical professional; and

(b) the sale of which requires professional advice from a pharmacist.

(3) Pharmacist only medicines must be—

(a) clearly labelled with dosage instructions or directions for use in the English language;

(b) clearly labelled with the words "PHARMACIST ONLY MEDICINE";

(c) stored in accordance with the manufacturer's storage requirements; and

(d) displayed in an area in the pharmacy that is not accessible to the public.

Prescription only medicines

6.—(1) The medicines listed in Schedule 4 are classified as prescription only medicines.

(2) Prescription only medicines are medicines, the sale of which requires a prescription from a medical professional.

(3) Prescription only medicine—

(a) when prescribed by a medical professional, must be clearly labelled with the dosage instructions or directions for use in the English language;

(b) that is not a vaccine, must be stored in accordance with the manufacturer's storage requirements; and

(c) that is a vaccine, must be stored and transported with the recommended cold chain requirements.

Hazardous poisons

7.—(1) The poisons listed in Schedule 5 are classified as hazardous poisons.

(2) Hazardous poisons are poisons with a low potential for causing harm to humans and animals.

(3) Hazardous poisons must be—

(a) packaged distinctively and clearly labelled with warnings and safety directions in the English language; and

(b) stored in accordance with the manufacturer's storage requirements.

Controlled poisons

8.—(1) The poisons listed in Schedule 6 are classified as controlled poisons.

(2) Controlled poisons are poisons with a moderate potential for causing harm to humans and animals.

(3) Controlled poisons must be—

(a) packaged distinctively and clearly labelled with warnings and safety directions in the English language; and

(b) stored in accordance with the manufacturer's storage requirements.

Dangerous poisons

9.—(1) The poisons listed in Schedule 7 are classified as dangerous poisons.

(2) Dangerous poisons are poisons with a high potential for causing harm to humans and animals at low exposure and which require special precautions during manufacture, handling or use and are available only to specialised or authorised users who have the skills necessary to handle these poisons safely.

(3) Dangerous poisons must be—

(a) packaged distinctively and clearly labelled with instructions or directions for use in the English language; and

(b) stored in accordance with the manufacturer's storage requirements.

Dangerous drugs

10.—(1) The drugs listed in Schedule 8 are classified as dangerous drugs.

(2) Dangerous drugs are substances or products which are available for use but can only be imported by the Chief Pharmacist for approved medical use.

(3) Dangerous drugs must be—

(a) clearly labelled with dosage instructions or directions for use in the English language as prescribed by a medical professional; and

(b) stored in accordance with the manufacturer's storage requirements.

Prohibited substances

11.—(1) The substances listed in Schedule 9 are classified as prohibited substances.

(2) Prohibited substances are substances which are prohibited for import or use except when required for industrial, educational, advisory or research purposes, the import and use of which requires a prohibited substance permit from the Minister.

(3) Prohibited substances must be—

(a) clearly labelled in the English language; and

(b) stored in accordance with the manufacturer's storage requirements.

Prohibited poisons

12.—(1) The substances listed in Schedule 10 are classified as prohibited poisons.

(2) Prohibited poisons are substances which are prohibited for the purpose listed for each poison unless otherwise exempted.

General exemptions

13.—(1) The substances listed in Schedule 11 are classified as general exemptions.

(2) General exemption refers to a list of products, goods, articles or things not regulated by the Board even if the product, good, article or thing contains substances listed in schedules 1 to 10.

Offence

14. Any person who fails to comply with these Regulations commits an offence and is liable under section 46 of the Act.

Made this 30th day of July 2021.

I. WAQAINABETE
Minister for Health and Medical Services

SCHEDULE 1
(Regulation 3)

GENERAL SALE MEDICINES

Antacids, when prepared as liquids, tablets and granules that do not contain a substance specified in schedules 2 to 10.

Antiseptics for use on the skin, when prepared as liquids, creams and sprays that do not contain a substance specified in schedules 2 to 10.

Castor oil.

Cod liver oil.

Complementary medicines that do not contain a substance specified in schedules 2 to 10, provided the labelling requirements and storage conditions recommended for such products are strictly complied with.

Cough preparations containing natural products that do not contain a substance specified in schedules 2 to 10.

Ear drops in packs of 15 ml or less that do not contain a substance specified in schedules 2 to 10.

Eucalyptus oil—

(a) when packed in containers having a nominal capacity of 15 ml or less fitted with a restricted flow insert, and labelled with the warnings—

(i) "KEEP OUT OF REACH OF CHILDREN"; and

(ii) "NOT TO BE TAKEN";

(b) when packed in containers having a nominal capacity of 25 ml or less fitted with a restricted flow insert and child-resistant closure, and labelled with the warnings—

(i) "KEEP OUT OF REACH OF CHILDREN"; and

(ii) "NOT TO BE TAKEN"; or

(c) in preparations containing 25 per cent or less of eucalyptus oil.

Eye drops, sterile, in packs of 15 ml or less that do not contain a substance specified in schedules 2 to 10.

Eye lotions, sterile, in packs of 150 ml or less that do not contain a substance specified in schedules 2 to 10.

Glycerol (glycerine).

Lozenges and pastilles that do not contain a substance specified in schedules 2 to 10.

Lucca oil.

Magnesium sulfate (epsom salts).

Medicines for use on the skin that do not contain a substance specified in schedules 2 to 10.

Mouthwashes that do not contain a substance specified in schedules 2 to 10.

Paracetamol for therapeutic use—

(a) except when included in schedules 2, 3 or 4;

(b) in tablets or capsules each containing 500 mg or less of paracetamol as the only therapeutically active constituent other than effervescent agents, when—

(i) packed in blister or strip packaging or in containers with child-resistant closures;

(ii) in a primary pack containing not more than 100 such tablets or capsules;

(iii) the primary pack is labelled with the statements to the following effect—

(A) "ADULTS—KEEP TO THE RECOMMENDED DOSE. DO NOT TAKE THIS MEDICINE FOR LONGER THAN A FEW DAYS AT A TIME UNLESS ADVISED TO BY A DOCTOR";

(B) "CHILDREN AND ADOLESCENTS—KEEP TO THE RECOMMENDED DOSE. DO NOT TAKE THIS MEDICINE FOR LONGER THAN 48 HOURS AT A TIME UNLESS ADVISED TO BY A DOCTOR";

(C) "IF AN OVERDOSE IS SUSPECTED, RING A DOCTOR OR GO TO A HOSPITAL STRAIGHT AWAY EVEN IF YOU FEEL WELL BECAUSE OF THE RISK OF DELAYED, SERIOUS LIVER DAMAGE";

(D) "DO NOT TAKE WITH OTHER PRODUCTS CONTAINING PARACETAMOL, UNLESS ADVISED TO DO SO BY A DOCTOR OR PHARMACIST"; and

(iv) not labelled for the treatment of children 6 years of age or less.

Potassium acid tartrate (cream of tartar).

Potassium nitrate (saltpetre).

Senna.

Sodium bicarbonate.

Sodium carbonate.

Sodium sulfate (glauber salts).

Sulfur.

Toothache drops in packs of 15 ml or less that do not contain a substance specified in schedules 2 to 10.

SCHEDULE 2
(Regulation 4)

PHARMACY MEDICINES

Acetic acid (excluding its salts and derivatives) and preparations containing more than 80 per cent of acetic acid (CH_3COOH) for therapeutic use.

Acetylcysteine in preparations for oral use except when labelled with a recommended daily dose of 1 g or less of acetylcysteine.

Aconitum spp. for therapeutic use in adults—

(a) in preparations for oral use in packs each containing 0.2 mg or less of total alkaloids except in packs containing 0.02 mg or less of total alkaloids; or

(b) in preparations for dermal use containing 0.02 per cent or less of total alkaloids, in packs each containing 0.2 mg or less of total alkaloids except in packs containing 0.02 mg or less of total alkaloids.

Alimemazine when combined with one or more other therapeutically active substances in solid oral preparations when—

(a) at least one of the other therapeutically active substances is a sympathomimetic decongestant; or

(b) in a day-night pack containing alimemazine in the bed-time dose where the day and night doses are in the same immediate container or immediate wrapper,

except in preparations for the treatment of children under 2 years of age.

Aloxiprin.

Amorolfine in preparations for topical use except in preparations for the treatment of tinea pedis.

Antazoline in eye drops.

Aspirin except—

(a) when included in schedules 4, 5 or 6;

(b) in individually wrapped powders or sachets of granules each containing 650 mg or less of aspirin as the only therapeutically active constituent other than an effervescent agent when—

(i) enclosed in a primary pack that contains 12 or less such powders or sachets of granules; and

(ii) compliant with the labelling requirements under the Act;

(c) in tablets or capsules each containing no other therapeutically active constituent other than an effervescent agent when—

(i) packed in blister or strip packaging or in a container with a child-resistant closure;

(ii) in a primary pack of not more than 25 tablets or capsules, each containing 325 mg or less of aspirin, or in a primary pack of not more than 16 tablets or capsules, each containing 500 mg or less of aspirin; and

(iii) compliant with the labelling requirements under the Act; or

(d) in tablets or capsules each containing no other therapeutically active constituent other than an effervescent agent when—

(i) packed in blister or strip packaging or in a container with a child-resistant closure;

(ii) in a primary pack containing 100 or less tablets or capsules, each containing 100 mg or less of aspirin when packed and labelled for the prevention of cardiovascular disease or for the inhibition of platelet aggregation; and

(iii) compliant with the labelling requirements under the Act.

Atropa belladonna (belladonna)—

(a) for external use in preparations containing 0.03 per cent or less of total solanaceous alkaloids; or

(b) for oral use—

(i) in undivided preparations containing 0.03 per cent or less of total solanaceous alkaloids when labelled with a dose of 0.3 mg or less of total solanaceous alkaloids and a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids; or

(ii) in divided preparations containing 0.3 mg or less of total solanaceous alkaloids per dosage unit, when labelled with a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids.

Atropine (excluding atropine methonitrate) for oral use—

(a) in undivided preparations containing 0.03 per cent or less of total solanaceous alkaloids when labelled with a dose of 0.3 mg or less of total solanaceous alkaloids and a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids; or

(b) in divided preparations containing 0.3 mg or less of total solanaceous alkaloids per dosage unit when labelled with a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids.

Azelaic acid in dermal preparations.

Azelastine—

(a) in preparations for nasal use;

(b) in topical eye preparations containing 0.05 per cent or less of azelastine.

Beclometasone in aqueous nasal sprays delivering 50 μg or less of beclometasone per actuation when the maximum recommended daily dose is no greater than 400 μg and when packed in a primary pack containing 200 actuations or less, for the prophylaxis or treatment of allergic rhinitis for up to 6 months in adults and children 12 years of age and over.

Benzocaine in preparations for topical use other than eye drops—

(a) containing 10 per cent or less of total local anaesthetic substances, except in dermal preparations containing 2 per cent or less of total local anaesthetic substances; or

(b) in divided preparations containing 200 mg or less of total local anaesthetic substances per dosage unit, except in lozenges containing 30 mg or less of total local anaesthetic substances per dosage unit.

Benzoyl peroxide in preparations for human external therapeutic use containing 10 per cent or less of benzoyl peroxide except in preparations containing 5 per cent or less of benzoyl peroxide.

Benzydamine in preparations for topical use, except—

(a) in preparations for dermal use;

(b) in divided topical oral preparations containing 3 mg or less of benzydamine; or

(c) in undivided topical oral preparations containing 0.3 per cent or less of benzydamine in a primary pack containing not more than 50 ml.

Bephenium salts.

Bifonazole in preparations for dermal use except—

(a) in preparations containing 1 per cent or less of bifonazole for the treatment of the scalp; or

(b) in preparations for the treatment of tinea pedis.

Bromhexine.

Brompheniramine when combined with one or more other therapeutically active substances in oral preparations when—

(a) at least one of the other therapeutically active substances is a sympathomimetic decongestant; or

(b) in a day-night pack containing brompheniramine in the bed-time dose where the day and night doses are in the same immediate container or immediate wrapper,

except in preparations for the treatment of children under 2 years of age.

Budesonide in aqueous nasal sprays delivering 64 μg or less of budesonide per actuation when the maximum recommended daily dose is no greater than 400 μg, for the prophylaxis or treatment of allergic rhinitis for up to 6 months in adults and children 12 years of age and over.

Carbetapentane except in preparations containing 0.5 per cent or less of carbetapentane.

Carbocisteine.

Cetirizine in preparations for oral use except in divided preparations for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when—

(a) in a primary pack containing not more than 10 days' supply; and

(b) labelled with a recommended daily dose not exceeding 10 mg of cetirizine.

Chlophedianol.

Chlorbutanol for human use in topical preparations containing 5 per cent or less of chlorbutanol except in preparations containing 0.5 per cent or less of chlorbutanol.

Chloroform in preparations for therapeutic use except—

(a) when included in Schedule 4; or

(b) in preparations containing 0.5 per cent or less of chloroform.

Chlorphenamine when combined with one or more other therapeutically active substances in oral preparations when—

(a) at least one of the other therapeutically active substances is a sympathomimetic decongestant; or

(b) in a day-night pack containing chlorphenamine in the bed-time dose where the day and night doses are in the same immediate container or immediate wrapper,

except in preparations for the treatment of children under 2 years of age.

Ciclopirox—

(a) in preparations for dermal use containing 2 per cent or less of ciclopirox except in preparations for the treatment of tinea pedis; or

(b) in preparations for application to the nails containing 8 per cent or less of ciclopirox.

Cinchocaine in preparations for topical use other than eye drops, containing 0.5 per cent or less of total local anaesthetic substances.

Cinnamedrine.

Clotrimazole for human use in dermal preparations and for application to the nails except in preparations for the treatment of tinea pedis.

Creosote derived from wood other than beechwood for human therapeutic use, except in preparations containing 10 per cent or less of creosote derived from wood other than beechwood.

Datura spp. for oral use—

(a) in undivided preparations containing 0.03 per cent or less of total solanaceous alkaloids when labelled with a dose of 0.3 mg or less of total solanaceous alkaloids and a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids, or

(b) in divided preparations containing 0.3 mg or less of total solanaceous alkaloids per dosage unit when labelled with a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids,

except when separately specified in the schedules to these Regulations.

Datura stramonium (stramonium) for oral use when—

(a) in undivided preparations containing 0.03 per cent or less of total solanaceous alkaloids when labelled with a dose of 0.3 mg or less of total solanaceous alkaloids and a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids; or

(b) in divided preparations containing 0.3 mg or less of total solanaceous alkaloids per dosage unit when labelled with a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids,

except for smoking or burning.

Datura tatula (stramonium) for oral use—

(a) in undivided preparations containing 0.03 per cent or less of total solanaceous alkaloids when labelled with a dose of 0.3 mg or less of total solanaceous alkaloids and a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids; or

(b) in divided preparations containing 0.3 mg or less of total solanaceous alkaloids per dosage unit when labelled with a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids,

except for smoking or burning.

Delphinium staphisagria except in preparations containing 0.2 per cent or less of delphinium staphisagria.

Desloratadine in preparations for oral use.

Dexchlorphenamine when combined with one or more other therapeutically active substances in oral preparations when—

(a) at least one of the other therapeutically active substances is a sympathomimetic decongestant; or

(b) in a day-night pack containing dexchlorphenamine in the bed-time dose where the day and night doses are in the same immediate container or immediate wrapper,

except in preparations for the treatment of children under 2 years of age.

Dextromethorphan (excluding its stereoisomers) when supplied in a pack containing 600 mg or less of dextromethorphan and with a recommended daily dose of 120 mg or less of dextromethorphan.

Dibromopropamidine for ophthalmic use.

Diclofenac when—

(a) in divided preparations for oral use containing 12.5 mg or less of diclofenac per dosage unit in a pack containing 20 or less dosage units and labelled with a recommended daily dose of 75 mg or less of diclofenac;

(b) in preparations for dermal use containing 4 per cent or less of diclofenac except in preparations for dermal use containing 2 per cent or less of diclofenac or for the treatment of solar keratosis; or

(c) in transdermal preparations for topical use containing 140 mg or less of diclofenac.

Dimenhydrinate in primary packs of 10 doses or less for the prevention or treatment of motion sickness, except in preparations for the treatment of children under 2 years of age.

Diphenhydramine in oral preparations—

(a) in a primary pack containing 10 dosage units or less for the prevention or treatment of motion sickness; or

(b) when combined with one or more other therapeutically active substances when—

(i) at least one of the other therapeutically active substances is a sympathomimetic decongestant; or

(ii) in a day-night pack containing diphenhydramine in the bed-time dose where the day and night doses are in the same immediate container or immediate wrapper,

except in preparations for the treatment of children under 2 years of age.

Doxylamine when combined with one or more other therapeutically active substances in oral preparations when—

(a) at least one of the other therapeutically active substances is a sympathomimetic decongestant; or

(a) in a day-night pack containing doxylamine in the bed-time dose where the day and night doses are in the same immediate container or immediate wrapper,

except in preparations for the treatment of children under 2 years of age.

Duboisia leichhardtii for oral use—

(a) in undivided preparations containing 0.03 per cent or less of total solanaceous alkaloids when labelled with a dose of 0.3 mg or less of total solanaceous alkaloids and a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids; or

(b) in divided preparations containing 0.3 mg or less of total solanaceous alkaloids per dosage unit when labelled with a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids.

Duboisia myoporoides for oral use—

(a) in undivided preparations containing 0.03 per cent or less of total solanaceous alkaloids when labelled with a dose of 0.3 mg or less of total solanaceous alkaloids and a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids; or

(b) in divided preparations containing 0.3 mg or less of total solanaceous alkaloids per dosage unit when labelled with a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids.

Econazole for human use in dermal preparations except in preparations for the treatment of tinea pedis.

Esomeprazole in oral preparations containing 20 mg or less per dosage unit for the relief of heartburn and other symptoms of gastro-oesophageal reflux disease, in packs containing not more than 14 days' supply.

Etafedrine.

Ether for therapeutic use except—

(a) when included in Schedule 4; or

(b) in preparations containing 10 per cent or less of ether.

Etofenamate in preparations for external use.

Famotidine when sold in the manufacturer's original pack containing not more than 14 days' supply.

Felbinac in preparations for external use.

Fexofenadine in preparations for oral use except in divided preparations for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when—

(a) in a primary pack containing 20 dosage units or less and not more than 10 days' supply; and

(b) labelled with a recommended daily dose not exceeding 120 mg of fexofenadine.

Fluorides for human use—

(a) in preparations for ingestion containing 0.5 mg or less of fluoride ion per dosage unit; or

(b) in liquid preparations for topical use containing 1000 mg/kg or less of fluoride ion, in a container with a child-resistant closure—

(i) for therapeutic use except in preparations containing 220 mg/kg or less of fluoride ion, in packs containing not more than 120 mg total fluoride when fitted with a child-resistant closure and compliant with the labelling requirements under the Act;

(ii) for non-therapeutic use when labelled with warnings to the following effect—

(A) "DO NOT SWALLOW"; and

(B) "DO NOT USE (THIS PRODUCT/INSERT NAME OF PRODUCT) IN CHILDREN 6 YEARS OF AGE OR LESS",

except in preparations containing 220 mg/kg or less of fluoride ion, in packs containing not more than 120 mg total fluoride, when fitted with a child-resistant closure and labelled with warnings to the following effect—

(AA) "DO NOT SWALLOW"; and

(BB) "DO NOT USE (THIS PRODUCT/INSERT NAME OF PRODUCT) IN CHILDREN 6 YEARS OF AGE OR LESS",

except in preparations containing 15 mg/kg or less of fluoride ion or preparations for supply to registered dental professionals or by approval of an appropriate authority.

Flurbiprofen in preparations for topical oral use when—

(a) in divided preparations containing 10 mg or less of flurbiprofen per dosage unit; or

(b) in undivided preparations containing 0.25 per cent or less, or 10 mg or less per dose, of flurbiprofen.

Fluticasone propionate (excluding its derivatives) in aqueous nasal sprays delivering 50 μg or less of fluticasone per actuation when the maximum recommended daily dose is no greater than 400 μg, for the prophylaxis or treatment of allergic rhinitis for up to 6 months in adults and children 12 years of age and over.

Folic acid for human therapeutic use except—

(a) when included in Schedule 4; or

(b) in preparations containing 500 μg or less of folic acid per recommended daily dose.

Folinic acid for human therapeutic use except—

(a) when included in Schedule 4; or

(b) in preparations containing 500 μg or less of folinic acid per recommended daily dose.

Formaldehyde (excluding its derivatives) for human therapeutic use except—

(a) in oral hygiene preparations containing 0.1 per cent or less of free formaldehyde; or

(b) in other preparations containing 0.2 per cent or less of free formaldehyde.

Gelsemium sempervirens.

Glutaral for human therapeutic use.

Guaifenesin in a modified release dosage form of 1200 mg or less of guaifenesin with a recommended daily dose of 2400 mg or less when not labelled for the treatment of children under 12 years of age.

Hexachlorophene in preparations for human use containing 3 per cent or less of hexachlorophene except—

(a) in preparations for use on infants, as specified in Schedule 4;

(b) in preparations for cosmetic use, as specified in Schedule 6; or

(c) in other preparations containing 0.75 per cent or less of hexachlorophene.

Hydrocortisone and hydrocortisone acetate, but excluding other salts and derivatives, in preparations for human therapeutic use—

(a) for dermal use in preparations containing 0.5 per cent or less of hydrocortisone, in packs containing 30 g or less of such preparations, containing no other therapeutically active constituent other than an antifungal substance;

(b) for dermal use in preparations containing 1 per cent or less of hydrocortisone, in packs containing 15 g or less of such preparations, containing an antifungal substance and no other therapeutically active constituent—

(i) for the treatment of tinea (tinea pedis, tinea cruris, tinea corporis) and other fungal skin infections; and

(ii) not labelled for the treatment of children under 12 years of age; or

(c) for rectal use in preparations containing 0.5 per cent or less of hydrocortisone, when combined with a local anaesthetic substance but no other therapeutically active constituent except unscheduled astringents—

(i) in undivided preparations in packs of 35 g or less; or

(ii) in packs containing 12 or less suppositories.

Hydroquinone (excluding monobenzone and alkyl ethers of hydroquinone included in Schedule 4) in preparations for human external therapeutic or cosmetic use containing 2 per cent or less of hydroquinone except—

(a) in hair preparations containing 0.3 per cent or less of hydroquinone; or

(b) in cosmetic nail preparations containing 0.02 per cent or less of hydroquinone.

Hyoscine—

(a) for transdermal use in preparations containing 2 mg or less of total solanaceous alkaloids per dosage unit; or

(b) for oral use—

(i) in undivided preparations containing 0.03 per cent or less of total solanaceous alkaloids, when labelled with a dose of 0.3 mg or less of total solanaceous alkaloids and a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids; or

(ii) in divided preparations containing 0.3 mg or less of total solanaceous alkaloids per dosage unit when labelled with a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids.

Hyoscine butylbromide as the only therapeutically active substance, in divided preparations for oral use, containing 20 mg or less of hyoscine butylbromide per dosage unit in a pack containing 200 mg or less of hyoscine butylbromide.

Hyoscyamine—

(a) for external use in preparations containing 0.03 per cent or less of total solanaceous alkaloids; or

(b) for oral use—

(i) in undivided preparations containing 0.03 per cent or less of total solanaceous alkaloids, when labelled with a dose of 0.3 mg or less of total solanaceous alkaloids and a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids; or

(ii) in divided preparations containing 0.3 mg or less of total solanaceous alkaloids per dosage unit when labelled with a recommended daily dose of 1.2 mg or less total solanaceous alkaloids.

Hyoscyamus niger for oral use—

(a) in undivided preparations containing 0.03 per cent or less of total solanaceous alkaloids when labelled with a dose of 0.3 mg or less of total solanaceous alkaloids and a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids; or

(b) in divided preparations containing 0.3 mg of total solanaceous alkaloids or less per dosage unit when labelled with a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids,

except in a pack containing 0.03 mg or less of total solanaceous alkaloids.

Ibuprofen in preparations for oral use when labelled with a recommended daily dose of 1200 mg or less of ibuprofen—

(a) in liquid preparations when sold in the manufacturer's original pack containing 8 g or less of ibuprofen; or

(b) in divided preparations, each containing 200 mg or less of ibuprofen, in packs of not more than 100 dosage units except when—

(i) it is the only therapeutically active constituent (other than phenylephrine or when combined with an effervescent agent);

(ii) packed in blister or strip packaging or in a container with a child-resistant closure;

(iii) in a primary pack containing not more than 25 dosage units;

(iv) compliant with the labelling requirements under the Act;

(v) not labelled for the treatment of children 6 years of age or less; and

(vi) not labelled for the treatment of children under 12 years of age when combined with phenylephrine.

Indanazoline.

Indometacin in preparations for external use containing 1 per cent or less of indometacin.

Iodine—

(a) in preparations for human internal therapeutic use containing 300 μg or more of iodine per recommended daily dose; or

(b) in preparations for human external therapeutic use containing more than 2.5 per cent of available iodine (excluding salts, derivatives or iodophors),

except in oral preparations for use in prophylaxis and treatment in the event of radioactive iodine exposure under an emergency plan approved by an appropriate authority.

Ipratropium in preparations for nasal use.

Iron compounds (excluding iron oxides when present as an excipient, in divided preparations containing 10 mg or less of total iron oxides per dosage unit or in undivided preparations containing 1 per cent or less of total iron oxides) for human internal use except—

(a) when included in Schedule 4; or

(b) when labelled with a recommended daily dose of 24 mg or less of iron—

(i) in undivided preparations supplied in packs each containing 750 mg or less of iron; or

(ii) in divided preparations—

(A) containing more than 5 mg of iron per dosage unit in packs each containing 750 mg or less of iron; or

(B) containing 5 mg or less of iron per dosage unit.

Isoconazole for human use in dermal preparations.

Isopropamide in preparations for dermal use containing 2 per cent or less of isopropamide.

Ketoconazole in preparations for dermal use except—

(a) in preparations containing 1 per cent or less of ketoconazole for the treatment of the scalp; or

(b) in preparations for the treatment of tinea pedis.

Ketotifen for ophthalmic use in preparations containing 0.025 per cent or less of ketotifen.

Lansoprazole in oral preparations 15 mg or less of lansoprazole per dosage unit for the relief of heartburn and other symptoms of gastro-oesophageal reflux disease, in packs containing not more than 7 days' supply.

Levocabastine in topical eye or nasal preparations.

Levocetirizine in preparations for oral use except in divided preparations for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when—

(a) in a primary pack containing not more than 5 days' supply; and

(b) labelled with a recommended daily dose not exceeding 5 mg of levocetirizine.

Lidocaine in preparations for topical use other than eye drops—

(a) containing 10 per cent or less of total local anaesthetic substances, except—

(i) in dermal preparations containing 2 per cent or less of total local anaesthetic substances; or

(ii) in aqueous sprays for oromucosal use containing 0.6 per cent or less of total local anaeasthetic substances; or

(b) in divided preparations containing 200 mg or less of total local anaesthetic substances, except in lozenges containing 30 mg or less of total local anaesthetic substances per dosage unit.

Lindane in preparations for human external therapeutic use containing 2 per cent or less of lindane.

Lithium in preparations for dermal use containing 1 per cent or less of lithium except—

(a) when present as an excipient at 0.25 per cent or less of lithium; or

(b) in preparations containing 0.01 per cent or less of lithium.

Lobelia inflate except for smoking or burning.

Lobeline except in preparations for smoking or burning.

Lodoxamide in preparations for ophthalmic use.

Loperamide in divided preparations for oral use in packs of 20 dosage units or less except in preparations containing 2 mg or less of loperamide per dosage unit, in a primary pack containing 8 dosage units or less.

Loratadine in preparations for oral use except in divided preparations for the treatment of seasonal allergic rhinitis when—

(a) in a primary pack containing 10 dosage units or less when labelled for adults and children 6 years of age and over; and

(b) labelled with a recommended daily dose not exceeding 10 mg of loratadine.

Macrogols in preparations for oral use as a liquid concentrate for laxative use.

Mebendazole for human therapeutic use.

Meclozine in primary packs containing 12 or less tablets or capsules of meclozine for the prevention or treatment of motion sickness, except in preparations for the treatment of children under 2 years of age.

Mefenamic acid in divided preparations for oral use in packs of 30 or less dosage units for the treatment of dysmenorrhoea.

Mepyramine for dermal use.

Mercurochrome in preparations for external use containing 2 per cent or less of mercurochrome except when included in Schedule 6.

Mercury for external use in preparations containing 0.5 per cent or less of mercury.

Methoxamine in preparations for external use except in preparations containing 1 per cent or less of methoxamine.

Methoxyphenamine.

Methylephedrine.

Miconazole for human use in dermal preparations and for application to the nails except in preparations for the treatment of tinea pedis.

Minoxidil in preparations for dermal use containing 5 per cent or less of minoxidil.

Mometasone in aqueous nasal sprays delivering 50 μg or less of mometasone per actuation when the maximum recommended daily dose is no greater than 200 μg for the prophylaxis or treatment of allergic rhinitis for up to 6 months in adults and children 12 years of age and over.

Naphazoline.

Naproxen in divided preparations containing 250 mg or less of naproxen per dosage unit in packs of 30 or less dosage units.

Nicotine for use as an aid in withdrawal from tobacco smoking in preparations for oromucosal or transdermal use.

Niclosamide for human therapeutic use.

Nizatidine when sold in the manufacturer's original pack containing not more than 14 days' supply.

Noscapine.

Nystatin in dermal preparations.

Omeprazole in oral preparations containing 20 mg or less of omeprazole per dosage unit for the relief of heartburn and other symptoms of gastro-oesophageal reflux disease, in packs containing not more than 7 days' supply.

Oxetacaine (oxethazaine) in preparations for internal use.

Oxiconazole for dermal use except in preparations for the treatment of tinea pedis.

Oxymetazoline.

Oxyquinoline and its non-halogenated derivatives for human therapeutic use, except in preparations for external use containing 1 per cent or less of such substances.

Papaverine except when included in Schedule 4.

Pantoprazole in oral preparations containing 20 mg or less of pantoprazole per dosage unit for the relief of heartburn and other symptoms of gastro-oesophageal reflux disease, in packs containing not more than 7 days' supply.

Paracetamol for therapeutic use—

(a) in liquid preparations for oral use containing a maximum of 10 g of paracetamol per container;

(b) in tablets or capsules enclosed in a primary pack containing not more than 100 tablets or capsules;

(c) in individually wrapped powders or sachets of granules enclosed in a primary pack containing not more than 50 wrapped powders or sachets of granules; or

(d) in other preparations except—

(i) when included in schedules 3 or 4;

(ii) in individually wrapped powders or sachets of granules each containing 1000 mg or less of paracetamol as the only therapeutically active constituent (other than caffeine, phenylephrine and/or guaifenesin or when combined with effervescent agents) when—

(A) enclosed in a primary pack that contains not more than 10 such powders or sachets of granules;

(B) compliant with the labelling requirements under the Act;

(C) not labelled for the treatment of children 6 years of age or less; and

(D) not labelled for the treatment of children under 12 years of age when combined with caffeine, phenylephrine and/or guaifenesin; or

(iii) in tablets or capsules each containing 500 mg or less of paracetamol as the only therapeutically active constituent (other than caffeine, phenylephrine and/or guaifenesin or when combined with effervescent agents) when—

(A) packed in blister or strip packaging or in a container with a child-resistant closure;

(B) in a primary pack containing not more than 20 tablets or capsules;

(C) compliant with labelling requirements under the Act;

(D) not labelled for the treatment of children 6 years of age or less; and

(E) not labelled for the treatment of children under 12 years of age when combined with caffeine, phenylephrine and/or guaifenesin.

Paraformaldehyde (excluding its derivatives) for human therapeutic use except—

(a) in oral hygiene preparations containing 0.1 per cent or less of free formaldehyde; or

(b) in other preparations containing 0.2 per cent or less of free formaldehyde.

Phedrazine.

Phenazone for human external use.

Pheniramine—

(a) in eye drops; or

(b) when combined with one or more therapeutically active substances in oral preparations when—

(i) at least one of the other therapeutically active substances is a sympathomimetic decongestant; or

(ii) in a day-night pack containing pheniramine in the bed-time dose where the day and night doses are in the same immediate container or immediate wrapper,

except in preparations for the treatment of children under 2 years of age.

Phenol, or any homologue boiling below 220°c, for human therapeutic use except—

(a) when included in Schedule 4; or

(b) in preparations for external use containing 1 per cent or less of phenol and in preparations for external use containing 3 per cent or less of cresols and xylenols and other homologues of phenol.

Phenylephrine except—

(a) when included in Schedule 4;

(b) in oral preparations containing 50 mg or less of phenylephrine per recommended daily dose in packs containing 250 mg or less of phenylephrine; or

(c) in topical eye or nasal preparations containing 1 per cent or less of phenylephrine.

Pholcodine—

(a) in liquid preparations containing 0.5 per cent or less of pholcodine and with a recommended dose not exceeding 25 mg of pholcodine; or

(b) when compounded with one or more other therapeutically active substances in divided preparations containing 10 mg or less of pholcodine per dosage unit and with a recommended dose not exceeding 25 mg of pholcodine.

Piperazine for human therapeutic use.

Podophyllotoxin in preparations containing 0.5 per cent or less of podophyllotoxin for human use for the treatment of warts other than anogenital warts.

Podophyllum emodi (podophyllin) in preparations containing 10 per cent or less of podophyllin for human use for the treatment of warts other than anogenital warts.

Podophyllum peltatum (podophyllin) in preparations containing 10 per cent or less of podophyllin for human use for the treatment of warts other than anogenital warts.

Potassium chlorate for therapeutic use except in preparations containing 10 per cent or less of potassium chlorate.

Prilocaine in preparations for dermal use containing 10 per cent or less of total local anaesthetic substances.

Procyclidine in preparations containing 5 per cent or less of procyclidine for dermal use.

Promethazine in oral preparations—

(a) in a primary pack containing 10 dosage units or less for the prevention or treatment of motion sickness; or

(b) when combined with one or more other therapeutically active substances when—

(i) at least one of the other therapeutically active substances is a sympathomimetic decongestant; or

(ii) in a day-night pack containing promethazine in the bed-time dose where the day and night doses are in the same immediate container or immediate wrapper,

except in preparations for the treatment of children under 2 years of age.

Propamidine for ophthalmic use.

Pyrantel for human therapeutic use.

Pyrethrins, naturally occurring, being pyrethrolone, cinerolone or jasmolone esters of chrysanthemic or pyrethric acids, for human therapeutic use in preparations containing more than 10 per cent of such substances.

Pyrithione zinc for human therapeutic use, except in preparations for the treatment of the scalp containing 2 per cent or less of pyrithione zinc when compliant with the labelling requirements under the Act.

Rabeprazole in oral preparations containing 10 mg or less of rabeprazole per dosage unit for the relief of heartburn and other symptoms of gastro-oesophageal reflux disease, in packs containing not more than 7 days' supply.

Ranitidine in preparations supplied in the manufacturer's original pack containing not more than 14 days' supply except—

(a) in divided preparations for oral use containing 150 mg or less of ranitidine per dosage unit in the manufacturer's original pack containing not more than 14 dosage units; or

(b) in divided preparations for oral use containing 300 mg or less of ranitidine per dosage unit in the manufacturer's original pack containing not more than 7 dosage units.

Salicylamide except when included in Schedule 4.

Selenium in preparations for human therapeutic use except—

(a) for topical use containing 3.5 per cent or less of selenium sulfide;

(b) when included in Schedule 4; or

(c) for oral use with a recommended daily dose of 150 μg or less.

Silver for therapeutic use except—

(a) in solutions for human oral use containing 0.3 per cent or less of silver when compliant with the labelling requirements under the Act ; or

(b) in other preparations containing 1 per cent or less of silver.

Sodium cromoglycate in preparations for nasal or ophthalmic use.

Sodium nitrite for therapeutic use (excluding when present as an excipient).

Squill except in preparations containing 1 per cent or less of squill.

Sulconazole in preparations for dermal use.

Terbinafine for dermal use except in preparations for the treatment of tinea pedis.

Tetracaine in preparations for topical use other than eye drops, containing 10 per cent or less of total local anaesthetic substances except in dermal preparations containing 2 per cent or less of total local anaesthetic substances.

Tetrachloroethylene for human therapeutic use.

Tetryzoline.

Thiabendazole for human therapeutic use.

Tioconazole in preparations for dermal use except in preparations for the treatment of tinea pedis.

Tramazoline.

Triamcinolone in aqueous nasal sprays delivering 55 μg or less of triamcinolone per actuation when the maximum recommended daily dose is no greater than 220 μg, for prophylaxis or treatment of allergic rhinitis for up to 6 months in adults and children 12 years of age and over.

Triprolidine when combined with one or more other therapeutically active substances in oral preparations when—

(a) at least one of the other therapeutically active substances is a sympathomimetic decongestant; or

(b) in a day-night pack containing triprolidine in the bed-time dose where the day and night doses are in the same immediate container or immediate wrapper,

except in preparations for the treatment of children under 2 years of age.

Tuaminoheptane.

Tymazoline.

Xylometazoline.

Zinc chloride for human dermal use except in preparations containing 5 per cent or less of zinc chloride.

SCHEDULE 3

(Regulation 5)

PHARMACIST ONLY MEDICINES

Adrenaline in preparations containing 1 per cent or less of adrenaline except in preparations containing 0.02 per cent or less of adrenaline unless packed and labelled for injection.

Alclometasone as the only therapeutically active substance in preparations for dermal use containing 0.05 per cent or less of alclometasone in packs containing 30 g or less of the preparation.

Alimemazine—

(a) in solid oral preparations except when included in Schedule 2; or

(b) in liquid oral preparations containing 10 mg or less of alimemazine per 5 ml,

except in preparations for the treatment of children under 2 years of age.

Aminophylline in liquid oral preparations containing 2 per cent or less of aminophylline.

Astodrimer sodium except in a condom lubricant.

Azatadine in oral preparations.

Brompheniramine in oral preparations except—

(a) when included in Schedule 2; or

(b) for the treatment of children under 2 years of age.

Buclizine in oral preparations.

Butoconazole in preparations for vaginal use.

Chloramphenicol for ophthalmic use only.

Chlorbutanol in preparations for human use except—

(a) when included in Schedule 2; or

(b) in preparations containing 0.5 per cent or less of chlorbutanol.

Chlorphenamine in oral preparations except—

(a) when included in Schedule 2; or

(b) for the treatment of children under 2 years of age.

Ciclopirox in preparations for dermal use and for application to the nails except—

(a) when included in Schedule 2; or

(b) in preparations for the treatment of tinea pedis.

Cimetidine in a primary pack containing not more than 14 days' supply.

Clemastine in preparations for oral use.

Clobetasone (clobetasone-17-butyrate) as the only therapeutically active substance in preparations for dermal use containing 0.05 per cent or less of clobetasone in packs containing 30 g or less of the preparation.

Clotrimazole in preparations for vaginal use.

Cyclizine in divided preparations for oral use in primary packs containing 6 dosage units or less.

Cyproheptadine in oral preparations.

Dexchlorphenamine in oral preparations except—

(a) when included in Schedule 2; or

(b) for the treatment of children under 2 years of age.

Diclofenac in divided preparations for oral use containing 25 mg or less of diclofenac per dosage unit in a pack containing 30 or less dosage units except when included in Schedule 2.

Dihydrocodeine when indicated for cough suppression and compounded with one or more other therapeutically active substances—

(a) in divided preparations containing 10 mg or less of dihydrocodeine per dosage unit and with a recommended dose not exceeding 15 mg of dihydrocodeine; or

(b) in undivided preparations containing 0.25 per cent or less of dihydrocodeine with a recommended dose not exceeding 15 mg of dihydrocodeine.

Diiodohydroxyquinoline (iodoquinol) for vaginal use.

Dimenhydrinate in oral preparations except when included in Schedule 2.

Dimethindene in oral preparations.

Diphenhydramine in oral preparations except—

(a) when included in Schedule 2; or

(b) for the treatment of children under 2 years of age.

Diphenoxylate in packs of 8 or less dosage units, each dosage unit containing 2.5 mg or less of diphenoxylate and a quantity of atropine sulfate equivalent to at least 1 per cent of the dose of diphenoxylate.

Dithranol for therapeutic use.

Doxylamine in oral preparations except—

(a) when included in Schedule 2; or

(b) for the treatment of children under 2 years of age.

Econazole in preparations for vaginal use.

Erythrityl tetranitrate for therapeutic use.

Famciclovir for oral use, in divided preparations containing a total dose of 1500 mg or less of famciclovir for the treatment of herpes labialis (cold sores).

Flavoxate.

Fluconazole in single-dose oral preparations containing 150 mg or less of fluconazole for the treatment of vaginal candidiasis.

Fluorides for human topical use—

(a) in liquid preparations containing 5500 mg/kg or less of fluoride ion, in a container with a child-resistant closure except when included in or expressly excluded from Schedule 2; or

(b) in non-liquid preparations containing 5500 mg/kg or less of fluoride ion except:

(i) in preparations for therapeutic use containing 1500 mg/kg or less of fluoride ion and, when containing more than 1000 mg/kg fluoride ion, compliant with the labelling requirements under the Act;

(ii) in preparations for non-therapeutic use containing 1500 mg/kg or less of fluoride ion and, when containing more than 1000 mg/kg fluoride ion, labelled with warnings to the following effect—

(A) "DO NOT SWALLOW"; and

(B) "DO NOT USE [THIS PRODUCT/NAME OF PRODUCT] IN CHILDREN 6 YEARS OF AGE OR LESS"; or

(iii) in preparations for supply to registered dental professionals or by approval of an appropriate authority.

Glucagon.

Glyceryl trinitrate—

(a) in preparations for oral use; or

(b) in preparations for rectal use.

Glycopyrronium except when included in Schedule 4.

Hydrocortisone and hydrocortisone acetate, but excluding other salts and derivatives, in preparations for human therapeutic use containing 1 per cent or less of hydrocortisone—

(a) for dermal use, in packs containing 30 g or less of such preparations, containing no other therapeutically active constituent other than an antifungal substance; or

(b) for dermal use, in packs containing 2 g or less of such preparations, containing no other therapeutically active constituent other than aciclovir (5% w/w or less) in adults and adolescents (12 years of age and over); or

(c) for rectal use when combined with a local anaesthetic substance but no other therapeutically active constituent except unscheduled astringents—

(i) in undivided preparations, in packs of 35 g or less; or

(ii) in packs containing 12 or less suppositories;

except when included in Schedule 2.

Ibuprofen—

(a) in divided preparations, each containing 400 mg or less of ibuprofen in a primary pack containing not more than 50 dosage units, when labelled—

(i) with a recommended daily dose of 1200 mg or less of ibuprofen; and

(ii) not for the treatment of children under 12 years of age; or

(b) in a modified release dosage form, each containing 600 mg of ibuprofen in a primary pack containing not more than 32 dosage units, when labelled—

(i) with a recommended daily dose of 1200 mg or less of ibuprofen; and

(ii) not for the treatment of children under 12 years of age;

except when included in or expressly excluded from Schedule 2.

Inositol nicotinate.

Isoconazole in preparations for vaginal use.

Isosorbide dinitrate in oral preparations containing 10 mg or less of isosorbide dinitrate per dosage unit.

Ketoprofen in divided preparations for oral use containing 25 mg or less of ketoprofen per dosage unit in a pack containing 30 or less dosage units.

Lansoprazole in oral preparations containing 15 mg or less of lansoprazole per dosage unit for the relief of heartburn and other symptoms of gastro-oesophageal reflux disease, in packs containing not more than 14 days' supply except when included in Schedule 2.

Levonorgestrel for emergency post-coital contraception.

Macrogols in preparations for oral use for bowel cleansing prior to diagnostic, medical or surgical procedures.

Magnesium sulfate for human therapeutic use in divided oral preparations except when containing 1.5 g or less of magnesium sulfate per recommended daily dose.

Malathion in preparations for human external use except in preparations containing 2 per cent or less of malathion.

Mannityl hexanitrate for therapeutic use.

Mepyramine in oral preparations.

Methdilazine in oral preparations.

Metoclopramide when combined with paracetamol in divided preparations, packed and labelled only for the treatment of nausea associated with migraine, in packs containing not more than 10 dosage units.

Miconazole for human use in topical preparations—

(a) for the treatment of oral candidiasis; or

(b) for vaginal use.

Naloxone when used for the treatment of opioid overdose.

Naproxen in a modified release dosage form of 600 mg or less of naproxen per dosage unit in packs of 16 or less dosage units when labelled not for the treatment of children under 12 years of age.

Nicotinic acid for human therapeutic use in divided preparations containing 250 mg or less of nicotinic acid per dosage unit except—

(a) in preparations containing 100 mg or less of nicotinic acid per dosage unit; or

(b) nicotinamide.

Nicotinyl alcohol except in preparations containing 100 mg or less of nicotinyl alcohol per dosage unit.

Nystatin in preparations for topical use except when included in Schedule 2.

Omeprazole in oral preparations containing 20 mg or less of omeprazole per dosage unit for the relief of heartburn and other symptoms of gastro-oesophageal reflux disease, in packs containing not more than 14 days' supply except when included in Schedule 2.

Orlistat in oral preparations for weight-control purposes containing 120 mg or less of orlistat per dosage unit.

Oxiconazole in preparations for vaginal use.

Pantoprazole in oral preparations containing 20 mg or less of pantoprazole per dosage unit for the relief of heartburn and other symptoms of gastro-oesophageal reflux disease, in packs containing not more than 14 days' supply except when included in Schedule 2.

Paracetamol—

(a) when combined with ibuprofen in a primary pack containing 30 dosage units or less or;

(b) when combined with ibuprofen in preparations for oral use when labelled with a recommended daily dose of 1200 mg or less of ibuprofen in divided doses in a primary pack containing no more than 12 dosage units per pack; or

(c) in liquid preparations for oral use except when included in Schedule 2.

Pheniramine in oral preparations except—

(a) when included in Schedule 2; or

(b) for the treatment of children under 2 years of age.

Podophyllotoxin in preparations containing 1 per cent or less of podophyllotoxin for human use for the treatment of warts other than anogenital warts except when included in Schedule 2.

Podophyllum emodi (podophyllin) in preparations containing 20 per cent or less of podophyllin for human use for the treatment of warts other than anogenital warts except when included in Schedule 2.

Podophyllum peltatum (podophyllin) in preparations containing 20 per cent or less of podophyllin for human use for the treatment of warts other than anogenital warts except when included in Schedule 2.

Prochlorperazine in divided preparations for oral use in packs containing not more than 10 dosage units for the treatment of nausea associated with migraine.

Promethazine in oral preparations except—

(a) when included in Schedule 2; or

(b) in preparations for the treatment of children under 2 years of age.

Rabeprazole in oral preparations containing 10 mg or less of rabeprazole per dosage unit for the relief of heartburn and other symptoms of gastro-oesophageal reflux disease, in packs containing not more than 14 days' supply except when included in Schedule 2.

Salbutamol as the only therapeutically active substance—

(a) in metered aerosols delivering 100 μg or less of salbutamol per metered dose; or

(b) in dry powders for inhalation delivering 200 μg or less of salbutamol per dose.

Salicylic acid in preparations for dermal use except in preparations containing 40 per cent or less of salicylic acid.

Santonin.

Sodium phosphate in preparations for oral use for bowel cleansing prior to diagnostic medical and surgical procedures.

Sodium picosulfate in preparations for oral use for bowel cleansing prior to diagnostic medical or surgical procedures.

Sulfacetamide in preparations for ophthalmic use containing 10 per cent or less of sulfacetamide.

Terbutaline as the only therapeutically active substance—

(a) in metered aerosols delivering 250 μg or less of terbutaline per metered dose; or

(b) in dry powders for inhalation delivering 500 μg or less of terbutaline per dose.

Theophylline in liquid oral preparations containing 2 per cent or less of theophylline.

Tioconazole in preparations for vaginal use.

Triamcinolone for buccal use in preparations containing 0.1 per cent or less of triamcinolone in a pack of 5 g or less.

Triprolidine in oral preparations except—

(a) when included in Schedule 2; or

(b) for the treatment of children under 2 years of age.

Ulipristal for emergency post-coital contraception.

Vitamin D for human internal therapeutic use in preparations containing 175 μg or less of vitamin D per recommended single weekly dose except in preparations containing 25 μg or less of vitamin D per recommended daily dose.

SCHEDULE 4

(Regulation 6)

PRESCRIPTION ONLY MEDICINES

Abacavir.

Abatacept.

Abiraterone acetate.

Abciximab.

Acamprosate calcium.

Acarbose.

Acebutolol.

Acepromazine.

Acetanilide and alkyl acetanilides (excluding when present as an excipient) for human therapeutic use.

Acetarsol.

Acetazolamide.

Acetohexamide.

Acetyl isovaleryltylosin.

Acetylcarbromal.

Acetylcholine.

Acetylcysteine except—

(a) when included in Schedule 2; or

(b) in preparations for oral use when labelled with a recommended daily dose of 1g or less of acetylcysteine.

Acetyldigitoxin.

Acetylmethyldimethyloximidophenylhydrazine.

Acetylstrophanthidin.

Aciclovir except in preparations containing 5 per cent or less of aciclovir for the treatment of herpes labialis in packs containing 10 g or less.

Acipimox.

Acitretin.

Aclidinium bromide.

Acokanthera ouabaio.

Acokanthera schimperi.

Aconitum spp. except—

(a) when included in Schedule 2;

(b) in preparations for oral use in adults in packs containing 0.02 mg or less of total alkaloids; or

(c) in preparations for dermal use in adults containing 0.02 per cent or less of total alkaloids in packs containing 0.02 mg or less of total alkaloids.

Acrivastine.

Adalimumab.

Adapalene.

Adefovir.

Adenosine for human therapeutic use in preparations for injection.

Adiphenine.

Adonis vernalis.

Adrafinil.

Adrenaline except—

(a) when included in Schedule 3; or

(b) in preparations containing 0.02 per cent or less of adrenaline unless packed and labelled for injection.

Adrenocortical hormones except when separately specified in the schedules to these Regulations.

Afamelanotide.

Afatinib dimaleate.

Aflibercept.

Agalsidase.

Aglepristone.

Agomelatine.

Alatrofloxacin mesilate.

Albendazole except—

(a) when included in schedules 5 or 6; or

(b) in intraruminal implants each containing 3.85 g or less of albendazole for the treatment of animals.

Alclofenac.

Alclometasone except when included in Schedule 3.

Alcuronium.

Aldesleukin.

Aldosterone.

Alectinib.

Alefacept.

Alemtuzumab.

Alendronic acid.

Alfacalcidol.

Alfuzosin.

Alglucerase.

Alglucosidase.

Alimemazine except when included in schedules 2 or 3.

Alirocumab.

Aliskiren.

Allergens for therapeutic use.

Allopurinol.

Allylestrenol.

Alogliptin.

Alosetron.

Alpha1-proteinase inhibitor (human).

Alphadolone.

Alphaxalone.

Alprenolol.

Alprostadil.

Alseroxylon.

Alteplase.

Altrenogest.

Altretamine (hexamethylmelamine).

Amantadine.

Ambenonium chloride.

Ambrisentan.

Ambucetamide.

Ambutonium bromide.

Amcinonide.

Amifostine.

Amikacin.

Amiloride.

Aminocaproic acid.

Aminoglutethimide.

5-aminolevulinic acid.

Aminometradine.

Aminophenazone (amidopyrine) and derivatives for the treatment of animals.

Aminophylline except when included in Schedule 3.

Aminopterin.

4-aminopyridine for therapeutic use.

Aminorex.

Aminosalicylic acid.

Amiodarone.

Amiphenazole.

Amisometradine.

Amisulpride.

Amitriptyline.

Amlodipine.

Ammi visnaga.

Ammonium bromide for therapeutic use.

Amobarbital when packed and labelled for injection.

Amodiaquine.

Amorolfine except—

(a) when included in Schedule 2; or

(b) in preparations for the treatment of tinea pedis.

Amoxapine.

Amoxicillin.

Amphomycin.

Amphotericin b.

Ampicillin.

Amprenavir.

Amrinone.

Amsacrine.

Amyl nitrite.

Amylocaine.

Anabolic steroidal agents.

Anagrelide.

Anakinra.

Anastrozole.

Ancestim.

Ancrod and its immunoglobulin antidote.

Anecortave.

Androgenic steroidal agents.

Androisoxazole.

Androstanolone.

Androstenediol.

Androstenedione.

Angiotensin amide.

Anidulafungin.

Anistreplase.

Antazoline except when included in Schedule 2.

Antibiotic substances except—

(a) when separately specified in the schedules to these Regulations; or

(b) nisin.

Antigens for human therapeutic use except when separately specified in this schedule.

Antihistamines except—

(a) when included in schedules 2 or 3; or

(b) when separately specified in this schedule.

Antimony for therapeutic use except when separately specified in the schedules to these Regulations.

Antisera (immunosera) for human use by injection except when separately specified in the schedules to these Regulations.

Aod-9604 (CAS No. 221231-10-3).

Apalutamide.

Apixaban.

Apocynum spp.

Apraclonidine.

Apramycin.

Apremilast.

Aprepitant.

Apronal.

Aprotinin.

Arecoline.

Aripiprazole.

Armodafinil.

Arsenic for human therapeutic use except when separately specified in the schedules to these Regulations.

Artemether.

Articaine.

Asenapine.

Asfotase alfa.

Asparaginase.

Aspirin—

(a) when combined with caffeine, paracetamol or salicylamide or any derivative of these substances; or

(b) for injection.

Astemizole.

Asunaprevir.

Atamestane.

Atazanavir.

Atenolol.

Atezolizumab.

Atipamezole.

Atomoxetine.

Atorvastatin.

Atosiban.

Atovaquone.

Atracurium besilate.

Atropa belladonna (belladonna) except when included in Schedule 2.

Atropine except when included in Schedule 2.

Atropine methonitrate.

Auranofin.

Aurothiomalate sodium.

Avelumab.

Avilamycin except—

(a) in animal feed premixes containing 15 per cent or less of avilamycin activity; or

(b) in animal feeds containing 50 mg/kg or less of avilamycin activity.

Aviptadil.

Axitinib.

Avoparcin.

Azacitidine.

Azacyclonol.

Azaperone.

Azapropazone.

Azaribine.

Azatadine except when included in Schedule 3.

Azathioprine.

Azelaic acid except—

(a) when included in Schedule 2; or

(b) in preparations containing 1 per cent or less of azelaic acid for non-human use.

Azelastine except when included in Schedule 2.

Azithromycin.

Azlocillin.

Aztreonam.

Bacampicillin.

Bacitracin.

Baclofen.

Balsalazide.

Bambermycin (flavophospholipol) except—

(a) when included in Schedule 6; or

(b) in animal feeds for growth promotion containing 50 mg/kg or less of antibiotic substances.

Bambuterol.

Bamethan.

Bamipine.

Barbiturates except when separately specified in the schedules to these Regulations.

Baricitinib.

Basiliximab.

Bazedoxifene.

Becaplermin.

Beclamide.

Beclometasone except when included in Schedule 2.

Belatacept.

Belimumab.

Bemegride.

Benactyzine.

Benazepril.

Bendamustine.

Bendrofluazide.

Benethamine penicillin.

Benorylate.

Benoxaprofen.

Benperidol.

Benralizumab.

Benserazide.

Benzathine penicillin.

Benzilonium.

Benzocaine except—

(a) when included in Schedule 2;

(b) in dermal preparations containing 2 per cent or less of total local anaesthetic substances; or

(c) in lozenges containing 30 mg or less of total local anaesthetic substances per dosage unit.

Benzodiazepine derivatives except when separately specified in the schedules to these Regulations.

Benzoyl peroxide in preparations for human therapeutic use except—

(a) when included in Schedule 2; or

(b) in preparations for external use containing 5 per cent or less of benzoyl peroxide.

Benzphetamine.

Benzthiazide.

Benzatropine.

Benzydamine except—

(a) when included in Schedule 2;

(b) in preparations for dermal use;

(c) in divided topical oral preparations containing 3 mg or less of benzydamine; or

(d) in undivided topical oral preparations containing 0.3 per cent or less of benzydamine in a primary pack containing not more than 50 ml.

Benzylpenicillin.

Bepridil.

Beractant.

Besifloxacin.

Betahistine.

Betamethasone.

Betaxolol.

Bethanechol chloride.

Bethanidine.

Bevacizumab.

Bevantolol.

Bexarotene.

Bezafibrate.

Bezlotoxumab.

Bicalutamide.

Bictegravir.

Bifonazole except—

(a) when included in Schedule 2;

(b) in preparations for dermal use containing 1 per cent or less of bifonazole for the treatment of the scalp; or

(c) in preparations for dermal use for the treatment of tinea pedis.

Bimatoprost.

Binimetinib.

Biperiden.

Bismuth compounds for cosmetic use, except—

(a) bismuth citrate when incorporated in hair colourant preparations in concentrations of 0.5 per or less; or

(b) bismuth oxychloride.

Bismuth compounds for human therapeutic use, except bismuth formic iodide or bismuth subiodide in dusting powders containing 3 per cent or less of bismuth.

Bisoprolol.

Bivalirudin.

Bleomycin.

Blinatumomab.

Boceprevir.

Bolandiol.

Bolasterone.

Bolazine.

Boldenone (dehydrotestosterone).

Bolenol.

Bolmantalate.

Boron, including boric acid and borax, for human therapeutic use except—

(a) in preparations for internal use containing 6 mg or less of boron per recommended daily dose;

(b) in preparations for dermal use containing 0.35 per cent or less of boron, which are not for paediatric or antifungal use; or

(c) when present as an excipient.

Bortezomib.

Bosentan.

Bosutinib.

Botulinum toxins for human use except when separately specified in the schedules to these Regulations.

Brentuximab vedotin.

Bretylium tosilate.

Brexpiprazole.

Brigatinib.

Brimonidine.

Brinzolamide.

Brivaracetam.

Bromazepam.

Bromides, inorganic, for therapeutic use except when separately specified in the schedules to these Regulations.

Bromocriptine.

Bromoform for therapeutic use.

Brompheniramine except when included in schedules 2 or 3.

Bromvaletone.

Brugmansia spp.

Buclizine except when included in Schedule 3.

Budesonide except when included in Schedule 2.

Bufexamac except—

(a) in preparations for dermal use containing 5 per cent or less of bufexamac; or

(b) in suppositories.

Bumetanide.

Buphenine.

Bupivacaine except when included in Schedule 5.

Bupropion.

Buserelin.

Buspirone.

Busulphan.

Butacaine.

Butamben except in dermal preparations containing 2 per cent or less of total local anaesthetic substances.

Butoconazole except when included in Schedule 3.

Butraconazole.

Butylchloral hydrate.

Butyl nitrite.

Cabazitaxel.

Cabergoline.

Cabozantinib.

Cadmium compounds for human therapeutic use.

Calcipotriol.

Calcitonin.

Calcitonin salmon.

Calcitriol.

Calcium carbimide for therapeutic use.

Calcium hydroxyapatite in preparations for injection or implantation—

(a) for tissue augmentation; or

(b) for cosmetic use.

Calcium polystyrene sulphonate.

Calotropis gigantea.

Calotropis procera.

Calusterone.

Camphorated oil for therapeutic use.

Camphotamide.

Canagliflozin.

Canakinumab.

Candesartan cilexetil.

Candicidin.

Canine tick anti-serum.

Cantharidin.

Capecitabine.

Capreomycin.

Captodiame.

Captopril.

Capuride.

Caramiphen.

Carbachol.

Carbamazepine.

Carbaryl for human therapeutic use.

Carbazochrome.

Carbenicillin.

Carbenoxolone for internal use.

Carbetocin.

Carbidopa.

Carbimazole.

Carbocromen.

Carboplatin.

Carboprost.

Carbromal.

Carbutamide.

Carbuterol.

Carfilzomib.

Carglumic acid (n-carbamoyl-l-glutamic acid).

Carindacillin.

Carisoprodol.

Carmustine.

Carnidazole.

Carprofen.

Carvedilol.

Caspofungin.

Cathine.

Catumaxomab.

Cefacetrile.

Cefaclor.

Cefadroxil.

Cefalexin.

Cefaloridine.

Cefalotin (also known as cephalothin).

Cefamandole.

Cefapirin.

Cefazolin (also known as cephazolin).

Cefepime.

Cefetamet.

Cefixime.

Cefodizime.

Cefonicid.

Cefoperazone.

Cefotaxime (also known as cephotaxime).

Cefotetan.

Cefotiam.

Cefovecin for veterinary use.

Cefoxitin.

Cefpirome.

Cefpodoxime.

Cefquinome.

Ceftaroline fosamil.

Cefsulodin.

Ceftazidime.

Ceftibuten.

Ceftiofur.

Ceftriaxone.

Cefuroxime.

Celecoxib.

Celiprolol.

Cephaelis acuminata (ipecacuanha) except in preparations containing 0.2 per cent or less of emetine.

Cephaelis ipecacuanha except in preparations containing 0.2 per cent or less of emetine.

Cephalonium.

Cephradine.

Ceritinib.

Cerivastatin.

Cerliponase alfa.

Certolizumab pegol.

Ceruletide.

Cetirizine except—

(a) when included in Schedule 2; or

(b) in divided preparations for oral use for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when—

(i) in a primary pack containing not more than 10 days' supply; and

(ii) labelled with a recommended daily dose not exceeding 10 mg of cetirizine.

Cetrorelix.

Cetuximab.

Chenodeoxycholic acid.

Chloral formamide.

Chloral hydrate except in preparations for topical use containing 2 per cent or less of chloral hydrate.

Chloralose except when included in Schedule 6.

Chlorambucil.

Chloramphenicol except when included in Schedule 3.

Chlorandrostenolone.

Chlorazanil.

Chlorcyclizine.

Chlordiazepoxide.

Chlormerodrin.

Chlormethiazole.

Chlormezanone.

Chloroform for use in anaesthesia.

4-chloromethandienone.

2-(4-chlorophenyl)-(1,2,4)triazolo[5,1-a]isoquinoline.

Chloroquine.

Chlorothiazide.

Chlorotrianisene.

Chloroxydienone.

Chlorphenamine except when included in schedules 2 or 3.

Chlorphentermine.

Chlorpromazine.

Chlorpropamide.

Chlorprothixene.

Chlorquinaldol for human topical use.

Chlortalidone.

Chlortetracycline except when included in Schedule 5.

Chlorzoxazone.

Cholera vaccine.

Cholic acid.

Chymopapain for human therapeutic use.

Ciclacillin.

Ciclesonide.

Ciclopirox except—

(a) when included in schedules 2 or 3; or

(b) in preparations for the treatment of tinea pedis.

Ciclosporin.

Cidofovir.

Cilastatin.

Cilazapril.

Cilostazol.

Cimetidine except when included in Schedule 3.

Cimicoxib.

Cinacalcet.

Cinchocaine except when included in Schedule 2.

Cinnarizine.

Cinoxacin.

Ciprofloxacin.

Cisapride.

Cisatracurium besilate.

Cisplatin.

Citalopram.

Cjc-1295 (CAS No. 863288-34-0).

Cladribine.

Clanobutin.

Clarithromycin.

Clavulanic acid.

Clemastine except when included in Schedule 3.

Clemizole.

Clenbuterol.

Clevidipine.

Clidinium bromide.

Clindamycin.

Clioquinol and other halogenated derivatives of oxyquinoline for human topical use exceptwhen separately specified in this schedule.

Clobazam.

Clobetasol.

Clobetasone (clobetasone-17-butyrate) except when included in Schedule 3.

Clocortolone.

Clodronic acid (includes sodium clodronate).

Clofarabine.

Clofazimine.

Clofenamide.

Clofibrate.

Clomifene.

Clomipramine.

Clomocycline.

Clonazepam.

Clonidine.

Clopamide.

Clopidogrel.

Cloprostenol.

Clorazepate.

Clorexolone.

Clorprenaline.

Clostebol (4-chlorotestosterone).

Clotrimazole except—

(a) when included in schedules 2, 3 or 6; or

(b) in preparations for dermal use for the treatment of tinea pedis.

Cloxacillin.

Clozapine.

Cobalt for human therapeutic use except as dicobalt edetate in preparations for the treatment of cyanide poisoning.

Cobicistat.

Cobimetinib.

Codeine when compounded with one or more other therapeutically active substances—

(a) in divided preparations containing 30 mg or less of codeine per dosage unit; or

(b) in undivided preparations containing 1 per cent or less of codeine.

Co-dergocrine.

Colchicine.

Colchicum autumnale.

Colestipol.

Colestyramine for human therapeutic use.

Colfosceril palmitate for human therapeutic use.

Colistin.

Collagen in preparations for injection or implantation—

(a) for tissue augmentation; or

(b) for cosmetic use.

Collagenase clostridium histolyticum.

Convallaria keiski.

Convallaria majalis.

Copper compounds for human use except—

(a) when separately specified in the schedules to these Regulations;

(b) in preparations for human internal use containing 5 mg or less of copper per recommended daily dose; or

(c) in other preparations containing 5 per cent or less of copper compounds.

Corifollitropin alfa.

Coronilla spp.

Corticosterone.

Corticotrophin.

Cortisone.

Co-trimoxazole.

Coumarin for therapeutic use (excluding when present as an excipient).

Crisaborole.

Crizotinib.

Crofelemer.

Cuprimyxin.

Curare.

Cyclandelate.

Cyclizine except when included in Schedule 3.

Cyclobenzaprine.

Cyclofenil.

Cycloheximide.

Cyclopenthiazide.

Cyclopentolate.

Cyclophosphamide.

Cyclopropane for therapeutic use.

Cycloserine.

Cyclothiazide.

Cycrimine.

Cymarin.

Cyproheptadine except when included in Schedule 3.

Cyproterone.

Cytarabine.

Dabrafenib mesilate.

Dabigatran.

Dacarbazine.

Daclatasvir.

Daclizumab.

Dactinomycin.

Dalfopristin.

Dalteparin (includes dalteparin sodium).

Danaparoid (includes danaparoid sodium).

Danazol.

Danthron for human use.

Dantrolene.

Dapagliflozin.

Dapoxetine.

Dapsone.

Daptomycin.

Daratumumab.

Darbepoetin.

Darifenacin.

Darunavir.

Datura spp. except—

(a) when included in Schedule 2; or

(b) when separately specified in this schedule.

Dasabuvir.

Dasatinib.

Datura stramonium (stramonium) except—

(a) when included in Schedule 2; or

(b) for smoking or burning.

Datura tatula (stramonium) except—

(a) when included in Schedule 2; or

(b) for smoking or burning.

Daunorubicin.

Deanol for therapeutic use.

Debrisoquine.

Decamethonium.

Deferasirox.

Deferiprone.

Deflazacort.

Degarelix.

Dehydrochloromethyltestosterone.

Dehydrocorticosterone.

Delavirdine mesilate.

Dembrexine except when included in Schedule 5.

Demecarium.

Demeclocycline.

Dengue vaccine.

Denosumab.

Deoxycholic acid.

Deoxycortone.

Deoxyribonuclease except—

(a) when separately specified in this schedule; or

(b) for external use.

Deracoxib.

Dermatophagoides pteronyssinus and dermatophagoides farinae extract.

Desferrioxamine.

Desflurane.

Desipramine.

Desirudin.

Deslanoside.

Desloratadine except when included in Schedule 2.

Deslorelin.

Desmopressin (d.d.a.v.p.).

Desogestrel.

Desonide.

Desoxymethasone.

Desvenlafaxine.

Detomidine.

Dexamethasone.

Dexchlorphenamine except when included in schedules 2 or 3.

Dexfenfluramine.

Dexmedetomidine.

Dextromethorphan (excluding its stereoisomers) except when included in Schedule 2.

Dextropropoxyphene–

(a) in divided preparations containing 135 mg of dextropropoxyphene or less per dosage unit; or

(b) liquid preparations containing 2.5 per cent or less of dextropropoxyphene.

Dextrorphan (excluding its stereoisomers).

Diamthazole.

Diaveridine.

Diazepam.

Diazoxide.

Dibenzepin.

Dibotermin.

Dibromopropamidine for therapeutic use except when included in Schedule 2.

Dichloralphenazone.

Dichlorophen for human therapeutic use.

Dichlorphenamide.

Diclofenac except—

(a) when included in schedules 2 or 3; or

(b) in preparations for dermal use unless—

(i) for the treatment of solar keratosis; or

(ii) containing more than 4 per cent of diclofenac.

Dicloxacillin.

Dicyclomine.

Didanosine.

Dienestrol.

Dienogest.

Diethazine.

Diethylcarbamazine for human therapeutic use.

Diethylpropion.

Difenoxin in preparations containing, per dosage unit, 0.5 mg or less of difenoxin and a quantity of atropine sulfate equivalent to at least 5 per cent of the dose of difenoxin.

Diflorasone.

Difloxacin.

Diflucortolone.

Diflunisal.

Digitalis lanata.

Digitalis purpurea.

Digitoxin.

Digoxin.

Digoxin-specific antibody fragment f (ab).

Dihydralazine.

Dihydrocodeine when compounded with one or more other therapeutically active substances—

(a) in divided preparations containing not more than 100 mg of dihydrocodeine per dosage unit; or

(b) in undivided preparations with a concentration of not more than 2.5 per cent of dihydrocodeine,

except when included in Schedule 3.

Dihydroergotoxine.

Dihydrolone.

Dihydrostreptomycin.

Dihydrotachysterol.

Diiodohydroxyquinoline (iodoquinol) except—

(a) when included in Schedule 3; or

(b) for human internal use.

Diisopropylamine dichloroacetate.

Diltiazem.

Dimenhydrinate except when included in schedules 2 or 3.

Dimercaprol.

Dimethandrostanolone.

Dimethazine.

Dimethindene except when included in Schedule 3.

Dimethothiazine.

Dimethoxanate.

Dimethyl fumarate.

Dimethyl sulfoxide (excluding dimethyl sulfone) for therapeutic use except—

(a) when included in Schedule 6;

(b) in in-vitro test kits; or

(c) when used as a flavour component in compliance with the current therapeutic goods (permissible ingredients) determination for listed medicines.

Dimetridazole.

2,4-dinitrochlorobenzene for therapeutic use.

Dinitrocresols for therapeutic use except when separately specified in the schedules to these Regulations.

Dinitronaphthols for therapeutic use except when separately specified in the schedules to these Regulations.

Dinitrophenols for therapeutic use.

Dinitrothymols for therapeutic use except when separately specified in the schedules to these Regulations.

Dinoprost.

Dinoprostone.

Diperodon.

Diphemanil except in preparations for dermal use.

Diphenhydramine except when included in schedules 2 or 3.

Diphenidol.

Diphenoxylate in preparations containing, per dosage unit, 2.5 mg or less of diphenoxylate and a quantity of atropine sulfate equivalent to at least 1 per cent of the dose of diphenoxylate except when included in Schedule 3.

Diphenylpyraline.

Diphtheria toxoid.

Dipivefrin.

Dipyridamole.

Dirithromycin.

Dirlotapide.

Disophenol.

Disopyramide.

Distigmine.

Disulfiram for therapeutic use.

Disulphamide.

Dithiazanine except when included in Schedule 6.

Ditiocarb.

Dobutamine.

Docetaxel.

Dofetilide.

Dolasetron.

Dolutegravir.

Domperidone.

Donepezil.

Dopamine.

Dopexamine.

Doripenem.

Dornase.

Dorzolamide.

Dosulepin.

Doxantrazole.

Doxapram.

Doxazosin.

Doxepin.

Doxorubicin.

Doxycycline.

Doxylamine except when included in schedules 2 or 3.

Dronedarone.

Droperidol.

Drospirenone.

Drostanolone.

Drotrecogin.

Duboisia leichhardtii except when included in Schedule 2.

Duboisia myoporoides except when included in Schedule 2.

Duloxetine.

Dupilumab.

Durvalumab.

Dutasteride.

Dydrogesterone.

Econazole except—

(a) when included in schedules 2, 3 or 6; or

(b) in preparations for dermal use for the treatment of tinea pedis.

Ecothiopate (includes ecothiopate iodide).

Ectylurea.

Eculizumab.

Edetic acid for human therapeutic use except—

(a) in preparations containing 0.25 per cent or less of edetic acid;

(b) as dicobalt edetate in preparations for the treatment of cyanide poisoning; or

(c) in contact lens preparations.

Edoxudine.

Edrophonium.

Efalizumab.

Efavirenz.

Eflornithine.

Elbasvir.

Eletriptan.

Elosulfase alfa.

Elotuzumab.

Eltenac.

Eltrombopag.

Eluxadoline.

Elvitegravir.

Emepronium.

Emetine except in preparations containing 0.2 per cent or less of emetine.

Empagliflozin.

Emtricitabine.

Enalapril.

Encorafenib.

Enestebol.

Enflurane for therapeutic use.

Enfuvirtide.

Enobosarm.

Enoxacin.

Enoxaparin.

Enoximone.

Enprostil.

Enrofloxacin.

Entacapone.

Entecavir.

Enzalutamide.

Ephedra spp. except in preparations containing 0.001 per cent or less of ephedrine.

Ephedrine.

Epicillin.

Epinastine.

Epirubicin.

Epitiostanol.

Eplerenone.

Epoetins.

Epoprostenol.

Eprosartan.

Eptifibatide.

Erenumab.

Ergometrine.

Ergot.

Ergotamine.

Ergotoxine.

Eribulin mesilate.

Erlotinib.

Ertapenem.

Ertugliflozin.

Erysimum spp.

Erythromycin.

Erythropoietin.

Erythropoietins except when separately specified in the schedules to these Regulations.

Escitalopram.

Esmolol.

Esomeprazole except when included in Schedule 2.

Estradiol except when included in Schedule 5.

Estriol.

Estramustine.

Estrogens except when separately specified in the schedules to these Regulations.

Estrone.

Estropipate (piperazine estrone sulfate).

Etacrynic acid.

Etanercept.

Ethambutol.

Ethamivan.

Ethchlorvynol.

Ether for use in anaesthesia.

Ethinamate.

Ethinylestradiol.

Ethionamide.

Ethisterone.

Ethoglucid.

Ethoheptazine.

Ethopropazine.

Ethosuximide.

Ethotoin.

Ethoxzolamide.

Ethyl chloride for human therapeutic use.

Ethyldienolone.

Ethylestrenol.

Etidocaine.

Etidronic acid (includes etidronate disodium)—

(a) for internal use; or

(b) in topical preparations except in preparations containing 1 per cent or less of etidronic acid.

Etilefrin.

Etiproston.

Etodolac.

Etofenamate except when included in Schedule 2.

Etonogestrel.

Etoposide.

Etoricoxib.

Etravirine.

Etretinate.

Etynodiol.

Everolimus.

Exemestane.

Exenatide.

Ezetimibe.

Famciclovir except when included in Schedule 3.

Famotidine except when included in Schedule 2.

Febuxostat.

Felbinac except when included in Schedule 2.

Felodipine.

Felypressin.

Fenbufen.

Fencamfamin.

Fenclofenac.

Fenfluramine.

Fenofibrate.

Fenoldopam.

Fenoprofen.

Fenoterol.

Fenpipramide.

Fenpiprane.

Fenproporex.

Fenprostalene.

Ferric derisomaltose.

Fexofenadine except—

(a) when included in Schedule 2; or

(b) in divided preparations for oral use for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when—

(i) in a primary pack containing 20 dosage units or less and not more than 10 days' supply; and

(ii) labelled with a recommended daily dose not exceeding 120 mg of fexofenadine.

Fibrinolysin except for external use.

Fibroblast growth factors.

Fidaxomicin.

Filgrastim.

Finasteride.

Fingolimod.

Firocoxib.

Flecainide.

Fleroxacin.

Floctafenine.

Florfenicol.

Fluanisone.

Fluclorolone.

Flucloxacillin.

Fluconazole except when included in Schedule 3.

Flucytosine.

Fludarabine.

Fludrocortisone.

Flufenamic acid.

Flumazenil.

Flumetasone.

Flumethiazide.

Flunisolide.

Flunixin meglumine.

Fluocinolone.

Fluocinonide.

Fluocortin.

Fluocortolone.

Fluorescein in preparations for injection.

Fluorides in preparations for human use except when included in or expressly excluded from schedules 2 or 3.

Fluorometholone.

Fluorouracil.

Fluoxetine.

Fluoxymesterone.

Flupentixol.

Fluphenazine.

Fluprostenol.

Flurandrenolone.

Flurazepam.

Flurbiprofen except when included in Schedule 2.

Fluroxene for human therapeutic use.

Fluspirilene.

Flutamide.

Fluticasone except when included in Schedule 2.

Fluvastatin.

Fluvoxamine.

Folic acid in preparations for human use for injection.

Folinic acid in preparations for human use for injection.

Follicle-stimulating hormone except when separately specified in this schedule.

Follistatin.

Follitropin alfa.

Follitropin beta.

Follitropin delta.

Fomepizole.

Fomivirsen.

Fondaparinux.

Formebolone.

Formestane.

Formoterol.

Fosamprenavir.

Fosaprepitant.

Foscarnet.

Fosfestrol (diethylstilbestrol diphosphate).

Fosfomycin.

Fosinopril.

Fosphenytoin.

Fotemustine.

Framycetin.

Fulvestrant.

Furaltadone.

Furazabol.

Furazolidone.

Furosemide (frusemide).

Fusidic acid.

Gabapentin.

Galantamine.

Galanthus spp.

Gallamine.

Galsulfase.

Ganciclovir.

Ganirelix.

Gatifloxacin.

Grazoprevir.

Gefitinib.

Gemcitabine.

Gemeprost.

Gemfibrozil.

Gemifloxacin.

Gemtuzumab ozogamicin.

Gentamicin.

Gestodene.

Gestonorone.

Gestrinone.

Ghrh injectable plasmid.

Gitalin.

Glatiramer acetate.

Glecaprevir.

Glibenclamide.

Glibornuride.

Gliclazide.

Glimepiride.

Glipizide.

Glisoxepide.

Glutathione for parenteral use.

Glutethimide.

Glyceryl trinitrate except when included in Schedule 3.

Glycopyrronium in preparations for injection.

Glymidine.

Gnrh vaccine.

Golimumab.

Gonadorelin.

Gonadotrophic hormones except when separately specified in this schedule.

Goserelin.

Gramicidin.

Granisetron.

Grepafloxacin.

Griseofulvin.

Growth hormone releasing hormones* (ghrhs).

Growth hormone releasing peptides (ghrps).

Growth hormone releasing peptide-6 (ghrp-6).

Growth hormone secretagogues* (ghss).

Guaifenesin for human therapeutic use except—

(a) when included in Schedule 2;

(b) in oral liquid preparations containing 2 per cent or less of guaifenesin; or

(c) in divided preparations containing 200 mg or less of guaifenesin per dosage unit.

Guanabenz.

Guanacline.

Guanethidine.

Guanfacine.

Guanidine for therapeutic use.

Guselkumab.

Hachimycin.

Haematin.

Haemophilus influenzae vaccine.

Halcinonide.

Halofantrine.

Halofenate.

Halofuginone in preparations containing 0.1 per cent or less of halofuginone for the treatment of animals.

Haloperidol.

Halothane for therapeutic use.

Hemerocallis (hemerocallis flava).

Heparins for internal use except when separately specified in this schedule.

Hepatitis a vaccine.

Hepatitis b vaccine.

Hetacillin.

Hexachlorophene—

(a) in preparations for use on infants; or

(b) in other preparations except—

(i) when included in schedules 2 or 6; or

(ii) in preparations containing 0.75 per cent or less of hexachlorophene.

Hexamethonium.

Hexarelin.

Hexetidine for human internal use.

Hexobendine.

Hexocyclium.

Hexoprenaline.

Hexyl aminolevulinate (as hydrochloride).

Histamine for therapeutic use except in preparations containing 0.5 per cent or less of histamine.

Hmg-coa reductase inhibitors (including "statins") except when separately specified in the schedules to these Regulations.

Homatropine.

Human chorionic gonadatrophin except in pregnancy test kits.

Human papillomavirus vaccine.

Hyaluronic acid and its polymers in preparations for injection or implantation—

(a) for tissue augmentation;

(b) for cosmetic use; or

(c) for the treatment of animals.

Hydralazine.

Hydrargaphen.

Hydrochlorothiazide.

Hydrocortisone—

(a) for human use except when included in schedules 2 or 3; or

(b) for the treatment of animals.

Hydrocyanic acid for therapeutic use.

Hydroflumethiazide.

Hydroquinone (other than its alkyl ethers separately specified in this schedule) in preparations for human therapeutic or cosmetic use except—

(a) when included in Schedule 2;

(b) in hair preparations containing 0.3 per cent or less of hydroquinone; or

(c) in cosmetic nail preparations containing 0.02 per cent or less of hydroquinone.

Hydroxycarbamide.

Hydroxychloroquine.

Hydroxyephedrine.

Hydroxyphenamate.

Hydroxyprogesterone.

Hydroxystenozol.

Hydroxyzine.

Hygromycin.

Hyoscine except when included in Schedule 2.

Hyoscyamine except when included in Schedule 2.

Hyoscyamus niger except—

(a) when included in Schedule 2; or

(b) in a pack containing 0.03 mg or less of total solanaceous alkaloids.

Hypothalamic releasing factors except when separately specified in this schedule.

Hypromellose in preparations for injection.

Ibafloxacin for veterinary use.

Ibandronic acid.

Ibogaine.

Ibritumomab.

Ibrutinib.

Ibufenac.

Ibuprofen except—

(a) when included in or expressly excluded from schedules 2 or 3; or

(b) in preparations for dermal use.

Ibutamoren.

Ibuterol.

Ibutilide.

Icatibant.

Idarubicin.

Idarucizumab.

Idebenone.

Idoxuridine except in preparations containing 0.5 per cent or less of idoxuridine for dermal use.

Idursulfase.

Ifosfamide.

Iloprost.

Imatinib.

Imepitoin.

Imidapril.

Imiglucerase.

Imipenim.

Imipramine.

Imiquimod.

Immunoglobulins for human parenteral use except when separately specified in the schedules to these Regulations.

Indacaterol.

Indapamide.

Indinavir.

Indometacin except when included in Schedule 2.

Indoprofen.

Indoramin.

Infliximab.

Influenza and coryza vaccines—

(a) for parenteral use; or

(b) for nasal administration.

Ingenol mebutate.

Inotuzumab ozogamicin.

Insulin degludec.

Insulin glargine.

Insulin-like growth factor 1.

Insulin-like growth factors except when separately specified in this schedule.

Insulins.

Interferons.

Interleukins except when separately specified in the schedules to these Regulations.

Iodothiouracil.

Ipamorelin.

Ipilimumab.

Ipratropium except when included in Schedule 2.

Ipriflavone.

Iprindole.

Iproniazid.

Irbesartan.

Irinotecan.

Iron compounds in injectable preparations for human use.

Isoaminile.

Isoamyl nitrite.

Isobutyl nitrite.

Isocarboxazid.

Isoconazole except when included in schedules 2, 3 or 6.

Isoetarine.

Isoflurane for therapeutic use.

Isometheptene.

Isoniazid.

Isoprenaline.

Isoprinosine.

Isopropamide except when included in Schedule 2.

Isosorbide dinitrate except when included in Schedule 3.

Isosorbide mononitrate.

Isotretinoin.

Isoxicam.

Isoxsuprine.

Isradipine.

Itraconazole.

Ivabradine.

Ivacaftor.

Ivermectin—

(a) for human use; or

(b) for the treatment of mange in dogs.

Ixabepilone.

Ixazomib.

Ixekizumab.

Japanese encephalitis vaccine.

Kanamycin.

Ketamine.

Ketanserin except in topical veterinary preparations containing 0.5 per cent or less of ketanserin.

Ketazolam.

Ketoconazole except—

(a) when included in Schedule 2;

(b) in preparations for dermal use containing 1 per cent or less of ketoconazole for the treatment of the scalp; or

(c) in preparations for dermal use for the treatment of tinea pedis.

Ketoprofen except—

(a) in preparations for dermal use; or

(b) when included in Schedule 3.

Ketorolac (includes ketoralac trometamol).

Ketotifen except when included in Schedule 2.

Khellin.

Kitasamycin except—

(a) when included in Schedule 5; or

(b) in animal feeds for growth promotion containing 100 mg/kg or less of antibiotic substances.

Labetalol.

Lacidipine.

Lacosamide.

Lamivudine.

Lamotrigine.

Lanadelumab.

Lanatosides.

Lanreotide.

Lansoprazole except when included in schedules 2 or 3.

Lanthanum for therapeutic use.

Lapatinib.

Laronidase.

Laropiprant.

Latamoxef.

Latanoprost.

Laudexium.

Lauromacrogols in preparations for injection except—

(a) when present as an excipient; or

(b) when separately specified in the schedules to these Regulations.

Lead for human therapeutic use.

Ledipasvir.

Lefetamine.

Leflunomide.

Lenalidomide.

Lenograstim.

Lenvatinib.

Lepirudin.

Leptazol.

Lercanidipine.

Lesinurad.

Letermovir.

Letrozole.

Leuprorelin.

Levallorphan.

Levamisole—

(a) for human therapeutic use; or

(b) in preparations for the prevention or treatment of heartworm in dogs.

Levetiracetam.

Levobunolol.

Levobupivacaine.

Levocabastine except when included in Schedule 2.

Levocetirizine except—

(a) when included in Schedule 2; or

(b) in divided preparations for oral use for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when—

(i) in a primary pack containing not more than 5 days' supply; and

(ii) labelled with a recommended daily dose not exceeding 5 mg of levocetirizine.

Levodopa.

Levomepromazine.

Levomilnacipran.

Levonorgestrel except when included in Schedule 3.

Levosimendan.

Lidocaine except—

(a) when included in schedules 2 or 5 ;

(b) in dermal preparations containing 2 per cent or less of total local anaesthetic substances per dosage unit; or

(c) in lozenges containing 30 mg or less of total anaesthetic substances per dosage unit.

Lidoflazine.

Lifitegrast.

Linagliptin.

Lincomycin.

Lindane for human therapeutic use except when included in Schedule 2.

Linezolid.

Liothyronine.

Lipegfilgrastim.

Liraglutide.

Lisinopril.

Lisuride.

Lithium for therapeutic use except—

(a) when included in Schedule 2;

(b) when present as an excipient in preparations for dermal use containing 0.25 per cent or less of lithium; or

(c) in preparations containing 0.01 per cent or less of lithium.

Lixisenatide.

Lodoxamide except when included in Schedule 2.

Lofexidine.

Logiparin for internal use.

Lomefloxacin.

Lomustine.

Loperamid except—

(a) when included in Schedule 2; or

(b) in divided oral preparations containing 2 mg or less of loperamide per dosage unit, in a primary pack containing 8 dosage units or less.

Lopinavir.

Loprazolam.

Loracarbef.

Loratadine except—

(a) when included in Schedule 2; or

(b) in divided preparations for oral use for the treatment of seasonal allergic rhinitis in adults and children 6 years of age and over, when—

(i) in a primary pack containing 10 dosage units or less; and

(ii) labelled with a recommended daily dose not exceeding 10 mg of loratadine.

Lorazepam.

Lormetazepam.

Losartan.

Loteprednol.

Loxapine.

Lumacaftor.

Lumefantrine.

Lumiracoxib.

Lurasidone.

Luteinising hormone except in ovulation test kits.

Lymecycline.

Macitentan for human use.

Mafenide except when included in Schedule 6.

Mandragora officinarum.

Mannomustine.

Maprotiline.

Maraviroc.

Marbofloxacin.

Maropitant.

Mavacoxib.

Mazindol.

Measles vaccine.

Mebanazine.

Mebeverine.

Mebhydrolin.

Mebolazine.

Mebutamate.

Mecamylamine.

Mecasermin.

Mecillinam.

Meclocycline.

Meclofenamate.

Meclofenoxate.

Meclozine except when included in Schedule 2.

Medazepam.

Medetomidine.

Medigoxin (methyldigoxin).

Medroxyprogesterone.

Medrysone.

Mefenamic acid except when included in Schedule 2.

Mefenorex.

Mefloquine.

Mefruside.

Megestrol.

Melagatran.

Melanotan ii.

Melatonin for human use.

Melengestrol except when included in Schedule 6.

Meloxicam.

Melphalan.

Memantine.

Meningococcal vaccine.

Meningococcal group b vaccine.

Menotrophin.

Mepacrine.

Mepenzolate.

Mephenesin.

Mephentermine.

Mepindolol.

Mepitiostane.

Mepivacaine.

Meprobamate.

Meptazinol.

Mepyramine except when included in schedules 2 or 3.

Mequitazine.

Mercaptamine for human therapeutic use.

Mercaptomerin.

Mercaptopurine.

Mercurochrome except when included in schedules 2 or 6.

Mercury for cosmetic or therapeutic use except—

(a) when separately specified in the schedules to these Regulations; or

(b) in a sealed device which prevents access to the mercury.

Meropenem.

Mersalyl.

Mesabolone.

Mesalazine.

Mesna.

Mestanolone (androstalone).

Mesterolone.

Mestranol.

Metandienone.

Metaraminol.

Metenolone.

Metergoline.

Metformin.

Methacholine.

Methacycline.

Methallenestril.

Methandriol.

Methanthelinium.

Methazolamide.

Methdilazine except when included in Schedule 3.

Methenolone.

Methicillin.

Methimazole.

Methisazone.

Methixene.

Methocarbamol.

Methohexitone.

Methoin.

Methotrexate.

Methoxamine except—

(a) when included in Schedule 2; or

(b) in preparations for external use containing 1 per cent or less of methoxamine.

Methoxsalen.

Methoxyflurane.

Methsuximide.

Methyclothiazide.

Methyl aminolevulinate.

Methylandrostanolone.

Methylclostebol.

Methyldopa.

Methylene blue in preparations for injection.

Methylergometrine.

Methylmercury for therapeutic use.

Methylnaltrexone.

Methylpentynol.

Methylphenobarbital.

Methylprednisolone.

Methylrosanilinium chloride for human use except when used as a dermal marker.

Methyl salicylate in preparations for internal therapeutic use.

Methyltestosterone.

Methylthiouracil.

Methyltrienolone.

Methyprylone.

Methysergide.

Metoclopramide except when included in Schedule 3.

Metolazone.

Metoprolol.

Metribolone.

Metrifonate (trichlorfon) for human therapeutic use.

Metronidazole.

Metyrapone.

Mexiletine.

Mezlocillin.

Mianserin.

Mibefradil.

Mibolerone.

Micafungin.

Miconazole except—

(a) when included in schedules 2, 3 or 6; or

(b) in preparations for dermal use for the treatment of tinea pedis.

Midazolam.

Midostaurin.

Midodrine.

Mifepristone.

Migalastat.

Miglitol.

Miglustat.

Milbemycin oxime except when included in Schedule 5.

Milnacipran.

Milrinone.

Minocycline.

Minoxidil except when included in Schedule 2.

Mirabegron.

Mirtazapine.

Misoprostol

Mitobronitol.

Mitomycin.

Mitotane.

Mitoxantrone.

Mitratapide.

Mivacurium chloride.

Moclobemide.

Modafinil.

Molgramostim.

Molindone.

Mometasone except when included in Schedule 2.

Monensin except—

(a) when included in schedules 5 or 6; or

(b) in animal feeds containing 360 mg/kg or less of antibiotic substances.

Monobenzone and alkyl ethers of hydroquinone for human therapeutic use or cosmetic use except in cosmetic nail preparations containing 0.02 per cent or less of monobenzone or alkyl ethers of hydroquinone.

Monoclonal antibodies for therapeutic use except—

(a) in diagnostic test kits; or

(b) when separately specified in the schedules to these Regulations.

Monoethanolamine in preparations for injection.

Montelukast.

Moperone.

Morazone.

Moricizine.

Motrazepam.

Motretinide.

Moxidectin in preparations for injection containing 10 per cent or less of moxidectin except when included in schedules 5 or 6.

Moxifloxacin.

Moxonidine.

Mumps vaccine.

Mupirocin.

Muraglitazar.

Muromonab.

Mustine (nitrogen mustard).

Mycophenolic acid (includes mycophenolate mofetil).

Nabumetone.

Nadolol.

Nadroparin.

Nafarelin.

Naftidrofuryl.

Nalbuphine.

Nalidixic acid.

Nalmefene.

Nalorphine.

Naloxegol.

Naloxone except when in Schedule 3.

Naltrexone.

Nandrolone.

Naproxen except when included in schedules 2 or 3.

Narasin except—

(a) when included in Schedule 6; or

(b) in animal feeds containing 100 mg/kg or less of antibiotic substances.

Naratriptan.

Natalizumab.

Natamycin except for use as a food additive.

Nateglinide.

Nebacumab.

Nebivolol.

Nedocromil.

Nefazodone.

Nefopam.

Nelfinavir (includes nelfinavir mesilate).

Neomycin.

Neostigmine.

Nepafenac.

Neratinib.

Nerium oleander.

Nesiritide.

Netilmicin.

Netupitant.

Nevirapine.

Nialamide.

Nicardipine.

Nicergoline.

Nicofuranose.

Nicorandil.

Nicotine in preparations for human therapeutic use except when included in Schedule 2.

Nicotinic acid for human therapeutic use except—

(a) when separately specified in the schedules to these Regulations;

(b) in preparations containing 100 mg or less of nicotinic acid per dosage unit; or

(c) nicotinamide.

Nicoumalone.

Nifedipine.

Nifenazone.

Nikethamide.

Nilotinib.

Nilutamide.

Nimesulide.

Nimodipine.

Nimorazole.

Nintedanib.

Niridazole.

Nisoldipine.

Nitisinone.

Nitrazepam.

Nitrendipine.

Nitric oxide for human therapeutic use.

Nitrofurantoin.

Nitrofurazone.

Nitrous oxide for therapeutic use.

Nitroxoline.

Nivolumab.

Nizatidine except when included in Schedule 2.

Nomegestrol.

Nomifensine.

Noradrenaline.

19-norandrostenediol.

19-norandrostenedione.

Norandrostenolone.

Norbolethone.

Norclostebol.

Norelgestromin.

Norethandrolone.

Norethisterone.

Norfloxacin.

Norgestrel.

Noribogaine.

Normal human immunoglobulin.

Normethandrone.

Nortriptyline.

Novobiocin.

Noxiptyline.

Nusinersen.

Nystatin except when included in schedules 2 or 3.

Obeticholic acid.

Oclacitinib.

Ocrelizumab.

Ocriplasmin.

Octamylamine.

Octatropine.

Octreotide.

Octyl nitrite.

Ofatumumab.

Ofloxacin.

Olanzapine.

Olaparib.

Olaratumab.

Oleandomycin except—

(a) when included in Schedule 5; or

(b) in animal feeds for growth promotion containing 50 mg/kg or less of antibiotic substances.

Oleandrin.

Olmesartan.

Olodaterol.

Olopatadine.

Olsalazine.

Omalizumab.

Ombitasvir.

Omega-3-acid ethyl esters (excluding salts and derivatives) for human therapeutic use, for the treatment of post-myocardial infarction and/or hypertriglyceridaemia.

Omeprazole except when included in schedules 2 or 3.

Ondansetron.

Opipramol.

Orbifloxacin.

Orciprenaline.

Organophosphorus compounds with anticholinesterase activity for human therapeutic use except—

(a) when separately specified in the schedules to these Regulations; or

(b) in preparations containing 2 per cent or less of malathion for external use.

Orlistat except when included in Schedule 3.

Ornidazole.

Ornipressin.

Orphenadrine.

Orthopterin.

Oseltamivir.

Osimertinib.

Ouabain.

Ovandrotone.

Oxabolone.

Oxacillin.

Oxaliplatin.

Oxandrolone.

Oxaprozin.

Oxazepam.

Oxcarbazepine.

Oxedrine for human internal use except in preparations labelled with a recommended daily dose of 30 mg or less of oxedrine.

Oxetacaine (oxethazaine) except when included in Schedule 2.

Oxiconazole except—

(a) when included in schedules 2 or 3; or

(b) in preparations for the treatment of tinea pedis.

Oxitropium.

Oxolamine.

Oxolinic acid.

Oxprenolol.

Oxybuprocaine.

Oxybutynin.

Oxymesterone.

Oxymetholone.

Oxyphenbutazone.

Oxyphencyclimine.

Oxyphenonium.

Oxytetracycline except when included in Schedule 5.

Oxytocin.

Paclitaxel.

Palbociclib.

Palifermin.

Paliperidone.

Palivizumab.

Palonosetron.

Pamaquin.

Pamidronic acid (includes pamidronate disodium).

Pancreatic enzymes except—

(a) in preparations containing 20,000 bp units or less of lipase activity per dosage unit; or

(b) when separately specified in the schedules to these Regulations.

Pancuronium.

Panitumumab.

Panobinostat.

Pantoprazole except when included in schedules 2 or 3.

Papaverine in preparations for injection.

Paracetamol—

(a) when combined with aspirin or salicylamide or any derivative of these substances except when separately specified in the schedules to these Regulations;

(b) when combined with ibuprofen in a primary pack containing more than 30 dosage units;

(c) in slow release tablets or capsules containing more than 665 mg paracetamol;

(d) in non-slow release tablets or capsules containing more than 500 mg paracetamol;

(e) in individually wrapped powders or sachets of granules each containing more than 1000 mg paracetamol;

(f) in tablets or capsules enclosed in a primary pack containing more than 100 tablets or capsules;

(g) in individually wrapped powders or sachets of granules enclosed in a primary pack containing more than 50 wrapped powders or sachets of granules except when included in Schedule 2; or

(h) for injection.

Paraldehyde.

Paramethadione.

Paramethasone.

Parecoxib.

Paricalcitol.

Paritaprevir.

Paromomycin.

Paroxetine.

Pasireotide.

Patiromer sorbitex calcium.

Pazopanib.

Pecazine.

Pefloxacin.

Pegaptanib.

Pegaspargase.

Pegfilgrastim.

Peginterferon.

Pegvisomant.

Pembrolizumab.

Pemetrexed.

Pemoline.

Pempidine.

Penbutolol.

Penciclovir except in preparations containing 1 per cent or less of penciclovir for the treatment of *herpes labialis* in packs containing 10 g or less.

Penethamate.

Penicillamine.

Pentaerythrityl tetranitrate.

Pentagastrin.

Pentamethonium.

Pentamidine (includes pentamidine isetionate).

Penthienate.

Pentobarbital when packed and labelled for injection.

Pentolinium.

Pentosan polysulfate sodium.

Pentoxifylline.

Peramivir.

Perampanel.

Pergolide.

Perhexiline.

Periciazine.

Perindopril.

Permethrin for human therapeutic use except in preparations containing 5 per cent or less of permethrin.

Perphenazine.

Pertussis antigen.

Pertuzumab.

Phenacemide.

Phenacetin for therapeutic use (excluding when present as an excipient).

Phenaglycodol.

Phenazone except when included in schedules 2 or 5.

Phenazopyridine.

Phenelzine.

Pheneticillin.

Phenformin.

Phenglutarimide.

Phenindione.

Pheniramine except when included in schedules 2 or 3.

Phenisatin.

Phenobarbital.

Phenol in preparations for injection.

Phenolphthalein for human therapeutic use.

Phenoxybenzamine.

Phenoxymethylpenicillin.

Phensuximide.

Phentermine.

Phenthimentonium.

Phentolamine.

Phenylbutazone.

Phenylephrine—

(a) in preparations for injection; or

(b) in preparations for human ophthalmic use containing 5 per cent or more of phenylephrine.

Phenylpropanolamine.

Phenyltoloxamine.

Phenytoin.

Phleum pratense pollen extract (timothy-grass pollen extract).

Pholcodine—

(a) in divided preparations containing 100 mg or less of pholcodine per dosage unit; or

(b) in undivided preparations containing 2.5 per cent or less of pholcodine,

except when included in Schedule 2.

Phosphodiesterase type 5 inhibitors except—

(a) when separately specified in the schedules to these Regulations; or

(b) when present as an unmodified, naturally occurring substance.

Phthalylsulfathiazole.

Physostigmine.

Pibrentasvir.

Picrotoxin.

Pilocarpine except in preparations containing 0.025 per cent or less of pilocarpine.

Pimecrolimus.

Pimobendan.

Pimozide.

Pinacidil.

Pindolol.

Pioglitazone.

Pipecuronium.

Pipemidic acid.

Pipenzolate.

Piperacillin.

Piperidine.

Piperidolate.

Pipobroman.

Pipothiazine.

Pipradrol.

Piracetam.

Pirbuterol.

Pirenoxine (catalin).

Pirenzepine.

Piretanide.

Pirfenidone.

Piroxicam except in preparations for dermal use.

Pirprofen.

Pitavastatin.

Pituitary hormones except when separately specified in the schedules to these Regulations.

Pivampicillin.

Pizotifen.

Plicamycin.

Plerixafor.

Pneumococcal vaccine.

Podophyllotoxin for human use—

(a) internally;

(b) in preparations for the treatment of anogenital warts; or

(c) in other preparations except when included in schedules 2 or 3.

Podophyllum emodi (podophyllin) for human use—

(a) internally;

(b) in preparations for the treatment of anogenital warts; or

(c) in other preparations except when included in schedules 2 or 3.

Podophyllum peltatum (podophyllin) for human use—

(a) internally;

(b) in preparations for the treatment of anogenital warts; or

(c) in other preparations except when included in schedules 2 or 3.

Polidexide.

Poliomyelitis vaccine.

Polyacrylamide in preparations for injection or implantation—

(a) for tissue augmentation; or

(b) for cosmetic use.

Polycaprolactone in preparations for injection or implantation—

(a) for tissue augmentation; or

(b) for cosmetic use.

Polyestradiol.

Polylactic acid in preparations for injection or implantation—

(a) for tissue augmentation; or

(b) for cosmetic use.

Polymyxin.

Polysulfated glycosaminoglycans in preparations for injection, except when separately specified in the schedules to these Regulations.

Polythiazide.

Pomalidomide.

Poractant.

Posaconazole.

Potassium bromide for therapeutic use.

Potassium chloride in oral preparations for human therapeutic use except—

(a) when containing less than 550 mg of potassium chloride per dosage unit;

(b) in preparations for oral rehydration therapy;

(c) in preparations for oral use for bowel cleansing prior to diagnostic medical and surgical procedures; or

(d) in preparations for enteral feeding.

Potassium perchlorate for therapeutic use.

Practolol.

Pradofloxacin.

Pralatrexate.

Pralidoxime.

Pramipexole.

Pramocaine.

Pralmorelin (growth hormone releasing peptide-2 (ghrp-2)).

Prampine.

Prasterone (dehydroepiandrosterone, dehydroisoandrosterone).

Prasugrel.

Pravastatin.

Prazepam.

Praziquantel for human therapeutic use.

Prazosin.

Prednisolone.

Prednisone.

Pregabalin.

Pregnenolone.

Prenalterol.

Prenylamine.

Prilocaine except when included in Schedule 2.

Primaquine.

Primidone.

Probenecid.

Probucol.

Procainamide.

Procaine.

Procaine benzylpenicillin.

Procarbazine.

Prochlorperazine except when included in Schedule 3.

Procyclidine except when included in Schedule 2.

Progesterone except when included in Schedule 5.

Progestogens except when separately specified in the schedules to these Regulations.

Proglumide.

Proguanil.

Prolintane.

Promazine.

Promethazine except when included in schedules 2 or 3.

Promoxolane.

Propafenone.

Propamidine for therapeutic use except when included in Schedule 2.

Propanidid.

Propantheline.

Propentofylline.

Propetandrol.

Propionibacterium acnes for therapeutic use.

Propofol.

Propranolol.

Propylhexedrine.

Propylthiouracil.

Propyphenazone.

Proquazone.

Proscillaridin.

Prostaglandins except when separately specified in this schedule.

Prostianol.

Protamine.

Prothionamide.

Prothipendyl.

Protirelin.

Protoveratrines.

Protriptyline.

Proxymetacaine.

Prucalopride.

Pseudoephedrine

Pyrazinamide.

Pyridinolcarbamate.

Pyridostigmine.

Pyridoxine, pyridoxal or pyridoxamine for human therapeutic use except—

(a) in oral preparations containing 200 mg or less but more than 50 mg of pyridoxine, pyridoxal or pyridoxamine per recommended daily dose when compliant with the labelling requirements under the Act; or

(b) in oral preparations containing 50 mg or less of pyridoxine, pyridoxal or pyridoxamine per recommended daily dose.

Pyrimethamine.

Pyrovalerone.

Pyrvinium.

Quazepam.

Quetiapine.

Quinagolide.

Quinapril.

Quinbolone.

Quinethazone.

Quinidine.

Quinine for human therapeutic use except when the maximum recommended daily dose is 50 mg or less of quinine.

Quinisocaine (dimethisoquin).

Quinupristin.

Rabeprazole except when included in schedules 2 or 3.

Rabies vaccine.

Ractopamine except when included in Schedule 5.

Raloxifene.

Raltegravir.

Raltitrexed.

Ramipril.

Ramucirumab.

Ranibizumab.

Ranitidine except—

(a) when included in Schedule 2;

(b) in divided preparations for oral use containing 150 mg or less of ranitidine per dosage unit when supplied in the manufacturer's original pack containing not more than 14 dosage units; or

(c) in divided preparations for oral use containing 300 mg or less of ranitidine per dosage unit in the manufacturer's original pack containing not more than 7 dosage units.

Ranolazine

Rapacuronium.

Rasagiline.

Rasburicase.

Rauwolfia serpentina.

Rauwolfia vomitoria.

Razoxane.

Reboxetine.

Red yeast rice for human therapeutic use.

Regorafenib.

Remoxipride.

Repaglinide.

Reserpine.

Reslizumab.

Retapamulin.

Reteplase.

Retigabine.

Ribavirin.

Ribociclib.

Ridaforolimus.

Rifabutin.

Rifampicin.

Rifamycin.

Rifapentine.

Rifaximin.

Rilpivirine.

Riluzole.

Rimexolone.

Rimiterol.

Rimonabant.

Riociguat.

Risedronic acid.

Risperidone.

Ritodrine.

Ritonavir.

Rituximab.

Rivaroxaban.

Rivastigmine.

Rizatriptan.

Robenacoxib.

Rocuronium.

Rofecoxib.

Roflumilast.

Rolitetracycline.

Romidepsin.

Romifidine.

Romiplostim.

Romosozumab.

Ronidazole.

Ropinirole.

Ropivacaine.

Rosiglitazone.

Rosoxacin.

Rosuvastatin.

Rotigotine.

Roxibolone.

Roxithromycin.

Rubella vaccine.

Ruboxistaurin.

Rufinamide.

Rupatadine.

Ruxolitinib.

Sacubitril.

Safinamide.

Salbutamol except when included in Schedule 3.

Salicylamide when combined with aspirin, caffeine or paracetamol or any derivative of these substances.

Salinomycin except—

(a) when included in Schedule 6; or

(b) in animal feeds containing 60 mg/kg or less of antibiotic substances.

Salmeterol.

Sapropterin.

Saquinavir.

Sarilumab.

Saxagliptin.

Schoenocaulon officinale (sabadilla) except in preparations containing 10 mg/kg or 10 mg/l or less of total alkaloids of schoenocaulon officinale.

Scopolia carniolica for therapeutic use.

Sebelipase alfa.

Secukinumab.

Selective androgen receptor modulators (sarm).

Selegiline.

Selenium—

(a) for human oral use with a recommended daily dose of more than 300 μg; or

(b) for the treatment of animals except—

(i) when included in schedules 6 or 7;

(ii) in solid, slow release bolus preparations each weighing 100 g or more and containing 300 mg or less of selenium per dosage unit;

(iii) in other divided preparations containing 30 μg or less of selenium per dosage unit;

(iv) as elemental selenium, in pellets containing 100 g/kg or less of selenium; or

(v) in feeds containing 1 g/tonne or less of selenium.

Serelaxin.

Selexipag.

Sermorelin.

Sertindole.

Sertraline.

Sevelamer.

Sevoflurane.

Sex hormones and all substances having sex hormonal activity except when separately specified in the schedules to these Regulations.

Sibutramine.

Silandrone.

Sildenafil.

Silicones for intra-ocular use.

Silodosin.

Siltuximab.

Silver sulfadiazine.

Simeprevir.

Simvastatin.

Sirolimus.

Sisomicin (sisomycin).

Sitagliptin.

Sitaxentan.

Sodium bromide for therapeutic use.

Sodium cellulose phosphate for human internal use.

Sodium cromoglycate except when included in Schedule 2.

Sodium morrhuate in preparations for injection.

Sodium nitroprusside for human therapeutic use.

Sodium phenylbutyrate.

Sodium phosphate in preparations for oral laxative use.

Sodium polystyrene sulphonate for human therapeutic use.

Sodium salicylate in preparations for injection for the treatment of animals.

Sodium tetradecylsulfate in preparations for injection.

Sodium zirconium cyclosilicate.

Sofosbuvir.

Solasodine.

Solifenacin.

Somatostatin.

Somatotropin equine.

Somatropin (human growth hormone).

Sonidegib.

Sontoquine.

Sorafenib.

Sotalol.

Sparfloxacin.

Sparteine.

Spectinomycin.

Spiramycin.

Spirapril.

Spironolactone.

Stanolone.

Stanozolol.

Stavudine.

Stenabolic (sr9009) and other synthetic rev-erb agonists.

Stenbolone.

Steroid hormones except when separately specified in the schedules to these Regulations.

Stilbestrol (diethylstilbestrol).

Stiripentol.

Streptodornase.

Streptokinase.

Streptomycin.

Strontium ranelate.

Strophanthins.

Strophanthus spp.

Strychnine in preparations containing 1.5 per cent or less of strychnine for the treatment of animals.

Strychnos spp. except in preparations containing 1 mg or less per litre or per kilogram of strychnine.

Styramate.

Succimer.

Sugammadex.

Sulbactam.

Sulconazole except when included in Schedule 2.

Sulfacetamide except when included in schedules 3 or 5.

Sulfadiazine except when included in Schedule 5.

Sulfadimethoxine.

Sulfadimidine except when included in Schedule 5.

Sulfadoxine.

Sulfafurazole.

Sulfaguanidine.

Sulfamerazine except when included in Schedule 5.

Sulfamethizole.

Sulfamethoxazole.

Sulfamethoxydiazine.

Sulfamethoxypyridazine.

Sulfametrole.

Sulfamonomethoxine.

Sulfamoxole.

Sulfaphenazole.

Sulfapyridine.

Sulfaquinoxaline.

Sulfasalazine.

Sulfathiazole except when included in Schedule 5.

Sulfatroxazole.

Sulfinpyrazone.

Sulfomyxin.

Sulfonamides except—

(a) when separately specified in this schedule;

(b) when included in schedules 3, 5 or 6; or

(c) when packed and labelled solely for use as a herbicide.

Sulfonmethane (sulfonal) and alkyl sulfonals.

Sulindac.

Sultamicillin.

Sulthiame.

Sumatriptan.

Sunitinib.

Suprofen.

Sutilains.

Suxamethonium.

Suxethonium.

Suvorexant.

Tacrine.

Tacrolimus.

Tadalafil.

Tafenoquine succinate.

Tafluprost.

Taliglucerase alfa.

Talimogene laherparepvec.

Tamoxifen.

Tamsulosin.

Tanacetum vulgare except in preparations containing 0.8 per cent or less of oil of tansy.

Tasonermin.

Tazarotene.

Tazobactam.

Tb-500.

T-cell receptor antibody.

Teduglutide.

Tegafur.

Tegaserod.

Telaprevir.

Telithromycin.

Teicoplanin.

Telbivudine.

Telmisartan.

Telotristat ethyl.

Temazepam.

Temozolomide.

Temsirolimus.

Tenecteplase.

Teniposide.

Tenofovir.

Tenoxicam.

Tepoxalin.

Terazosin.

Terbinafine except—

(a) when included in Schedule 2; or

(b) in preparations for dermal use for the treatment of tinea pedis.

Terbutaline except when included in Schedule 3.

Terfenadine.

Teriflunomide.

Teriparatide.

Terlipressin.

Terodiline.

Teropterin.

Testolactone.

Testosterone except when included in Schedule 6.

Tetanus antitoxin except when used for short-term protection or treatment of tetanus in animals.

Tetanus toxoid for human use.

Tetrabenazine.

Tetracaine except—

(a) when included in Schedule 2; or

(b) in dermal preparations containing 2 per cent or less of total local anaesthetic substances.

Tetracosactide.

Tetracycline except when included in Schedule 5.

Tetraethylammonium.

Tetroxoprim.

Tezacaftor.

Thalidomide.

Thenyldiamine.

Theophylline except when included in Schedule 3.

Thevetia peruviana.

Thevetin.

Thiacetarsamide in preparations for the prevention or treatment of heartworm in dogs.

Thiambutosine.

Thiazosulfone.

Thiethylperazine.

Thioacetazone.

Thiocarlide.

Thiomesterone (tiomesterone).

Thiopental.

Thiopropazate.

Thioproperazine.

Thioridazine.

Thiostrepton.

Thiotepa.

Thiothixene.

Thiouracil.

Thiourea for therapeutic use except in preparations containing 0.1 per cent or less of thiourea.

Thymosin beta 4 (thymosin β4).

Thymoxamine (includes thymoxamine hydrochloride).

Thyroid except when separately specified in this schedule.

Thyrotrophin.

Thyroxine (includes thyroxine sodium).

Tiagabine.

Tiamulin.

Tianeptine.

Tiaprofenic acid.

Tiaramide.

Tibolone.

Ticagrelor.

Ticarcillin.

Ticlopidine.

Tiemonium.

Tienilic acid.

Tigecycline.

Tigloidine.

Tildipirosin.

Tiletamine.

Tilmanocept.

Tilmicosin.

Tiludronic acid (includes disodium tiludronate).

Timolol.

Tinidazole.

Tinzaparin (includes tinzaparin sodium).

Tioconazole except—

(a) when included in schedules 2 or 3; or

(b) in preparations for dermal use for the treatment of tinea pedis.

Tioguanine.

Tiotropium.

Tipepidine.

Tipiracil.

Tipranavir.

Tirilazad.

Tirofiban.

Tobramycin.

Tocainide.

Toceranib.

Tocilizumab.

Tofacitinib.

Tolazamide.

Tolazoline.

Tolbutamide.

Tolcapone.

Tolfenamic acid.

Tolmetin.

Tolonium.

Tolpropamine.

Tolrestat.

Tolterodine.

Tolvaptan.

Topiramate.

Topotecan.

Torasemide.

Toremifene.

Toxoids for human parenteral use except when separately specified in the schedules to these Regulations.

Tramadol.

Trandolapril.

Trametinib dimethyl sulfoxide.

Tranexamic acid except in preparations containing 3 per cent or less of cetyl tranexamate hydrochloride for dermal cosmetic use.

Tranylcypromine.

Trastuzumab.

Trastuzumab emtansine.

Travoprost.

Trazodone.

Trenbolone (trienbolone, trienolone) except when included in Schedule 5.

Treosulphan.

Treprostinil.

Trestolone.

Tretamine.

Tretinoin.

Triacetyloleandomycin.

Triamcinolone except when included in schedules 2 or 3.

Triamterene.

Triaziquone.

Triazolam.

Trichlormethiazide.

Trichloroacetic acid for human dermal use except when in preparations containing 12.5 per cent or less of trichloroacetic acid for the treatment of warts other than anogenital warts.

Trichloroethylene for therapeutic use.

Triclofos.

Tricyclamol.

Tridihexethyl.

Trifluoperazine.

Trifluperidol.

Triflupromazine.

Trifluridine.

Trihexyphenidyl.

Trilostane.

Trimetaphan.

Trimethoprim.

Trimipramine.

Trimustine.

Trinitrophenol (excluding its derivatives) in preparations for human therapeutic use.

Trioxysalen.

Tripelennamine.

Triple antigen vaccine.

Triprolidine except when included in schedules 2 or 3.

Triptorelin.

Troglitazone.

Trolamine when in preparations for tattoo removal.

Trometamol in preparations for injection except in preparations containing 3 per cent or less of trometamol.

Tropicamide.

Tropisetron.

Trovafloxacin.

Troxidone.

Tryptophan for human therapeutic use except in preparations labelled with a recommended daily dose of 100 mg or less of tryptophan.

Tuberculin.

Tubocurarine.

Tulathromycin.

Tulobuterol.

Tylosin.

Typhoid vaccine.

Ulipristal except when included in Schedule 3.

Umeclidinium.

Unoprostone.

Uracil.

Urapidil.

Urethane (excluding its derivatives) for therapeutic use.

Urofollitropin.

Urokinase.

Ursodeoxycholic acid.

Ustekinumab.

Vaccines for human therapeutic use except when separately specified in this schedule.

Vaccines – plasmid DNA for animal use except when separately specified in the schedules to these Regulations.

Vaccines, veterinary live virus except—

(a) poultry vaccines;

(b) pigeon pox vaccine; or

(c) scabby mouth vaccine.

Vaccinia virus vaccine.

Valaciclovir.

Valdecoxib.

Valganciclovir.

Valnoctamide.

Valproic acid.

Valsartan.

Vancomycin.

Vandetanib.

Vardenafil.

Varenicline.

Varicella vaccine.

Recombinant varicella zoster virus glycoprotein E antigen.

Vasopressin.

Vecuronium.

Vedaprofen.

Vedolizumab.

Velaglucerase alfa.

Velpatasvir.

Vemurafenib.

Venetoclax.

Venlafaxine.

Verapamil.

Veratrum spp. except when separately specified in this schedule.

Vernakalant.

Verteporfin.

Vidarabine.

Vigabatrin.

Vilanterol.

Vildagliptin.

Viloxazine.

Vinblastine.

Vincamine.

Vincristine.

Vindesine.

Vinflunine.

Vinorelbine.

Vinyl ether for therapeutic use.

Virginiamycin except when included in Schedule 5.

Vismodegib.

Visnadine.

Vitamin A for human therapeutic or cosmetic use except—

(a) in preparations for topical use containing 1 per cent or less of vitamin A;

(b) in preparations for internal use containing 3000 μg retinol equivalents or less of vitamin A per daily dose; or

(c) in preparations for parenteral nutrition replacement.

Vitamin D for human internal therapeutic use except—

(a) in preparations containing 25 μg or less of vitamin D per recommended daily dose ; or

(b) when included in Schedule 3.

Vorapaxar.

Voriconazole.

Vorinostat.

Vortioxetine.

Voxilaprevir.

Warfarin for therapeutic use.

Xamoterol.

Xanthinol nicotinate.

Ximelagatran.

Xipamide.

Xylazine.

Yohimbine.

Zafirlukast.

Zalcitabine.

Zaleplon.

Zanamivir.

Zeranol except when included in Schedule 6.

Zidovudine.

Zilpaterol.

Zimeldine.

Zinc compounds for human internal use except—

(a) in preparations with a recommended daily dose of 25 mg or less of zinc; or

(b) in preparations with a recommended daily dose of more than 25 mg but not more than 50 mg of zinc when compliant with the labelling requirements under the Act.

Ziprasidone.

Zolazepam.

Zoledronic acid.

Zolmitriptan.

Zolpidem.

Zonisamide.

Zopiclone.

Zoxazolamine.

Zuclopenthixol.

SCHEDULE 5

(Regulation 7)

HAZARDOUS POISONS

Abamectin—

(a) in preparations, for internal use for the treatment of animals, containing 1 per cent or less of abamectin; or

(b) in gel formulations containing 0.05 per cent or less of abamectin in applicators containing 50 mg or less of abamectin.

Abscisic acid.

Acequinocyl.

Acetic acid (excluding its salts and derivatives) in preparations containing more than 30 per cent of acetic acid (CH_3COOH) except—

(a) when included in schedules 2 or 6; or

(b) for therapeutic use.

Acetone except in preparations containing 25 per cent or less of designated solvents.

Acriflavinium chloride in preparations for veterinary use containing 2.5 per cent or less of acriflavinium chloride.

Afoxolaner in oral divided preparations each containing 150 mg or less of afoxolaner per dosage unit—

(a) for the treatment and prevention of flea infestations and control of ticks in dogs; or

(b) for the treatment and prevention of flea infestations, control of ticks, gastrointestinal nematodes and heartworm in dogs, when combined with milbemycin oxime.

Aklomide.

Albendazole for the treatment of animals, in preparations containing 12.5 per cent or less of albendazole except in intraruminal implants each containing 3.85 g or less of albendazole.

Alkaline salts, being the carbonate, silicate or phosphate salts of sodium or potassium alone or in any combination—

(a) in solid orthodontic device cleaning preparations, the pH of which as an "in-use" aqueous solution is more than 11.5;

(b) in solid automatic dishwashing preparations, the pH of which in a 500 g/l aqueous solution or mixture is more than 11.5 but less than or equal to 12.5;

(c) in other solid preparations, the pH of which in a 10 g/l aqueous solution is more than 11.5; or

(d) in liquid or semi-solid preparations, the pH of which is more than 11.5, unless—

(i) in food additive preparations for domestic use; or

(ii) in automatic dish washing preparations for domestic use with a pH of more than 12.5,

except when separately specified in the schedules to these Regulations.

Alkoxylated fatty alkylamine polymer in preparations containing 50 per cent or less of alkoxylated fatty alkylamine polymer except in preparations containing 20 per cent or less of alkoxylated fatty alkylamine polymer.

Allethrin in preparations containing 10 per cent or less of allethrin except—

(a) in insecticidal mats; or

(b) in other preparations containing 1 per cent or less of allethrin.

Alloxydim.

Alpha-cypermethrin—

(a) in aqueous preparations containing 3 per cent or less of alpha-cypermethrin; or

(b) in other preparations containing 1.5 per cent or less of alpha-cypermethrin.

Ametryn.

Amines for use as curing agents for epoxy resins except when separately specified in the schedules to these Regulations.

Aminoacridine in preparations for veterinary use containing 2.5 per cent or less of aminoacridine.

Aminopyralid in preparations containing 22 per cent or less of aminopyralid.

Amitrole.

Aminocyclopyrachlor.

Amisulbrom.

Ammonia (excluding its salts and derivatives other than ammonium hydroxide) in preparations containing 5 per cent or less of ammonia except—

(a) in preparations for human internal therapeutic use;

(b) in preparations for inhalation when absorbed in an inert solid material; or

(c) in preparations containing 0.5 per cent or less of free ammonia.

Ammonium thiocyanate except in preparations containing 10 per cent or less of ammonium thiocyanate.

Anhydrides, organic acid for use as curing agents for epoxy resins except when separately specified in the schedules to these Regulations.

Anise oil except—

(a) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 50 ml or less fitted with a restricted flow insert and compliant with the labelling requirements under the Act;

(b) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 50 ml or less fitted with a restricted flow insert, and labelled with the warning "KEEP OUT OF REACH OF CHILDREN"; or

(c) in preparations containing 50 per cent or less of anise oil.

Aspirin for the treatment of animals, in divided preparations when packed in blister or strip packaging or in a container with a child-resistant closure.

Atrazine.

Azadirachta indica extracts (neem extracts), extracted from neem seed kernels using water, methanol or ethanol, in preparations containing 5 per cent or less of total limonoids, for agricultural use.

Azoxystrobin.

Bacillus thuringiensis delta endotoxin encapsulated in killed pseudomonas fluorescens.

Barium silicofluoride when coated on paper in an amount not exceeding 8 mg of barium silicofluoride per sq. cm.

Basil oil except—

(a) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 ml or less fitted with a restricted flow insert and compliant with the labelling requirements under the Act;

(b) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 ml or less fitted with a restricted flow insert, and labelled with the warning "KEEP OUT OF REACH OF CHILDREN"; or

(c) in preparations containing 5 per cent or less of methyl chavicol.

Beauveria bassiana in preparations containing 1 x 10^8 Colony Forming Units (CFU)/ml or less of beauveria bassiana.

Benalaxyl.

Bendiocarb in preparations containing 2 per cent or less of bendiocarb.

Bentazone.

Benzalkonium chloride in preparations containing 10 per cent or less of benzalkonium chloride except in preparations containing 5 per cent or less of benzalkonium chloride.

Benzofenap.

Benzoyl peroxide except—

(a) when included in schedules 2 or 4; or

(b) in preparations containing 5 per cent or less of benzoyl peroxide.

Bergamot oil except—

(a) when steam distilled or rectified;

(b) in preparations for internal use;

(c) in preparations containing 0.4 per cent or less of bergamot oil;

(d) in soaps or bath or shower gels that are washed off the skin;

(e) in medicines for human therapeutic use when compliant with the labelling requirements under the Act; or

(f) in other preparations when packed in containers labelled with the statement "Application to the skin may increase sensitivity to sunlight".

Betacyfluthrin—

(a) in aqueous preparations containing 2.5 per cent or less of betacyfluthrin; or

(b) in solid preparations containing 8 per cent or less of betacyfluthrin in a plastic matrix.

Bicyclopyrone in preparations containing 20 per cent or less of bicyclopyrone.

Bifluorides (including ammonium, potassium and sodium salts), in preparations containing 0.3 per cent or less of total bifluorides.

Bioallethrin in preparations containing 10 per cent or less of bioallethrin except in preparations containing 1 per cent or less of bioallethrin.

Bioresmethrin except in preparations containing 10 per cent or less of bioresmethrin.

Bispyribac except in preparations containing 10 per cent or less of bispyribac.

Bixafen.

Boric acid (excluding its salts) and borax except—

(a) when included in Schedule 4;

(b) in preparations, other than insect baits, containing 1 per cent or less of boron; or

(c) in hand cleaning preparations.

Boron trifluoride in preparations containing 0.1 per cent or less of boron trifluoride (BF_3).

Broflanilide in preparations containing 0.3 per cent or less of broflanilide.

Bromuconazole in preparations containing 20 per cent or less of bromuconazole.

Bupivacaine in aqueous gel preparations containing 0.5 per cent or less of bupivacaine, for the dermal spray-on administration to post-surgical wounds associated with 'mulesing' of sheep; tail docking and castration of lambs; or castration and disbudding/dehorning in calves.

Buprofezin except in preparations containing 40 per cent or less of buprofezin.

Buthidazole.

Butoxycarboxim in solid preparations containing 10 per cent or less of butoxycarboxim.

Butralin.

Butroxydim.

n-butyl alcohol in preparations containing 10 per cent or less of n-butyl alcohol except—

(a) in preparations containing 5 per cent or less of n-butyl alcohol; or

(b) in preparations for cosmetic or therapeutic use other than spray form.

Camphor as a natural component in essential oils containing 10 per cent or less of camphor except—

(a) in medicines for human therapeutic use, in essential oils when packed in containers having a nominal capacity of 25 ml or less fitted with a restricted flow insert and compliant with the labelling requirements under the Act;

(b) in preparations other than medicines for human therapeutic use, in essential oils when packed in containers having a nominal capacity of 25 ml or less fitted with a restricted flow insert, and labelled with the warnings "KEEP OUT OF REACH OF CHILDREN" and "NOT TO BE TAKEN";

(c) in rosemary oil, sage oil (Spanish), or lavandin oils; or

(d) in preparations containing 2.5 per cent or less of camphor.

Carbamide peroxide in preparations containing 18 per cent or less of carbamide peroxide except in preparations containing 9 per cent or less of carbamide peroxide.

Carbaryl—

(a) in preparations containing 10 per cent or less of carbaryl except when included in Schedule 4; or

(b) when impregnated into plastic resin material containing 20 per cent or less of carbaryl.

Cassia oil except—

(a) in food additives;

(b) in preparations for dermal use as a rubefacient containing 5 per cent or less of cassia oil; or

(c) in other preparations containing 2 per cent or less of cassia oil.

Chlorfenac.

Chlorfenapyr in preparations containing 0.5 per cent or less of chlorfenapyr.

Chlorfenson.

Chlorhexidine in preparations containing 3 per cent or less of chlorhexidine except—

(a) in preparations containing 1 per cent or less of chlorhexidine; or

(b) when in solid preparations.

Chlorinating compounds containing 20 per cent or less of available chlorine, except—

(a) when separately specified in the schedules to these Regulations;

(b) sodium hypochlorite preparations with a pH of less than 11.5;

(c) liquid preparations containing not less than 2 per cent but not more than 4 per cent of available chlorine when labelled with the statement "WARNING – Ensure adequate ventilation when using. Vapour may be harmful. May give off dangerous gas if mixed with other products";

(d) liquid preparations containing less than 2 per cent of available chlorine; or

(e) other preparations containing 4 per cent or less of available chlorine.

Chlornidine.

Chlorocresol except in preparations containing 3 per cent or less of chlorocresol.

Chlorpropham.

Chlorpyrifos—

(a) in aqueous preparations containing 20 per cent or less of microencapsulated chlorpyrifos;

(b) in controlled release granular preparations containing 10 per cent or less of chlorpyrifos; or

(c) in other preparations containing 5 per cent or less of chlorpyrifos,

except in prepared potting or soil mixes containing 100 g or less of chlorpyrifos per cubic metre.

Chlorsulfuron.

Chlortetracycline in preparations—

(a) for topical application to animals for ocular use only; or

(b) containing 40 per cent or less of chlortetracycline, when packed and labelled for the treatment of ornamental caged birds or ornamental fish only.

Chlorthal-dimethyl.

Cinmethylin.

Cinnamon bark oil except—

(a) in food additives; or

(b) in preparations containing 2 per cent or less of cinnamon bark oil.

Clethodim.

Climbazole in preparations containing 40 per cent or less of climbazole except—

(a) in leave-on hair, face and foot cosmetic preparations containing 0.5 per cent or less of climbazole; or

(b) in other preparations (that are not leave-on cosmetic preparations) containing 2 per cent or less of climbazole.

Clofentezine.

Clopyralid.

Cloquintocet.

Clorsulon.

Clothianidin in preparations containing 20 per cent or less of clothianidin except in gel preparations dispensed in sealed cartridges containing 1 per cent or less of clothianidin.

Clove oil for topical use in the mouth in a pack containing 5 ml or less of clove oil except in preparations containing 25 per cent or less of clove oil.

Copper acetate in preparations containing 20 per cent or less of copper acetate except in preparations containing 5 per cent or less of copper acetate.

Copper compounds in animal feed additives containing 5 per cent or less of copper except in preparations containing 1 per cent or less of copper.

Copper hydroxide in preparations containing 50 per cent or less of copper hydroxide except in preparations containing 12.5 per cent or less of copper hydroxide.

Copper oxides in preparations containing 25 per cent or less of copper oxides except—

(a) in preparations for internal use;

(b) in marine paints; or

(c) in other preparations containing 5 per cent or less of copper oxides.

Copper oxychloride in preparations containing 50 per cent or less of copper oxychloride except in preparations containing 12.5 per cent or less of copper oxychloride.

Copper sulfate in preparations containing 15 per cent or less of copper sulfate except—

(a) in preparations for internal use; or

(b) in other preparations containing 5 per cent or less of copper sulfate.

Coumatetralyl in rodenticides containing 0.05 per cent or less of coumatetralyl.

4-cpa.

Cyanatryn.

Cyanoacrylate esters in contact adhesives except—

(a) when labelled with the warning—

"KEEP OUT OF REACH OF CHILDREN. Avoid contact with skin and eyes and avoid breathing vapour. Bonds on contact. Should fingers stick together apply a solvent such as acetone to contact areas then wash off with water. Do not use solvents near eyes or open wounds. In case of eye contact immediately flush with water"; or

(b) when packed in sealed measure packs each containing 0.5 g or less of cyanoacrylate esters—

(i) labelled with the approved name or trade name of the poison, the quantity and the warning "Can cause eye injury. Instantly bonds skin"; and

(ii) enclosed in a primary pack labelled with the warning—

"KEEP OUT OF REACH OF CHILDREN. Avoid contact with skin and eyes and avoid breathing vapour. Bonds on contact. Should fingers stick together apply a solvent such as acetone to contact areas then wash off with water. Do not use solvents near eyes or open wounds. In case of eye contact immediately flush with water".

Cyantraniliprole.

Cyanuric acid (excluding its salts and derivatives).

Cyazofamid.

Cyclohexanone peroxide.

Cycloprothrin except in preparations containing 10 per cent or less of cycloprothrin.

Cycloxydim.

Cyflufenamid.

Cyfluthrin—

(a) in wettable powders containing 10 per cent or less of cyfluthrin;

(b) in emulsifiable concentrates containing 2 per cent or less of cyfluthrin; or

(c) in emulsions containing 5 per cent or less of cyfluthrin.

Cyhalofop-butyl.

Cymiazole.

Cypermethrin in preparations containing 10 per cent or less of cypermethrin.

Cyphenothrin in preparations containing 10 per cent or less of cyphenothrin.

Cyproconazole except in preparations containing 10 per cent or less of cyproconazole.

Cyprodinil.

Cythioate for the treatment of animals—

(a) in divided preparations containing 30 mg or less of cythioate per dosage unit when packed in blister or strip packaging or in a container with a child-resistant closure; or

(b) in undivided preparations containing 5 per cent or less of cythioate.

2,4-D in preparations containing 20 per cent or less of 2,4-D.

Daminozide.

2,4-DB.

Decoquinate.

Deltamethrin—

(a) when impregnated in plastic resin strip material containing 4 per cent or less of deltamethrin;

(b) in aqueous preparations containing 5 per cent or less of deltamethrin when no organic solvent other than a glycol is present;

(c) in wettable granular preparations containing 25 per cent or less of deltamethrin when packed in child-resistant packaging each containing 3 g or less of the formulation;

(d) in water-dispersible tablets each containing 500 mg or less of deltamethrin in child-resistant packaging; or

(e) in other preparations containing 0.5 per cent or less of deltamethrin,

except—

(i) in factory prepared mosquito nets containing 1 per cent or less deltamethrin; or

(ii) in preparations containing 0.1 per cent or less of deltamethrin.

Dembrexine in oral preparations for the treatment of animals.

2,4-des.

Diafenthiuron.

N,n-diallyldichloroacetamide except in preparations containing 10 per cent or less of *n,n*-diallyldichloroacetamide.

Diazinon in dust preparations containing 2 per cent or less of diazinon.

Dicamba (including its salts and derivatives) in preparations containing 20 per cent or less of dicamba.

Dichlone.

P-dichlorobenzene.

Dichloroisocyanuric acid containing 40 per cent or less of available chlorine, except in—

(a) liquid preparations containing not less than 2 per cent but not more than 4 per cent of available chlorine when labelled with the statement "WARNING – Ensure adequate ventilation when using. Vapour may be harmful. May give off dangerous gas if mixed with other products";

(b) liquid preparations containing less than 2 per cent of available chlorine; or

(c) other preparations containing 4 per cent or less of available chlorine.

Dichloromethane (methylene chloride) except—

(a) in preparations in pressurised spray packs labelled as degreasers, decarbonisers or paint strippers and containing 10 per cent or less of dichloromethane;

(b) in other preparations in pressurised spray packs; or

(c) in paints and tinters containing 5 per cent or less of dichloromethane.

Dichlorophen for the treatment of animals.

Dichlorvos—

(a) when impregnated in plastic resin strip material containing 20 per cent or less of dichlorvos;

(b) in sustained release resin pellets containing 20 per cent or less of dichlorvos for the treatment of animals; or

(c) in pressurised spray packs containing 10 g or less of dichlorvos.

Diclobutrazol.

Dicloran.

Dicofol.

Diethanolamine (excluding its salts and derivatives) in preparations containing 20 per cent or less of diethanolamine except in preparations containing 5 per cent or less of diethanolamine.

Diethylene glycol (excluding its salts and derivatives) in preparations containing not less than 10 mg/kg of denatonium benzoate as a bittering agent except—

(a) in paints or paint tinters;

(b) in toothpastes or mouthwashes containing more than 0.25 per cent of diethylene glycol; or

(c) in other preparations containing 2.5 per cent or less of diethylene glycol.

Diethylene glycol monobutyl ether except in preparations containing 10 per cent or less of diethylene glycol monobutyl ether.

Diethyltoluamide (deet) except—

(a) in medicines for human therapeutic use containing 20 per cent or less of diethyltoluamide, when compliant with the labelling requirements under the Act;

(b) in preparations for human use, other than medicines, containing 20 per cent or less of diethyltoluamide, when labelled with the warning statement "WARNING— May be dangerous, particularly to children, if you use large amounts on the skin, clothes or bedding or on large areas of the body, especially if you keep using it for a long time."; or

(c) in preparations other than for human use containing 20 per cent or less of diethyltoluamide.

Difenoconazole.

Diflubenzuron.

Dimethicodiethylbenzalmalonate except when included in preparations containing 10 per cent or less of dimethicodiethylbenzalmalonate.

Dimethirimol.

Dimethomorph except in preparations containing 10 per cent or less of dimethomorph.

Dimethylacetamide in preparations containing 20 per cent or less of dimethylacetamide.

Dimethylformamide in preparations containing 10 per cent or less of dimethylformamide except in silicone rubber mastic containing 2 per cent or less of dimethylformamide.

3,7-dimethyl-2,6-octadienal and its isomers in cosmetic and household cleaning preparations except in preparations containing 5 per cent or less of 3,7-dimethyl-2,6,-octadienal isomers.

Diniconazole.

Dinotefuran except in preparations containing 1 per cent or less of dinotefuran.

Di-n-propyl isocinchomeronate except in preparations containing 25 per cent or less of di-n-propyl isocinchomeronate.

Diphenamid.

Direct red 254 in preparations containing 30 per cent or less of direct red 254 calculated as free acid.

Dithiopyr.

N-(n-dodecyl)-2-pyrrolidone in preparations containing 50 per cent or less of *n*-(*n*-dodecyl)-2-pyrrolidone or preparations containing 50 per cent or less of a mixture of any 2 or more of *N*-(*N*-dodecyl)-2-pyrrolidone, *N*-methyl-2-pyrrolidone or *N*-(*N*-octyl)-2-pyrrolidone except in preparations containing 25 per cent or less of designated solvents.

Doramectin for internal use for the treatment of animals, in preparations containing 2 per cent or less of doramectin.

Emamectin in preparations containing 2 per cent or less of emamectin.

Emodepside in preparations—

(a) containing 2.5 per cent or less of emodepside for the external treatment of animals; or

(b) containing 30 mg or less of emodepside per dosage unit for the oral treatment of animals.

Epoxiconazole.

Epoxy resins, liquid.

Eprinomectin in preparations containing 0.5 per cent or less of eprinomectin.

Esbiothrin in preparations containing 10 per cent or less of esbiothrin except in pressurised spray packs containing 1 per cent or less of esbiothrin.

Esfenvalerate in preparations containing 0.1 per cent or less of esfenvalerate.

Estradiol in implant preparations for growth promotion in animals.

1,2-ethanediamine polymerwith (chloromethyl) oxirane and n-Methylmethanamine.

Ether in preparations containing more than 10 per cent of ether for use in internal combustion engines.

Ethofumesate.

Ethoxyquin except in preparations containing 10 per cent or less of ethoxyquin.

Ethoxysulfuron.

Ethylene glycol (excluding its salts and derivatives) in preparations containing not less than 10 mg/kg of denatonium benzoate as a bittering agent except—

(a) in paints or paint tinters;

(b) in toothpastes or mouthwashes containing more than 0.25 per cent of ethylene glycol; or

(c) in other preparations containing 2.5 per cent or less of ethylene glycol.

Ethyl methacrylate (excluding its derivatives) for cosmetic use except in preparations containing 1 per cent or less of ethyl methacrylate as residual monomer in a polymer.

Etridiazole.

Eugenol for topical use in the mouth in a pack containing 5 ml or less of eugenol except in preparations containing 25 per cent or less of eugenol.

Extract of lemon eucalyptus, being acid modified oil of lemon eucalyptus (Corymbia citriodora), except in preparations containing 40 per cent or less of extract of lemon eucalyptus.

Fenarimol.

Fenbendazole for the treatment of animals.

Fenbuconazole.

Fenchlorazole-ethyl.

Fennel oil except—

(a) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 ml or less fitted with a restricted flow insert and compliant with the requirements under the Act;

(b) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 ml or less fitted with a restricted flow insert, and labelled with the warning "KEEP OUT OF REACH OF CHILDREN"; or

(c) in preparations containing 5 per cent or less of methyl chavicol.

Fenoprop.

Fenoxaprop-ethyl.

Fenoxaprop-*p*-ethyl.

Fenpyrazamine except in preparations containing 40 per cent or less of fenpyrazamine.

Fenson.

Fenthion—

(a) in preparations containing 25 per cent or less of fenthion when packed in single-use containers having a capacity of 2 ml or less; or

(b) in preparations containing 10 per cent or less of fenthion.

Fipronil in preparations containing 10 per cent or less of fipronil except in preparations containing 0.05 per cent or less of fipronil.

Flamprop-methyl.

Flamprop-*m*-methyl.

Flazasulfuron.

Florasulam.

Fluazuron.

Flubendazole for the treatment of animals.

Flubendiamide.

Fluchloralin.

Fludioxonil except in preparations containing 10 per cent or less of fludioxonil.

Flumethrin—

(a) when impregnated in plastic resin strip material containing 3 per cent or less of flumethrin; or

(b) in oil based preparations containing 1 per cent or less of flumethrin.

Flumiclorac pentyl.

Fluopyram except in preparations containing 50 per cent or less of fluopyram.

Fluorides in preparations containing 3 per cent or less of fluoride ion except—

(a) in preparations for human use; or

(b) in preparations containing 15 mg/kg or less of fluoride ion.

Fluralaner.

Fluvalinate in aqueous preparations containing 25 per cent or less of fluvalinate.

Fluxapyroxad.

Foramsulfuron.

Formic acid (excluding its salts and derivatives) except in preparations containing 0.5 per cent or less of formic acid.

Fospirate when impregnated in plastic resin strip material containing 20 per cent or less of fospirate.

Furalaxyl.

Furathiocarb in microencapsulated suspensions containing 50 per cent or less of furathiocarb.

Gamma-cyhalothrin in aqueous preparations containing 15 per cent or less of microencapsulated gamma-cyhalothrin.

Glufosinate-ammonium.

Glutaral in preparations containing 5 per cent or less of glutaral except—

(a) when included in Schedule 2; or

(b) in preparations containing 0.5 per cent or less of glutaral when labelled with the statements "IRRITANT" and "Avoid contact with eyes.".

Glyphosate.

Halosulfuron-methyl.

Hexaconazole except in preparations containing 5 per cent or less of hexaconazole.

Hexazinone in preparations containing 25 per cent or less of hexazinone.

Hydramethylnon in solid baits containing 2 per cent or less of hydramethylnon in welded plastic labyrinths.

Hydrocarbons, liquid, including kerosene, diesel (distillate), mineral turpentine, white petroleum spirit, toluene, xylene and light mineral and paraffin oils (excluding its derivatives), except—

(a) toluene and xylene when included in Schedule 6;

(b) benzene and liquid aromatic hydrocarbons when included in Schedule 7;

(c) food grade and pharmaceutical grade white mineral oils;

(d) in solid or semi-solid preparations;

(e) in preparations containing 25 per cent or less of designated solvents;

(f) in preparations packed in pressurised spray packs;

(g) in adhesives packed in containers each containing 50 g or less of adhesive;

(h) in writing correction fluids and thinners for writing correction fluids packed in containers having a capacity of 20 ml or less; or

(i) in other preparations when packed in containers with a capacity of 2 ml or less.

Hydrochloric acid (excluding its salts and derivatives) in preparations containing 10 per cent or less of hydrochloric acid (HCl) except—

(a) in preparations containing 0.5 per cent or less of hydrochloric acid (HCl); or

(b) for therapeutic use.

Hydrofluoric acid (excluding its salts and derivatives) and admixtures that generate hydrofluoric acid, in preparations containing 0.1 per cent or less of hydrogen fluoride.

Hydrogen peroxide (excluding its salts and derivatives)—

(a) in hair dye preparations containing 12 per cent or less of hydrogen peroxide except in hair dyes containing 6 per cent or less of hydrogen peroxide; or

(b) in other preparations containing 6 per cent (20 volume) or less of hydrogen peroxide except in preparations containing 3 per cent (10 volume) or less of hydrogen peroxide.

Hydrosilicofluoric acid (excluding its salts and derivatives) in preparations containing 0.1 per cent or less of hydrosilicofluoric acid (H_2SiF_6).

2-hydroxyethyl methacrylate except when included in dental restorative preparations for therapeutic use or in nail preparations when labelled "avoid contact with skin".

2-hydroxypropyl methacrylate in nail preparations except when labelled "avoid contact with skin".

Imazalil.

Imazamox except in preparations containing 25 per cent or less of imazamox.

Imazapic except in preparations containing 25 per cent or less of imazapic.

Imazapyr except in preparations containing 25 per cent or less of imazapyr.

Imazethapyr except in preparations containing 25 per cent or less of imazethapyr.

Imidacloprid in preparations containing 20 per cent or less of imidacloprid except in preparations containing 5 per cent or less of imidacloprid.

Imiprothrin in preparations containing 50 per cent or less of imiprothrin except in preparations containing 10 per cent or less of imiprothrin.

Indoxacarb (includes the R and S enantiomers) in preparations containing 1 per cent or less of indoxacarb.

3-iodo-2-propynyl butyl carbamate (iodocarb) in preparations containing 10 per cent or less of 3-iodo-2-propynyl butyl carbamate except—

(a) in aqueous preparations not for cosmetic use containing 10 per cent or less 3-iodo-2-propynyl butyl carbamate; or

(b) in cosmetic preparations (other than aerosolised preparations) containing 0.1 per cent or less of 3-iodo-2-propynyl butyl carbamate.

Iodosulfuron-methyl-sodium.

Ipconazole in preparations containing 2 per cent or less of ipconazole.

Iron compounds—

(a) for the treatment of animals (excluding up to 1 per cent of iron oxides when present as an excipient)—

(i) in preparations for injection containing 20 per cent or less of iron except in preparations containing 0.1 per cent or less of iron; or

(ii) in other preparations containing 4 per cent or less of iron except—

(A) in liquid or gel preparations containing 0.1 per cent or less of iron; or

(B) in animal feeds or feed premixes; or

(b) in garden preparations except in preparations containing 4 per cent or less of iron.

Isoeugenol in preparations not intended for skin contact containing 25 per cent or less of isoeugenol except in preparations containing 10 per cent or less of isoeugenol.

Isophorone.

Isoxaben.

Isoxaflutole.

Ivermectin for use in animals—

(a) in preparations for the prophylaxis of heartworm in cats and dogs;

(b) in intraruminal implants containing 160 mg or less of ivermectin;

(c) in preparations containing 3.5 per cent or less of ivermectin when packed in child-resistant packaging or in packaging approved by the relevant registration authority; or

(d) in other preparations containing 2 per cent or less of ivermectin.

Kitasamycin in animal feed premixes for growth promotion containing 2 per cent or less of antibiotic substances.

Lambda-cyhalothrin—

(a) in aqueous preparations containing 1 per cent or less of lambda- cyhalothrin; or

(b) in aqueous preparations containing 10 per cent or less of microencapsulated lambda-cyhalothrin.

Lasiodiplodia pseudotheobromae except when used as a herbicide in capsule preparations at a concentration of 16 CFU or less per capsule.

Lead compounds in preparations for use as hair cosmetics.

Lemon oil except—

(a) when steam distilled or rectified;

(b) in preparations for internal use;

(c) in preparations containing 0.05 per cent or less of lemon oil;

(d) in soaps or bath or shower gels that are washed off the skin;

(e) in medicines for human therapeutic use, when compliant with the labelling requirements under the Act; or

(f) in other preparations when packed in containers labelled with the statement "Application to the skin may increase sensitivity to sunlight".

Lemongrass oil in cosmetic and household cleaning preparations except in preparations containing 5 per cent or less of 3,7-dimethyl-2,6-octadienal.

Levamisole in preparations containing 15 per cent or less of levamisole for the treatment of animals except—

(a) when included in Schedule 4; or

(b) in preparations for the treatment of ornamental birds or ornamental fish, in packs containing 10 mg or less of levamisole.

Lidocaine in aqueous gel preparations containing 4.5 per cent or less of lidocaine, for the dermal spray-on administration to post-surgical wounds associated with 'mulesing' of sheep; tail docking and castration of lambs; or castration and disbudding/dehorning in calves.

Lime oil except—

(a) when steam distilled or rectified;

(b) in preparations for internal use;

(c) in preparations containing 0.5 per cent or less of lime oil;

(d) in soaps or bath or shower gels that are washed off the skin;

(e) in medicines for human therapeutic use, when compliant with the labelling requirements under the Act; or

(f) in other preparations when packed in containers labelled with the statement—"Application to the skin may increase sensitivity to sunlight".

Lindane in preparations containing 10 per cent or less of lindane except when included in schedules 2 or 4.

Lotilaner.

Lufenuron except—

(a) in divided preparations each containing 500 mg or less of lufenuron for the treatment of animals; or

(b) in single use syringes each containing 500 mg or less of lufenuron for the treatment of animals.

Macrophomina phaseolina except when used as a herbicide in capsule preparations at a concentration of 16 CFU or less per capsule.

Maduramicin in animal feed premixes containing 1 per cent or less of antibiotic substances.

Magnesium chlorate except in preparations containing 10 per cent or less of magnesium chlorate.

Malachite green in preparations for veterinary use containing 10 per cent or less of malachite green.

Malathion in preparations containing 10 per cent or less of malathion except—

(a) for human therapeutic use; or

(b) in dust preparations containing 2 per cent or less of malathion.

Mancozeb.

Mandestrobin except in preparations containing 25 per cent or less of mandestrobin.

Mandipropamid.

Marjoram oil except—

(a) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 50 ml or less fitted with a restricted flow insert and compliant with the labelling requirements under the Act;

(b) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 50 ml or less fitted with a restricted flow insert, and labelled with the warning "KEEP OUT OF REACH OF CHILDREN"; or

(c) in preparations containing 50 per cent or less of marjoram oil.

Mcpa—

(a) in preparations containing 25 per cent or less of mcpa (acid); or

(b) in preparations containing 50 per cent or less of the salts and esters of mcpa.

Mebendazole for the treatment of animals—

(a) in divided preparations each containing 300 mg or less of mebendazole per dosage unit; or

(b) in undivided preparations containing 25 per cent or less of mebendazole.

Meclofenamic acid for the treatment of animals.

Mecoprop in preparations containing 2 per cent or less of mecoprop.

Mefenpyr-diethyl.

Mefentrifluconazole except in preparations containing 7.5 per cent or less of Mefentrifluconazole.

Mepiquat.

Mercaptamine in cosmetic preparations containing 6 per cent or less of mercaptamine except in preparations containing 1 per cent or less of mercaptamine.

Mercaptoacetic acid and its salts, but excluding its derivatives, in cosmetic preparations containing 20 per cent or less of mercaptoacetic acid or its salts (as mercapturic acid), except in preparations containing 5 per cent or less of mercaptoacetic acid or its salts (as mercapturic acid).

Mesotrione.

Metaflumizone.

Metalaxyl in preparations containing 35 per cent or less of metalaxyl.

Metaldehyde in preparations containing 2 per cent or less of metaldehyde.

Metazachlor.

Methabenzthiazuron.

Methanol (excluding its derivatives) in preparations containing 10 per cent or less of methanol except in preparations containing 2 per cent or less of methanol.

Methenamine in cosmetic preparations, except in preparations containing 0.15 per cent or less of methenamine.

Methiocarb in pelleted preparations containing 2 per cent or less of methiocarb.

Methiozolin.

Methoxychlor.

Methylated spirit (being ethanol denatured with denatonium benzoate, methyl isobutyl ketone and fluorescein) except—

(a) when included in preparations or admixtures; or

(b) when packed in containers having a capacity of more than 5 litres.

Methylated spirit when packed and labelled as a 'biofuel' suitable for use in 'spirit burners'.

Methylene blue in preparations for veterinary use containing 50 per cent or less of methylene blue.

Methyl ethyl ketone except in preparations containing 25 per cent or less of designated solvents.

Methyl ethyl ketone peroxide.

Methyl isoamyl ketone except in preparations containing 25 per cent or less of designated solvents.

Methyl isobutyl ketone except in preparations containing 25 per cent or less of designated solvents.

N-methyl-2-pyrrolidone—

(a) when packed in single use containers having a capacity of 2 ml or less; or

(b) in preparations containing 50 per cent or less of N-methyl-2-pyrrolidone or preparations containing 50 per cent or less of a mixture of any 2 or more of N-methyl-2-pyrrolidone, N-(N-octyl)-2-pyrrolidone or N-(N-dodecyl)-2-pyrrolidone except in preparations containing 25 per cent or less of designated solvents.

Methyl salicylate in preparations containing 25 per cent or less of methyl salicylate except—

(a) in preparations for therapeutic use; or

(b) in preparations containing 5 per cent or less of methyl salicylate.

2-methylthio-4-(2-methylprop-2-yl) amino-6-cyclopropylamino-5-triazine.

Metiram.

Metofluthrin—

(a) in impregnated fabric mosquito repellent preparations for use in a vaporiser containing 15 mg or less of metofluthrin per disk; or

(b) when impregnated into a polyethylene slow release matrix containing 250 mg or less of metofluthrin.

Metolachlor.

Metrafenone in preparations containing 50 per cent or less of metrafenone.

Milbemectin in preparations containing 1 per cent or less of milbemectin.

Milbemycin oxime—

(a) for the prophylaxis of heartworm in dogs and cats; or

(b) for the treatment and prevention of flea infestations, control of ticks, gastrointestinal nematodes and heartworm in dogs, when combined with afoxolaner, in oral divided preparations each containing 150 mg or less of afoxolaner per dosage unit.

Monensin in intraruminal implants for cattle, each containing 35 g or less of monensin.

Monepantel.

Monoethanolamine (excluding its salts and derivatives) in preparations containing 20 per cent or less of monoethanolamine except—

(a) when included in Schedule 4; or

(b) in preparations containing 5 per cent or less of monoethanolamine.

Morantel in preparations containing 25 per cent or less of morantel except in preparations containing 10 per cent or less of morantel.

Moxidectin—

(a) in preparations for external use for the treatment of animals other than cats and dogs, containing 0.5 per cent or less of moxidectin;

(b) in preparations for external use for the treatment of cats and dogs, containing 2.5 per cent or less of moxidectin packed in single dose tubes with a volume of 1 ml or less; or

(c) for internal use for the treatment of animals—

(i) in divided preparations for dogs, containing 250 μg or less of moxidectin per dosage unit in a pack containing 6 or less dosage units; or

(ii) in other preparations containing 2 per cent or less of moxidectin.

Myclobutanil.

NAA except in preparations containing 25 per cent or less of NAA.

Naled when impregnated in plastic resin strip material containing 20 per cent or less of naled.

Naptalam.

Neoscytalidium novaehollandiae except when used as a herbicide in capsule preparations at a concentration of 16 cfu or less per capsule.

Netobimin for the treatment of animals, in preparations containing 12.5 per cent or less of netobimin.

Nitric acid (excluding its salts and derivatives) in preparations containing 10 per cent or less of nitric acid (HNO_3) except in preparations containing 0.5 per cent or less of nitric acid.

Nitroscanate for the treatment of animals.

Nonanoic acid—

(a) when used in a pesticide; or

(b) in other preparations except in preparations containing 10 per cent or less of nonanoic acid.

Nonoxinol 9 in preparations containing 25 per cent or less of nonoxinol 9 except—

(a) when labelled with the statements " IRRITANT" and "Avoid contact with eyes";

(b) in preparations containing 12.5 per cent or less of nonoxinol 9; or

(c) in preparations for human use.

Norbormide.

Nutmeg oil except—

(a) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 ml or less fitted with a restricted flow insert and compliant with the labelling requirements under the Act;

(b) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 ml or less fitted with a restricted flow insert, and labelled with the warning "KEEP OUT OF REACH OF CHILDREN"; or

(c) in preparations containing 50 per cent or less of nutmeg oil.

N-octyl bicycloheptene dicarboximide except in preparations containing 10 per cent or less of *n*-octyl bicycloheptene dicarboximide.

N-(*n*-octyl)-2-pyrrolidone in preparations containing 50 per cent or less of—

(a) N-(N-octyl)-2-pyrrolidone or preparations containing 50 per cent or less of a mixture of any 2 or more of N-(N-octyl)-2-pyrrolidone, N-methyl-2-pyrrolidone; or

(b) N-(N-dodecyl)-2-pyrrolidone except in preparations containing 25 per cent or less of designated solvents.

Oleandomycin in animal feed premixes for growth promotion.

Omethoate in pressurised spray packs containing 0.2 per cent or less of omethoate.

Orange oil (bitter) except—

(a) when steam distilled or rectified;

(b) in preparations for internal use;

(c) in preparations containing 1.4 per cent or less of orange oil (bitter);

(d) in soaps or bath or shower gels that are washed off the skin;

(e) in medicines for human therapeutic use, when compliant with the labelling requirements under the Act; or

(f) in other preparations when packed in containers labelled with the statement "Application to the skin may increase sensitivity to sunlight".

Oxadiargyl.

Oxadixyl.

Oxantel embonate for the treatment of animals.

Oxfendazole for the treatment of animals.

Oxibendazole for the treatment of animals.

Oxycarboxin.

Oxytetracycline in preparations—

(a) for topical application to animals for ocular use only; or

(b) containing 40 per cent or less of oxytetracycline per dose, when packed and labelled for the treatment of ornamental caged birds or ornamental fish only.

Oxythioquinox.

Paclobutrazol.

Penconazole.

Pendimethalin.

Penflufen.

Penthiopyrad except in preparations containing 20 per cent or less of penthiopyrad.

Peracetic acid in concentrations of 10 per cent or less of peracetic acid.

Permethrin (excluding preparations for human therapeutic use)—

(a) in preparations containing 25 per cent or less of permethrin; or

(b) in preparations for external use, for the treatment of dogs, containing 50 per cent or less of permethrin when packed in single use containers having a capacity of 4 ml or less,

except in preparations containing 2 per cent or less of permethrin.

Petrol except preparations containing 25 per cent or less of petrol.

Phenazone for the external treatment of animals.

Phenisopham.

Phenol, including cresols and xylenols and any other homologue of phenol boiling below 220°C, when in animal feed additives containing 15 per cent or less of such substances, except in preparations containing 1 per cent or less of phenol and in preparations containing 3 per cent or less of cresols and xylenols and other homologues of phenol.

Phenyl methyl ketone except in preparations containing 25 per cent or less of designated solvents.

O-phenylphenol except in preparations containing 5 per cent or less of *o*-phenylphenol.

Phosphonic acid (excluding its salts and derivatives) except in preparations containing 10 per cent or less of phosphonic acid (H_3PO_3).

Phosphoric acid (excluding its salts and derivatives) in preparations containing 35 per cent or less of phosphoric acid (H_3PO_4) except—

(a) in preparations containing 15 per cent or less of phosphoric acid (H3PO4);

(b) in solid or semi-solid preparations; or

(c) in professional dental kits.

O-phthalaldehyde in preparations containing 1 per cent or less of *o*-phthalaldehyde.

Picaridin except in preparations containing 20 per cent or less of picaridin.

Pine oils in preparations containing 25 per cent or less of pine oils when packed and labelled as a herbicide.

Pinoxaden in preparations containing 10 per cent or less of pinoxaden.

Piperazine for animal use.

Pirimicarb in preparations containing 0.5 per cent or less of pirimicarb.

Polixetonium salts in preparations containing 60 per cent or less of polixetonium salts except in preparations containing 1 per cent or less of polixetonium salts.

Polyethanoxy (15) tallow amine.

Poly(oxy-1,2-ethanediyl), α -[2-[(2-hydroxyethyl)amino]-2-oxoethyl]- α -hydroxy-,mono-c_{13-15}-alkyl ethers.

Potassium chlorate except—

(a) when included in Schedule 2; or

(b) in preparations containing 10 per cent or less of potassium chlorate.

Potassium hydroxide (excluding its salts and derivatives) in preparations containing 5 per cent or less of potassium hydroxide being—

(a) solid preparations, the pH of which in a 10 g/l aqueous solution is more than 11.5; or

(b) liquid or semi-solid preparations, the pH of which is more than 11.5 except in food additive preparations for domestic use.

Potassium metabisulphite when packed for domestic use except in preparations containing 10 per cent or less of potassium metabisulphite.

Potassium nitrite in preparations containing 1 per cent or less of potassium nitrite except—

(a) in preparations containing 0.5 per cent or less of potassium nitrite;

(b) when present as an excipient in preparations for therapeutic use; or

(c) in aerosols.

Potassium peroxomonosulfate triple salt in preparations containing 5 per cent or less of potassium peroxomonosulfate triple salt being—

(a) solid preparations, the pH of which in a 10 g/l aqueous solution is less than 2.5; or

(b) liquid or semi-solid preparations, the pH of which is less than 2.5.

Potassium sulfide in preparations for metal treatment in containers each containing 50 g or less of potassium sulfide.

Prallethrin (cis:trans=20:80) in preparations containing 10 per cent or less of prallethrin except in insecticidal mats containing 1 per cent or less of prallethrin.

Profoxydim except in preparations containing 20 per cent or less of profoxydim.

Progesterone—

(a) in implant preparations or controlled release pessaries for synchronisation of oestrus in cattle, sheep or goats; or

(b) in implant preparations for growth promotion in cattle.

Prohexadione calcium.

Prometryn.

Propamocarb.

Propanil.

Propaquizafop.

Propiconazole in preparations containing 20 per cent or less of propiconazole.

Propionic acid (excluding its salts and derivatives) in preparations containing 80 per cent or less of propionic acid, except—

(a) in preparations containing 30 per cent or less of propionic acid; or

(b) for therapeutic use.

Propoxur—

(a) when impregnated in plastic resin strip material containing 10 per cent or less of propoxur;

(b) in dust preparations containing 3 per cent or less of propoxur;

(c) in granular sugar-based fly baits containing 1 per cent or less of propoxur, a dark colouring agent and a separate bittering agent;

(d) in pressurised spray packs containing 2 per cent or less of propoxur; or

(e) in printed paper sheets for pest control containing 0.5 per cent or less of propoxur and in any case not more than 100 mg of propoxur per sheet.

N-propyl alcohol in preparations containing 10 per cent or less of *n*-propyl alcohol except—

(a) in preparations containing 5 per cent or less of n-propyl alcohol; or

(b) in preparations for cosmetic or therapeutic use other than in spray form.

Propyzamide.

Prothioconazole-deschloro except in preparations containing 0.5 per cent or less of prothioconazole-deschloro.

Prothioconazole-triazolidinethione except in preparations containing 0.5 per cent or less of prothioconazole-triazolidinethione.

Pymetrozine.

Pyraclostrobin.

Pyraflufen-ethyl.

Pyrasulfotole.

Pyrethrins, naturally occurring, being pyrethrolone, cinerolone or jasmolone esters of chrysanthemic or pyrethric acids except—

(a) in preparations for human therapeutic use; or

(b) in preparations containing 10 per cent or less of such substances.

Pyridaben in preparations containing 25 per cent or less of pyridaben.

Pyrifenox.

Pyrithiobac sodium.

Pyrithione zinc in paints containing 0.5 per cent or less of pyrithione zinc calculated on the non-volatile content of the paint except in paints containing 0.1 per cent or less of pyrithione zinc calculated on the non-volatile content of the paint.

Pyriofenone in preparations containing 30 per cent or less of pyriofenone.

Quaternary ammonium compounds in preparations containing 20 per cent or less of quaternary ammonium compounds except—

(a) when separately specified in the schedules to these Regulations;

(b) dialkyl or dialkoyl quaternary ammonium compounds where the alkyl or alkoyl groups are derived from tallow or hydrogenated tallow or similar chain length (C16/C18) sources; or

(c) in preparations containing 5 per cent or less of such quaternary ammonium compounds.

Quinclorac.

Quinine in preparations for veterinary use containing 1 per cent or less of quinine.

Quintozene.

Quizalofop-*p*-ethyl in aqueous preparations containing 40 per cent or less of quizalofop-*p*-ethyl.

Ractopamine in animal feed premixes containing 10 per cent or less of ractopamine.

Resmethrin in preparations containing 10 per cent or less of resmethrin.

Rimsulfuron.

Robenidine except in preparations containing 20 per cent or less of robenidine.

Rosin when packaged for use as a soldering flux or in flux-cored solder.

Saflufenacil in water dispersible granules or a water-based suspension concentrate.

Salicylanilide.

Sarolaner for veterinary use in divided preparations each containing 120 mg or less of sarolaner per dosage unit.

Sedaxane.

Selamectin except in preparations containing 12 per cent or less of selamectin.

Sethoxydim.

Siduron.

Silicofluorides in preparations containing 3 per cent or less of fluoride ion except—

(a) barium silicofluoride when separately specified in this schedule; or

(b) in preparations containing 15 mg/kg or less of fluoride ion.

Sinbioallethrin in preparations containing 10 per cent or less of sinbioallethrin except in preparations containing 1 per cent or less of sinbioallethrin.

Sodium chlorate except in preparations containing 10 per cent or less of sodium chlorate.

Sodium d\iacetate except in preparations containing 60 per cent or less of sodium diacetate.

Sodium dodecylbenzene sulfonate except in preparations containing 30 per cent or less of sodium dodecylbenzene sulfonate.

Sodium hydrogen sulfate except in preparations containing 10 per cent or less of sodium hydrogen sulfate.

Sodium hydrosulfite when packed for domestic use except in preparations containing 10 per cent or less of sodium hydrosulfite.

Sodium hydroxide (excluding its salts and derivatives) in preparations containing 5 per cent or less of sodium hydroxide being—

(a) solid preparations, the pH of which in a 10 g/l aqueous solution is more than 11.5; or

(b) liquid or semi-solid preparations, the pH of which is more than 11.5 except in food additive preparations for domestic use.

Sodium laureth-6 carboxylate except in preparations containing 1 per cent or less of sodium laureth-6 carboxylate.

Sodium metabisulphite when packed for domestic use except in preparations containing 10 per cent or less of sodium metabisulphite.

Sodium nitrite in preparations containing 1 per cent or less of sodium nitrite except—

(a) in preparations containing 0.5 per cent or less of sodium nitrite;

(b) when present as an excipient in preparations for therapeutic use; or

(c) in aerosols.

Sodium percarbonate (CAS No. 15630-89-4) in preparations containing 35 per cent or less of sodium percarbonate except in preparations containing 15 per cent or less of sodium percarbonate.

Sodium polystyrene sulphonate in preparations for cosmetic use except in preparations containing 10 per cent or less of sodium polystyrene sulphonate.

Sodium stannate except in preparations for cosmetic use containing 1 per cent or less of sodium stannate.

Sodium sulfide in preparations for metal treatment in containers each containing 50 g or less of sodium sulfide.

Spinetoram.

Spinosad except in aqueous suspensions containing 25 per cent or less of spinosad.

Star anise oil except—

(a) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 50 ml or less fitted with a restricted flow insert and compliant with the labelling requirements under the Act;

(b) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 50 ml or less fitted with a restricted flow insert, and labelled with the warning "KEEP OUT OF REACH OF CHILDREN"; or

(c) in preparations containing 50 per cent or less of star anise oil.

Styrene (excluding its derivatives).

Sulfacetamide when packed and labelled for the treatment of ornamental caged birds or ornamental fish only.

Sulfadiazine when packed and labelled for the treatment of ornamental caged birds or ornamental fish only.

Sulfadimidine when packed and labelled for the treatment of ornamental caged birds or ornamental fish only.

Sulfamerazine when packed and labelled for the treatment of ornamental caged birds or ornamental fish only.

Sulfamic acid (excluding its salts and derivatives) in preparations containing 10 per cent or less of sulfamic acid (H_3No_3S).

Sulfathiazole when packed and labelled for the treatment of ornamental caged birds or ornamental fish only.

Sulfometuron-methyl.

Sulfoxaflor in preparations containing 25 per cent or less of sulfoxaflor.

Symphytum spp. (comfrey) for dermal therapeutic or dermal cosmetic use.

2,3,6-tba.

Tde (1,1-dichloro-2,2-bis[4-chlorophenyl]ethane) in preparations containing 10 per cent or less of tde.

Tebuconazole.

Tebufenozide.

Tefluthrin in preparations containing 2 per cent or less of tefluthrin.

Temephos—

(a) in liquid preparations containing 10 per cent or less of temephos;

(b) in powders containing 2 per cent or less of temephos; or

(c) in preparations containing 40 per cent or less of temephos when packed in single use containers having a capacity of 2 ml or less.

Tepraloxydim.

Terbutryn.

Tetrachloroethylene in preparations containing 5 per cent or less of tetrachloroethylene except—

(a) when included in Schedule 2;

(b) in preparations for the treatment of animals; or

(c) when absorbed into an inert solid.

Tetrachlorvinphos except in animal feeds containing 0.2 per cent or less of tetrachlorvinphos.

Tetraconazole in preparations containing 20 per cent or less of tetraconazole.

Tetracycline in preparations—

(a) for topical application to animals for ocular use only; or

(b) containing 40 per cent or less of tetracycline when packed and labelled for the treatment of ornamental caged birds or ornamental fish only.

Tetramethrin [(R, cis): (R, trans) = 20:80] except in pressurised spray packs.

Tetraniliprole except in preparations containing 20 per cent or less tetraniliprole.

Thiabendazole—

(a) for the treatment of animals; or

(b) when packed and labelled for use as a fungicide except in preparations containing 50 per cent or less of thiabendazole.

Thiamethoxam in preparations containing 60 per cent or less of thiamethoxam.

Thiazopyr.

Thifensulfuron.

Thiobencarb.

Thiodicarb in pelleted preparations containing 1.5 per cent or less of thiodicarb.

Thiophanate-methyl in preparations containing 25 per cent or less of thiophanate-methyl.

Thyme oil except—

(a) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 ml or less fitted with a restricted flow insert and compliant with the labelling requirements under the Act;

(b) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 ml or less fitted with a restricted flow insert, and labelled with the warning "KEEP OUT OF REACH OF CHILDREN"; or

(c) in preparations containing 50 per cent or less of thyme oil.

Tiocarbazil.

Tolclofos-methyl.

Toltrazuril.

Topramezone.

Tralkoxydim.

Trenbolone in implant preparations for growth promotion in animals.

Triadimefon in wettable powders containing 25 per cent or less of triadimefon.

Triadimenol.

Tri-allate.

Tribenuron-methyl.

Trichloroacetic acid, alkali salts of.

1,1,1-trichloroethane except—

(a) in preparations packed in pressurised spray packs;

(b) in preparations containing 25 per cent or less of designated solvents;

(c) in preparations, other than writing correction fluids or thinners for writing correction fluidsin containers having a capacity of 50 ml or less; or

(d) in writing correction fluids or thinners for writing correction fluids, in containers having a capacity of 50 ml or less labelled with—

(i) the word "Trichloroethane" written in letters not less than 1 mm in height and in distinct contrast to the background; and

(ii) the expression "WARNING – DO NOT DELIBERATELY SNIFF THIS PRODUCT. SNIFFING MIGHT HARM OR KILL YOU" written in bold face sans serif capital letters not less than 1 mm in height and in distinct contrast to the background.

Tridiphane.

Trietazine.

Trifloxystrobin.

Trifludimoxazin except in preparations containing 12.5 per cent or less.

Triflumizole.

Triflumuron.

Triisopropanolamine lauryl ether sulfate except in preparations containing 30 per cent or less of triisopropanolamine lauryl ether sulfate when labelled with the statements "Avoid contact with eyes and skin" and "Wash hands after handling".

Trinexapac-ethyl except—

(a) when packed in a sealed water-soluble measure pack; or

(b) in solid preparations containing 25 per cent or less of trinexapac-ethyl in packs of 50 g or less.

3,6,9-trioxaundecanedioic acid except in preparations containing 5 per cent or less of 3,6,9-trioxaundecanedioic acid, the pH of which is 3.5 or greater.

Triticonazole.

Trolamine (excluding its salts and derivatives) except—

(a) when in Schedule 4; or

(b) in preparations containing 5 per cent or less of trolamine.

Turpentine oil except in preparations containing 25 per cent or less of turpentine oil.

Virginiamycin in animal feed additives containing 1 per cent or less of virginiamycin for the prevention of laminitis in horses when in a pack of 5 kg or less.

Vernolate.

Warfarin in rodent baits containing 0.1 per cent or less of warfarin.

Zineb.

SCHEDULE 6
(Regulation 8)

CONTROLLED POISONS

Abamectin—

(a) in preparations for pesticidal use containing 4 per cent or less of abamectin except when included in Schedule 5; or

(b) in slow-release plastic matrix ear tags for livestock use containing 1 g or less of abamectin.

Acephate.

Acetamiprid except in preparations containing 1 per cent or less of acetamiprid.

Acetic acid (excluding its salts and derivatives) and preparations containing more than 80 per cent of acetic acid (CH_3COOH) except when included in Schedule 2.

Acetic anhydride excluding its derivatives.

Acifluorfen.

Acinitrazole except in preparations containing 20 per cent or less of acinitrazole.

Albendazole for the treatment of animals except—

(a) when included in Schedule 5; or

(b) in intraruminal implants each containing 3.85 g or less of albendazole.

Aldrin.

Alkaline salts, being the carbonate, silicate or phosphate salts of sodium or potassium alone or in any combination for non-domestic use—

(a) in solid automatic dishwashing preparations, the pH of which in a 500 g/l aqueous solution or mixture is more than 12.5; or

(b) in liquid or semi-solid automatic dishwashing preparations, the pH of which is more than 12.5.

Alkoxylated fatty alkylamine polymer except—

(a) when included in Schedule 5; or

(b) in preparations containing 20 per cent or less of alkoxylated fatty alkylamine polymer.

Allethrin except—

(a) when included in Schedule 5;

(b) in insecticidal mats containing 20 per cent or less of allethrin; or

(c) in other preparations containing 1 per cent or less of allethrin.

Allyl esters (excluding its derivatives) being—

(a) allyl cyclohexaneacetate (CAS No. 4728-82-9);

(b) allyl cyclohexanepropionate (CAS No. 2705-87-5);

(c) allyl heptanoate/allyl heptylate (CAS No. 142-19-8);

(d) allyl hexanoate (CAS No. 123-68-2);

(e) allyl isovalerate (CAS No. 2835-39-4);

(f) allyl nonanoate (CAS No. 7493-72-3);

(g) allyl octanoate (CAS No. 4230-97-1);

(h) allyl phenylacetate (CAS No. 1797-74-6);

(i) allyl trimethylhexanoate (CAS No. 68132-80-9),

in preparations containing 0.1 per cent or less of free allyl alcohol by weight of allyl ester except in preparations containing 5 per cent or less of allyl esters with 0.1 per cent or less of free allyl alcohol by weight of allyl esters.

Alpha-cypermethrin—

(a) in aqueous preparations containing 30 per cent or less of alpha-cypermethrin; or

(b) in other preparations containing 10 per cent or less of alpha-cypermethrin,

except when included in Schedule 5.

Amicarbazone.

Amidithion.

Amidopropyl betaines except—

(a) in cosmetic wash-off preparations containing 30 per cent or less of amidopropyl betaines and, if containing more than 5 per cent of amidopropyl betaines when labelled with a warning to the following effect "IF IN EYES WASH OUT IMMEDIATELY WITH WATER";

(b) in cosmetic leave-on preparations containing 1.5 per cent or less of amidopropyl betaines; or

(c) in other preparations containing 30 per cent or less of amidopropyl betaines and, if containing more than 5 per cent of amidopropyl betaines, when labelled with warnings to the following effect "IF IN EYES WASH OUT IMMEDIATELY WITH WATER" and "IF SKIN OR HAIR CONTACT OCCURS, REMOVE CONTAMINATED CLOTHING AND FLUSH SKIN AND HAIR WITH RUNNING WATER".

2-amino-6-chloro-4-nitrophenol in hair dye and eyebrow/eyelash colouring preparations, except—

(a) in preparations containing 2 per cent or less of 2-amino-6-chloro-4-nitrophenol when applied directly to the hair, or containing 2 per cent or less of 2-amino-6-chloro-4-nitrophenol after mixing and when the immediate container and primary pack are labelled with the following statements "KEEP OUT OF REACH OF CHILDREN" and "WARNING – This product contains ingredients which may

cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye", written in letters not less than 1.5mm in height; or

(b) in eyelash and eyebrow tinting products containing 1.5 per cent or less of 2-amino-6-chloro-4-nitrophenol after mixing for use when the immediate container and primary pack are labelled with the following statement "WARNING – This product contains ingredients which may cause skin sensitisation to certain individuals, and when used for eyelash or eyebrow tinting may cause injury to the eye. A preliminary test according to the accompanying directions should be made before use, written in letters not less than 1.5mm in height.

4-amino-*m*-cresol in hair dyes and eyebrow/eyelash colouring preparations except—

(a) in hair dye preparations containing 1.5 per cent or less of 4-amino-m-cresol after mixing for use when the immediate container and primary pack are labelled with the following statements "KEEP OUT OF REACH OF CHILDREN and "WARNING – This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye", written in letters not less than 1.5mm in height; or

(b) in eyelash and eyebrow tinting products containing 1.5 per cent or less of 4-amino-m-cresol after mixing for use when the immediate container and primary pack are labelled with the following statement "WARNING – This product contains ingredients which may cause skin sensitisation to certain individuals, and when used for eyelash or eyebrow tinting may cause injury to the eye. A preliminary test according to the accompanying directions should be made before use", written in letters not less than 1.5mm in height.

2-amino-5-ethylphenol in hair dye preparations except in preparations containing 1 per cent or less of 2-amino-5-ethylphenol when the immediate container and primary pack are labelled with the following statements "KEEP OUT OF REACH OF CHILDREN" and "WARNING – This product contains ingredients which may cause skin irritation to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not be used for dyeing eyelashes and eyebrows; to do so may be injurious to the eye", written in letters not less than 1.5 mm in height.

4-amino-2-hydroxytoluene in hair dyes and eyebrow/eyelash colouring products except—

(a) in hair dye preparations containing 1.5 per cent or less of 4-amino-2-hydroxytoluene after mixing for use when the immediate container and primary pack are labelled with the following statements "KEEP OUT OF REACH OF CHILDREN" and "WARNING – This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye", written in letters not less than 1.5mm in height; or

(b) in eyelash and eyebrow tinting products containing 1.5 per cent or less of 4-amino-2-hydroxytoluene after mixing for use when the immediate container and primary pack are labelled with the following statement "WARNING – This product contains ingredients which may cause skin sensitisation to certain individuals, and when used for eyelash or eyebrow tinting may cause injury to the eye. A preliminary test according to the accompanying directions should be made before use", written in letters not less than 1.5mm in height.

Aminocarb in preparations containing 25 per cent or less of aminocarb.

Aminoethoxyvinylglycine except in preparations containing 15 per cent or less of aminoethoxyvinylglycine.

1-aminomethanamide dihydrogen tetraoxosulfate.

4-amino-3-nitrophenol except—

(a) in non-oxidative hair dye preparations and eyebrow/eyelash colouring products containing 1 per cent or less of 4-amino-3-nitrophenol when the immediate container and primary pack are labelled with the following statements "KEEP OUT OF REACH OF CHILDREN" and "WARNING - This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use", written in letters not less than 1.5 mm in height; or

(b) in oxidative hair dye preparations and eyebrow/eyelash colouring products containing 1 per cent or less of 4-amino-3-nitrophenol after mixing under oxidative conditions when the immediate container and primary pack are labelled with the following statements "KEEP OUT OF REACH OF CHILDREN" and "WARNING - This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use", written in letters not less than 1.5 mm in height.

2,2'-[(4-amino-3-nitrophenyl)imino]bisethanol (including its salts) except—

(a) in non-oxidative hair dye preparations containing 2.5 per cent or less of 2,2'-[(4-amino-3-nitrophenyl)imino]bisethanol after mixing when the immediate container and primary pack are labelled with the following statements "KEEP OUT OF REACH OF CHILDREN" and "WARNING - This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use", written in letters not less than 1.5 mm in height; or

(b) in oxidative hair dye preparations containing 1.25 per cent or less of 2,2'-[(4-amino-3-nitrophenyl)imino]bisethanol after mixing under oxidative conditions when the immediate container and primary pack are labelled with the following statements "KEEP OUT OF REACH OF CHILDREN" and "WARNING - This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye", written in letters not less than 1.5 mm in height.

m-aminophenol except when used in hair dye and eyebrow/eyelash preparations at a concentration of 1.2 per cent or less of *m*-aminophenol after mixing for use when the immediate container and primary pack are labelled with the following statements "KEEP OUT OF REACH OF CHILDREN" and "WARNING – This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use", written in letters not less than 1.5 mm in height.

p-aminophenol except when used in hair dye and eyebrow/eyelash colouring products at a concentration of 1 per cent or less of *p*-aminophenol after mixing for use when the immediate container and primary pack are labelled with the following statements "KEEP OUT OF REACH OF CHILDREN" and "WARNING – This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use", written in letters not less than 1.5 mm in height.

Aminopyralid except when included in Schedule 5.

Amitraz.

Ammonia (excluding its salts and derivatives other than ammonium hydroxide) except—

(a) when included in Schedule 5;

(b) in preparations for human internal therapeutic use;

(c) in preparations for inhalation when absorbed in an inert solid material; or

(d) in preparations containing 0.5 per cent or less of ammonia.

Ammonium cocoyl isethionate, except in cosmetic rinse-off preparations containing 30 per cent or less of ammonium cocoyl isethionate and, if containing more than 5 per cent of ammonium cocoyl isethionate, when labelled with a warning to the following effect "IF IN EYES WASH OUT IMMEDIATELY WITH WATER".

Ammonium persulfate in hair preparations.

Aniline (excluding its salts and derivatives) except in preparations containing 1 per cent or less of aniline.

Antimony compounds except—

(a) when included in Schedule 4;

(b) antimony chloride in polishes;

(c) antimony titanate pigments in paint; or

(d) in paints or tinters containing 5 per cent or less of antimony calculated on the non-volatile content of the paint or tinter.

Arsenic—

(a) in ant poisons containing 0.4 per cent or less of arsenic;

(b) in animal feed premixes containing 4 per cent or less of arsenic; or

(c) in preparations for the treatment of animals except thiacetarsamide when included in Schedule 4,

except when separately specified in this schedule.

Aspirin for the treatment of animals except when included in schedules 4 or 5.

Azaconazole except in preparations containing 1 per cent or less of azaconazole.

Azadirachta indica (Neem) including its extracts and derivatives except—

(a) when included in Schedule 5;

(b) in preparations for human internal use;

(c) debitterised neem seed oil;

(d) in preparations for human dermal therapeutic use containing cold pressed neem seed oil, when in a container fitted with a child-resistant closure and compliant with the labelling requirements under the Act; or

(e) in preparations for dermal use containing 1 per cent or less of cold pressed neem seed oil.

Azamethiphos.

Azobenzene.

Bambermycin (flavophospholipol) in animal feed premixes for growth promotion containing 2 per cent or less of antibiotic substances.

Barium salts except—

(a) when included in Schedule 5;

(b) barium sulfate; or

(c) in paints or tinters containing 5 per cent or less of barium calculated on the non-volatile content of the paint or tinter.

Basic blue 26 (CAS No. 2580-56-5) except when used as a colourant in cosmetics not intended to be in contact with mucous membranes.

Basic orange 31 (2-[(4-aminophenyl)azo]-1,3-dimethyl-1h-imidazolium chloride) except—

(a) in preparations for skin colouration and dyeing of eyelashes or eyebrows; or

(b) in hair dye preparations containing 1 per cent or less of Basic Orange 31 when the immediate container and primary pack are labelled with the following statements—

(i) "KEEP OUT OF REACH OF CHILDREN";

(ii) "IF IN EYES WASH OUT IMMEDIATELY WITH WATER"; and

(iii) "WARNING – This product contains ingredients which may cause skin irritation to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye",

written in letters not less than 1.5 mm in height.

Basic red 76 (CAS No. 68391-30-0) in non-oxidative hair dye preparations and eyebrow/eyelash colouring products containing 2 per cent or less of Basic Red 76 and 0.001 per cent or less of free *o*-anisidine.

Bay oil except—

(a) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 ml or less fitted with a restricted flow insert and compliant with the labelling requirements under the Act;

(b) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 ml or less fitted with a restricted flow insert and a child-resistant closure and compliant with the labelling requirements under the Act;

(c) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 ml or less fitted with a restricted flow insert and labelled with the warnings "KEEP OUT OF REACH OF CHILDREN" and "NOT TO BE TAKEN";

(d) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 ml or less fitted with a restricted flow insert and a child-resistant closure and labelled with the warnings "KEEP OUT OF REACH OF CHILDREN" and "NOT TO BE TAKEN"; or

(e) in preparations containing 25 per cent or less of bay oil.

Beauveria bassiana except when included in Schedule 5.

Bendiocarb—

(a) in wettable powders containing 80 per cent or less of bendiocarb when packed in containers or primary packs containing not less than 100 g of bendiocarb;

(b) in wettable powders containing 20 per cent or less of bendiocarb and not less than 0.002 per cent of denatonium benzoate when packed in containers or primary packs containing not less than 48 g of bendiocarb and labelled for use as a fly control preparation;

(c) in insoluble granular preparations containing 5 per cent or less of bendiocarb; or

(d) when impregnated in plastic resin strip material containing 10 per cent or less of bendiocarb,

except when included in Schedule 5.

Benquinox.

Bensulide.

Benzalkonium chloride except—

(a) when included in Schedule 5; or

(b) in preparations containing 5 per cent or less of benzalkonium chloride.

1,2-benzenediol.

Benzovindiflupyr.

6-benzyladenine except in preparations containing 10 per cent or less of 6-benzyladenine.

Beryllium.

Betacyfluthrin in preparations containing 12.5 per cent or less of betacyfluthrin except when included in Schedule 5.

Beta-cypermethrin.

Bhc (excluding lindane).

Bicyclopyrone except when included in Schedule 5.

Bifenthrin in preparations containing 25 per cent or less of bifenthrin except in preparations containing 0.5 per cent or less of bifenthrin.

Bifluorides (including ammonium, potassium and sodium salts) in preparations containing 3 per cent or less of total bifluorides except when included in Schedule 5.

Bioallethrin except—

(a) when included in Schedule 5; or

(b) in preparations containing 1 per cent or less of bioallethrin.

1,3-bis(2,4-diaminophenoxy) propane (including its salts) except when in hair dye preparations containing 1.2 per cent or less of 1,3-bis(2,4-diaminophenoxy)propane after mixing when the immediate container and primary pack are labelled with the following statements "KEEP OUT OF REACH OF CHILDREN" and "WARNING - This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye", written in letters not less than 1.5 mm in height.

Bis-isobutyl peg/ppg-20/35/amodimeticone copolymer except in rinse-off cosmetic products containing 1 per cent or less of bis-isobutyl PEG/PPG-20/35/amodimeticone copolymer when labelled with a warning to the following effect "IF IN EYES, WASH OUT IMMEDIATELY WITH WATER".

N,*N*-BIS(PHENYLMETHYLENE)-BICYCLO-(2.2.1)HEPTANE-2,5-DIMETHANAMINE except in preparations containing 1 per cent or less of *N*,*N*-bis(phenylmethylene)-bicyclo- (2.2.1)heptane-2,5-dimethanamine, or a combination of *N*,*N*-bis(phenylmethylene)-bicyclo-(2.2.1)heptane-2,5-dimethanamine and N,N-bis(phenylmethylene)-bicyclo-(2.2.1)heptane-2,6-dimethanamine, when labelled with statements to the effect of—

(a) "IRRITANT";

(b) "REPEATED EXPOSURE MAY CAUSE SENSITISATION";

(c) "Avoid contact with eyes";

(d) "Avoid contact with skin";

(e) "Wear protective gloves when mixing or using"; and

(f) "Ensure adequate ventilation when using".

N,*n*-bis(phenylmethylene)-bicyclo-(2.2.1)heptane-2,6-dimethanamine except in preparations containing 1 per cent or less of *n*,*n*-bis(phenylmethylene)-bicyclo-(2.2.1)heptane-2,6-dimethanamine, or a combination of *N*,*N*-bis(phenylmethylene)-bicyclo-(2.2.1) heptane-2,5-dimethanamine and *N*,*N*-bis(phenylmethylene)-bicyclo-(2.2.1)heptane-2,6-dimethanamine, when labelled with statements to the effect of—

(a) "IRRITANT";

(b) "REPEATED EXPOSURE MAY CAUSE SENSITISATION";

(c) "Avoid contact with eyes";

(d) "Avoid contact with skin";

(e) "Wear protective gloves when mixing or using"; and

(f) "Ensure adequate ventilation when using".

Bithionol for the treatment of animals.

Boron trifluoride in preparations containing 1 per cent or less of boron trifluoride (BF_3) except when included in Schedule 5.

Brodifacoum in preparations containing 0.25 per cent or less of brodifacoum.

Broflanilide except when included in Schedule 5.

Bromadiolone in preparations containing 0.25 per cent or less of bromadiolone.

Bromethalin in rodent baits containing 0.01 per cent or less of bromethalin.

Bromoform except when included in Schedule 4.

Bromophos.

Bromophos-ethyl.

Bromoxynil.

Bromuconazole except when included in Schedule 5.

Brotianide.

Bunamidine.

Butacarb.

Butoxycarboxim except when included in Schedule 5.

2-butoxyethanol and its acetates except—

(a) in plant growth regulator preparations containing 20 per cent or less of such substances; or

(b) in other preparations containing 10 per cent or less of such substances.

2-butoxy-2'-thiocyanodiethyl ether.

N-butyl alcohol except—

(a) when included in Schedule 5;

(b) in preparations containing 5 per cent or less of n-butyl alcohol; or

(c) in preparations for cosmetic or therapeutic use other than in spray form.

Butyric acid in preparations for use as insect lures.

Cacodylic acid—

(a) in animal feed premixes containing 4 per cent or less of arsenic; or

(b) in herbicide or defoliant preparations containing 10 per cent or less of cacodylic acid.

Cadmium compounds except—

(a) when included in Schedule 4; or

(b) in paints or tinters containing 0.1 per cent or less of cadmium calculated on the non-volatile content of the paint or tinter.

Cadusafos in aqueous preparations containing 20 per cent or less of microencapsulated cadusafos.

Caffeine except—

(a) when included in Schedule 4;

(b) in divided preparations for internal human therapeutic use when labelled with a maximum recommended daily dose of no greater than 600 mg of total caffeine;

(c) in undivided preparations for internal human therapeutic use with a concentration of less than 5 per cent of total caffeine and when labelled with a maximum recommended daily dose of no greater than 600 mg of total caffeine;

(d) in preparations for external use; or

(e) in other preparations with a concentration of less than 5 per cent of caffeine.

Cajuput oil except—

(a) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 ml or less fitted with a restricted flow insert and compliant with the labelling requirements under the Act;

(b) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 ml or less fitted with a restricted flow insert and a child-resistant closure and compliant with the labelling requirements under the Act;

(c) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 ml or less fitted with a restricted flow insert and labelled with the warnings "KEEP OUT OF REACH OF CHILDREN" and "NOT TO BE TAKEN";

(d) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 ml or less fitted with a restricted flow insert and a child-resistant closure and labelled with the warnings "KEEP OUT OF REACH OF CHILDREN" and "NOT TO BE TAKEN";

(e) in preparations containing 25 per cent or less of cajuput oil; or

(f) in oils containing 25 per cent or less of cajuput oil.

Calciferol in rodent baits containing 0.1 per cent or less of calciferol.

Cambendazole.

Camphor except—

(a) when included in schedules 4 or 5;

(b) when enclosed in an inhaler device which prevents ingestion of its contents;

(c) in solid or semi-solid preparations containing 12.5 per cent or less of camphor;

(d) in liquid preparations containing 2.5 per cent or less of camphor;

(e) in essential oils when the camphor is present as a natural component of the oil—

(i) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 ml or less fitted with a restricted flow insert and compliant with the labelling requirements under the Act;

(ii) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 ml or less fitted with a restricted flow insert and a child-resistant closure and compliant with the labelling requirements under the Act;

(iii) in essential oils other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 ml or less fitted with a restricted flow insert and labelled with the warnings "KEEP OUT OF REACH OF CHILDREN" and "NOT TO BE TAKEN"; or

(iv) in essential oils other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 ml or less fitted with a restricted flow insert and a child-resistant closure and labelled with the warnings "KEEP OUT OF REACH OF CHILDREN" and "NOT TO BE TAKEN"; or

(f) in rosemary oil, sage oil (Spanish), or lavandin oil as such.

Captan.

Carbaryl except when included in schedules 4 or 5.

Carbon disulfide.

Carbamide peroxide except—

(a) when included in Schedule 5; or

(b) in other preparations containing 9 per cent or less of carbamide peroxide.

Castor oil, monomaleate (excluding its salts and derivatives) in preparations for cosmetic use except in wash-off preparations containing 1 per cent or less of castor oil, monomaleate.

Chloralose (alpha-chloralose) when packed and labelled for use as a pesticide.

Chlordane.

Chlorfenapyr in preparations containing 36 per cent or less of chlorfenapyr except when included in Schedule 5.

Chlorfenethol.

Chlorhexidine in preparations containing 7 per cent or less of chlorhexidine except—

(a) when included in Schedule 5;

(b) in preparations containing 1 per cent or less of chlorhexidine; or

(c) when in solid preparations.

Chlorinating compounds except—

(a) when included in Schedule 5;

(b) when separately specified in the schedules to these Regulations;

(c) sodium hypochlorite preparations with a pH of less than 11.5;

(d) in liquid preparations containing not less than 2 per cent but not more than 4 per cent of available chlorine when labelled with the statements "Warning – ensure adequate ventilation when using. Vapour may be harmful. May give off dangerous gas if mixed with other products";

(e) in liquid preparations containing less than 2 per cent of available chlorine; or

(f) in other preparations containing 4 per cent or less of available chlorine.

Chlormequat.

Chloroacetamide—

(a) in preparations for cosmetic use;

(b) in preparations for topical therapeutic use; or

(c) in other preparations containing more than 0.3 per cent of chloroacetamide.

2-chloro-6-(ethylamino)-4-nitrophenol except—

(a) in non-oxidative hair dye preparations containing 3 per cent or less of 2-chloro-6-(ethylamino)-4-nitrophenol after mixing for use when the immediate container and primary pack are labelled with the following statements "KEEP OUT OF REACH OF CHILDREN" and "WARNING – This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use", written in letters not less than 1.5 mm in height; or

(b) in oxidative hair dye preparations containing 1.5 per cent or less of 2-chloro-6-(ethylamino)-4-nitrophenol after mixing for use when the immediate container and primary pack are labelled with the following statements "KEEP OUT OF REACH OF CHILDREN" and "WARNING – This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use", written in letters not less than 1.5 mm in height.

Chloroform except—

(a) when included in schedules 2 or 4; or

(b) in preparations containing 10 per cent or less of chloroform.

Alpha-chlorohydrin.

Chlorophacinone.

(*e*)-(*s*)-1-(4-chlorophenyl)-4,4-dimethyl-2-(1h-1,2,4-triazol-1-yl)pent-1-en-3-ol (uniconazole-p) except in preparations containing 5 per cent or less of (*e*)-(*s*)-1-(4-chlorophenyl)-4,4-dimethyl-2-(1*h*-1,2,4-triazol-1-yl)pent-1-en-3-ol.

Chloropicrin in preparations containing 5 per cent or less of chloropicrin.

Chlorothalonil except in water-based paint containing 0.5 per cent or less of chlorothalonil.

2-chloro-6-(trichloromethyl)-pyridine.

Chlorpyrifos except—

(a) when included in Schedule 5; or

(b) in prepared potting or soil mixes containing 100 g or less of chlorpyrifos per cubic metre.

Chlorpyrifos-methyl.

Chlorthiamid.

Chromates (including dichromates) except in paints or tinters containing 5 per cent or less of chromium as the ammonium, barium, calcium, iron, potassium, sodium, strontium or zinc chromate calculated on the non-volatile content of the paint or tinter.

Chromium trioxide (excluding its salts and derivatives).

Chrysoidine base except when in Schedule 10.

Cineole except—

(a) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 ml or less fitted with a restricted flow insert and compliant with the labelling requirements under the Act;

(b) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 ml or less fitted with a restricted flow insert and a child-resistant closure and compliant with the labelling requirements under the Act;

(c) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 ml or less fitted with a restricted flow insert and labelled with the warnings "KEEP OUT OF REACH OF CHILDREN" and "NOT TO BE TAKEN";

(d) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 ml or less fitted with a restricted flow insert and a child-resistant closure and labelled with the warnings "KEEP OUT OF REACH OF CHILDREN" and "NOT TO BE TAKEN";

(e) in preparations containing 25 per cent or less of cineole;

(f) in oils containing 25 per cent or less of cineole; or

(g) in rosemary oil or camphor oil (white).

Cinnamon leaf oil except—

(a) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 ml or less fitted with a restricted flow insert and compliant with the labelling requirements under the Act;

(b) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 ml or less fitted with a restricted flow insert and a child-resistant closure and compliant with the labelling requirements under the Act;

(c) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 ml or less fitted with a restricted flow insert and labelled with the warnings "KEEP OUT OF REACH OF CHILDREN" and "NOT TO BE TAKEN";

(d) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 ml or less fitted with a restricted flow insert and a child-resistant closure and labelled with the warnings "KEEP OUT OF REACH OF CHILDREN" and "NOT TO BE TAKEN"; or

(e) in preparations containing 25 per cent or less of cinnamon leaf oil.

Climbazole except—

(a) when included in Schedule 5;

(b) in leave-on hair, face and foot cosmetic preparations containing 0.5 per cent or less of climbazole; or

(c) in other preparations (that are not leave-on cosmetic preparations) containing 2 per cent or less of climbazole.

Clodinafop-propargyl.

Clomazone.

Closantel.

Clothianidin except—

(a) when included in Schedule 5; or

(b) when in gel preparations dispensed in sealed cartridges containing 1 per cent or less of clothianidin.

Clotrimazole for the external treatment of animals.

Clove oil except—

(a) when included in Schedule 5;

(b) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 ml or less fitted with a restricted flow insert and compliant with the labelling requirements under the Act;

(c) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 ml or less fitted with a restricted flow insert and a child-resistant closure and compliant with the labelling requirements under the Act;

(d) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 ml or less fitted with a restricted flow insert and labelled with the warnings "KEEP OUT OF REACH OF CHILDREN" and "NOT TO BE TAKEN";

(e) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 ml or less fitted with a restricted flow insert and a child-resistant closure and labelled with the warnings "KEEP OUT OF REACH OF CHILDREN" and "NOT TO BE TAKEN"; or

(f) in preparations containing 25 per cent or less of clove oil.

N-coco-1,3-diaminopropane.

Cocoyl glycinate in cosmetic preparations except—

(a) in leave-on preparations containing 5 per cent or less of cocoyl glycinate; or

(b) in wash-off preparations containing 30 per cent or less of cocoyl glycinate and, when containing more than 5 per cent of cocoyl glycinate labelled with a warning to the following effect "If in eyes wash out immediately with water".

Copper acetate except—

(a) when included in Schedule 5; or

(b) in preparations containing 5 per cent or less of copper acetate.

Copper compounds except—

(a) when separately specified in the schedules to these Regulations;

(b) in preparations for human internal use containing 5 mg or less of copper per recommended daily dose;

(c) pigments where the solubility of the copper compound in water is 1 g per litre or less;

(d) in feed additives containing 1 per cent or less of copper; or

(e) in other preparations containing 5 per cent or less of copper compounds.

Copper hydroxide except—

(a) when included in Schedule 5; or

(b) in preparations containing 12.5 per cent or less of copper hydroxide.

Copper nitrate in preparations containing copper chloride for the treatment of footrot in sheep.

Copper oxides except—

(a) when included in Schedule 5;

(b) in preparations for internal use;

(c) in marine paints; or

(d) in other preparations containing 5 per cent or less of copper oxides.

Copper oxychloride except—

(a) when included in Schedule 5; or

(b) in preparations containing 12.5 per cent of less of copper oxychloride.

Copper sulfate except—

(a) when included in Schedule 5;

(b) in preparations for internal use; or

(c) in other preparations containing 5 per cent or less of copper sulfate.

Coumaphos—

(a) in slow-release plastic matrix ear tags for livestock use containing 6 g or less of coumaphos; or

(b) in other preparations containing 5 per cent or less of coumaphos.

Coumatetralyl in rodenticides containing 1 per cent or less of coumatetralyl except when included in Schedule 5.

Creosote derived from wood other than beechwood except—

(a) when included in Schedule 2;

(b) in preparations for human therapeutic use containing 10 per cent or less of creosote derived from wood other than beechwood; or

(c) in other preparations containing 3 per cent or less of phenols and homologues of phenol boiling below 220°C.

Crotoxyphos.

Crufomate.

Cyanamide.

Cyanazine.

Cyclanilide.

N-cyclohexyldiazeniumdioxy-potassium.

Cyclosilazanes, di-me, me hydrogen, polymers with di-me, me-hydrogen silazanes, reaction products with 3-(triethoxysilyl)-1-propanamine (CAS No. 475645-84-2) when presented in a wipe and when packaged in a container with a child-resistant closure, with chemical resistant gloves and labelled with the following effect "DO NOT USE WITHOUT PROTECTIVE GLOVES" and "KEEP OUT OF EYES".

Cyfluthrin except—

(a) when included in Schedule 5; or

(b) in pressurised spray packs containing 1 per cent or less of cyfluthrin.

Cyometrinil.

Cypermethrin except when included in Schedule 5.

Cyphenothrin except when included in Schedule 5.

Cythioate except when included in Schedule 5.

2,4-D except when included in Schedule 5.

Dazomet.

Deltamethrin—

(a) in aqueous preparations containing 25 per cent or less of deltamethrin, when no organic solvent, other than 10 per cent or less of a glycol, is present;

(b) in wettable granular preparations containing 25 per cent or less of deltamethrin;

(c) in water-dispersible tablets each containing 500 mg or less of deltamethrin;

(d) in emulsifiable concentrates containing 11 per cent or less of deltamethrin in a solvent containing 40 per cent or less of acetophenone and 45 per cent or less of liquid hydrocarbons; or

(e) in other preparations containing 3 per cent or less of deltamethrin,

except—

(i) when included in Schedule 5;

(ii) in factory prepared mosquito nets containing 1 per cent or less of deltamethrin; or

(iii) in preparations containing 0.1 per cent or less of deltamethrin.

Derquantel.

1-deoxy-1-(methylamino)-D-glucitol *n*-coco acyl.

Derivatives except—

(a) in cosmetic rinse-off preparations containing 8 per cent or less of 1-deoxy-1-(methylamino)-d-glucitol N-coco acyl derivatives when labelled with the following statement "IF IN EYES WASH OUT IMMEDIATELY WITH WATER"; or

(b) in household cleaning preparations, other than those intended to be sprayed, containing 10 per cent or less of 1-deoxy-1-(methylamino)-d-glucitol N-coco acyl derivatives when labelled with the following statement "IF IN EYES WASH OUT IMMEDIATELY WITH WATER".

2,4-diaminophenoxyethanol except when used in hair dye and eyebrow/eyelash preparations at concentrations of 2 per cent or less of 2,4-diaminophenoxyethanol after mixing for use when the immediate container and primary pack are labelled with the following statements "KEEP OUT OF REACH OF CHILDREN" and "WARNING – This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use", written in letters not less than 1.5 mm in height.

Diazinon except when included in Schedule 5.

Dicamba (including its salts and derivatives) except when included in Schedule 5.

Dichlobenil.

Dichlofenthion.

Dichlofluanid.

O-dichlorobenzene.

Dichloroethyl ether.

Dichloroisocyanuric acid except—

(a) when included in Schedule 5;

(b) in liquid preparations containing not less than 2 per cent but not more than 4 per cent of available chlorine when labelled with the statements "WARNING – Ensure adequate ventilation when using. Vapour may be harmful. May give off dangerous gas if mixed with other products";

(c) in liquid preparations containing less than 2 per cent of available chlorine; or

(d) in other preparations containing 4 per cent or less of available chlorine.

4,5-dichloro-2-n-octyl-3(2*h*)-isothiazolone.

Dichlorophen except—

(a) when included in schedules 4 or 5; or

(b) in fabrics other than when—

(i) for human therapeutic use; or

(ii) as part of a registered pesticidal product.

1,2-dichloropropane.

2,4-dichlorprop (including the r and s enantiomers).

Dichlorvos in preparations containing 50 per cent or less of dichlorvos except when included in Schedule 5.

Diclofop-methyl.

Dicyclanil except in preparations containing 6.5 per cent or less of dicyclanil.

Didecyldimethylammonium salts except in preparations containing 1 per cent or less of didecyldimethylammonium salts labelled with the statement "Avoid contact with eyes".

Dieldrin.

Diethanolamine (excluding its salts and derivatives) except—

(a) when included in Schedule 5; or

(b) in preparations containing 5 per cent or less of diethanolamine.

Diethylene glycol (excluding its salts and derivatives) except—

(a) when included in Schedule 5;

(b) in paints or paint tinters;

(c) in toothpastes or mouthwashes containing more than 0.25 per cent of diethylene glycol; or

(d) in other preparations containing 2.5 per cent or less of diethylene glycol.

Diethylene glycol monomethyl ether.

Difenacoum in preparations containing 0.25 per cent or less of difenacoum.

Difenzoquat.

Difethialone in rodent baits containing 0.0025 per cent or less of difethialone.

5,6-dihydroxyindoline.

Dimethenamid-p.

Dimethipin.

Dimethoate.

2,6-dimethoxy-3,5-pyridinediamine except when used in hair dye and eyebrow/eyelash colouring products at a concentration of 0.25 per cent or less of 2,6-dimethoxy-3,5-pyridinediamine after mixing for use when the immediate container and primary pack are labelled with the following statements "KEEP OUT OF REACH OF CHILDREN" and "WARNING – This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use", written in letters not less than 1.5 mm in height.

Dimethylacetamide except when included in Schedule 5.

N,n-dimethyldecanamide.

Dimethylformamide except—

(a) when included in Schedule 5; or

(b) in silicone rubber mastic containing 2 per cent or less of dimethylformamide.

4,4-dimethyl-1-cyclohexene-1-propanal except—

(a) in leave-on cosmetic preparations containing 0.1 per cent or less of 4,4-dimethyl-1-cyclohexene-1-propanal;

(b) in rinse-off cosmetic preparations containing 0.5 per cent or less of 4,4-dimethyl-1-cyclohexene-1-propanal; or

(c) in other preparations containing 1 per cent or less of 4,4-dimethyl-1-cyclohexene-1-propanal.

3,7-dimethyl-2,6-octadien-1-ol and its isomers except in products containing 5 per cent or less 3,7-dimethyl-2,6-octadien-1-ol and its isomers.

N,*n*-dimethyloctanamide.

Dimethyl sulfoxide (excluding dimethyl sulfone)—

(a) when not for therapeutic use;

(b) in cosmetic preparations;

(c) for the treatment of animals—

(i) when combined with no other therapeutic substance;

(ii) in liquid preparations containing copper salicylate and 1 per cent or less of methyl salicylate as the only other therapeutic substances; or

(iii) in clay poultices containing 2 per cent or less of dimethyl sulfoxide; or

(d) in other preparations except when containing 10 per cent or less of dimethyl sulfoxide.

Dinitrocresols and their homologues in preparations containing 5 per cent or less of such compounds except—

(a) when included in Schedule 4; or

(b) when separately specified in this schedule.

Dinitrophenols and their homologues in preparations containing 5 per cent or less of such compounds except—

(a) when included in Schedule 4; or

(b) when separately specified in this schedule.

Dioxacarb.

Dioxane.

Diphacinone.

Diquat in preparations containing 20 per cent or less of diquat.

Direct red 254 except when included in Schedule 5.

Disperse yellow 3 except when in Schedule 10.

Disulfiram except when included in Schedule 4.

Disulfoton in granular preparations containing 5 per cent or less of disulfoton.

Dithianon.

Dithiazanine in preparations containing 2 per cent or less of dithiazanine for the treatment of animals.

Diuredosan.

N-(*n*-dodecyl)-2-pyrrolidone except—

(a) when included in Schedule 5; or

(b) in preparations containing 25 per cent or less of designated solvents.

Dodine.

Doramectin for external use for the treatment of animals, in preparations containing 2 per cent or less of doramectin.

Dsma in herbicide or defoliant preparations containing 10 per cent or less of dsma.

Econazole for the external treatment of animals.

Emamectin in preparations containing 5 per cent or less of emamectin except when included in Schedule 5.

Emodepside for the treatment of animals except when included in Schedule 5.

Endosulfan in aqueous preparations containing 33 per cent or less of microencapsulated endosulfan.

Endothal in preparations containing 20 per cent or less of endothal.

Eprinomectin for internal use in preparations containing 5 per cent or less of eprinomectin except when included in Schedule 5.

Eptc.

Esbiothrin except—

(a) when included in Schedule 5; or

(b) in pressurised spray packs containing 1 per cent or less of esbiothrin.

Esfenvalerate except when included in Schedule 5.

Ethephon (excluding its salts and derivatives).

Ether except—

(a) when included in schedules 2, 4 or 5; or

(b) in preparations containing 10 per cent or less of ether.

Ethiofencarb.

Ethoate-methyl.

Ethoprophos in granular formulations containing 10 per cent or less of ethoprophos and 2 per cent of linseed oil.

Ethyl bromide.

Ethylene chlorohydrin.

Ethylene dichloride.

Ethylene glycol (excluding its salts and derivatives) except—

(a) when included in Schedule 5;

(b) in paints or paint tinters;

(c) in toothpastes or mouthwashes containing more than 0.25 per cent of ethylene glycol; or

(d) in other preparations containing 2.5 per cent or less of ethylene glycol.

Ethylene glycol monoalkyl ethers and their acetates, except—

(a) when separately specified in the schedules to these Regulations; or

(b) in preparations containing 10 per cent or less of such substances.

Ethyl formate when packed and labelled for use as a fumigant.

Ethylhexanediol except in preparations containing 5 per cent or less of ethylhexanediol.

2-ethylhexanoic acid and its alkyl esters except in preparations containing 5 per cent or less calculated as 2-ethylhexanoic acid.

Etrimfos.

Eucalyptus oil except—

(a) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 ml or less fitted with a restricted flow insert and compliant with the labelling requirements under the Act;

(b) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 ml or less fitted with a restricted flow insert and a child-resistant closure and compliant with the labelling requirements under the Act;

(c) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 ml or less fitted with a restricted flow insert and labelled with the warnings "KEEP OUT OF REACH OF CHILDREN" and "NOT TO BE TAKEN";

d) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 ml or less fitted with a restricted flow insert and a child-resistant closure and labelled with the warnings "KEEP OUT OF REACH OF CHILDREN" and "NOT TO BE TAKEN"; or

(e) in preparations containing 25 per cent or less of eucalyptus oil.

Eugenol except—

(a) when included in Schedule 5;

(b) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 ml or less fitted with a restricted flow insert and compliant with the labelling requirements under the Act;

(c) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 ml or less fitted with a restricted flow insert and a child-resistant closure and compliant with the labelling requirements under the Act;

(d) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 ml or less fitted with a restricted flow insert and labelled with the warnings "KEEP OUT OF REACH OF CHILDREN" and "NOT TO BE TAKEN";

(e) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 ml or less fitted with a restricted flow insert and a child-resistant closure and labelled with the warnings "KEEP OUT OF REACH OF CHILDREN" and "NOT TO BE TAKEN"; or

(f) in preparations containing 25 per cent or less of eugenol.

Famphur in preparations containing 20 per cent or less of famphur.

Febantel except—

(a) in divided preparations containing 1000 mg or less of febantel per dosage unit; or

(b) in undivided preparations containing 10 per cent or less of febantel.

Fenamiphos in granular preparations containing 5 per cent or less of fenamiphos.

Fenazaflor.

Fenbutatin oxide.

Fenchlorphos.

Fenitrothion.

Fenoxacrim in preparations for the treatment of carpets during manufacture.

Fenpyroximate.

Fenthion in preparations containing 60 per cent or less of fenthion except when included in Schedule 5.

Fenvalerate.

Fipronil except—

(a) when included in Schedule 5; or

(b) in preparations containing 0.05 per cent or less of fipronil.

Flocoumafen in preparations containing 0.005 per cent or less of flocoumafen.

Flonicamid.

Fluazifop-butyl.

Fluazifop-*p*-butyl.

Fluazinam.

Flucofuron in preparations for the treatment of carpets during manufacture.

Fluensulfone.

Flumethrin except when included in Schedule 5.

Flumioxazin when contained in water soluble bags individually packed in sealed sachets.

Fluorides except—

(a) when included in Schedule 5;

(b) in preparations for human use; or

(c) in preparations containing 15 mg/kg or less of fluoride ion.

Flupropanate.

Flupyradifurone.

Fluquinconazole.

Flusilazol.

Flutriafol except in fertilisers containing 0.5 per cent or less of flutriafol.

Fluvalinate except when included in Schedule 5.

Formaldehyde (excluding its derivatives) in preparations containing 0.05 per cent or more of free formaldehyde except—

(a) for human therapeutic use;

(b) in oral hygiene preparations;

(c) in nail hardener cosmetic preparations containing 5 per cent or more of free formaldehyde;

(d) in nail hardener cosmetic preparations containing 0.2 per cent or less of free formaldehyde when labelled with the statement "PROTECT CUTICLES WITH GREASE OR OIL";

(e) in all other cosmetic preparations; or

(f) in other preparations containing 0.2 per cent or less of free formaldehyde when labelled with the warning statement "CONTAINS FORMALDEHYDE".

Formothion.

Fospirate except when included in Schedule 5.

Fumagillin.

Furfural except in preparations containing 0.1 per cent or less of furfural.

Glutaral except—

(a) when included in schedules 2 or 5; or

(b) in preparations containing 0.5 per cent or less of glutaral when labelled with the statements "IRRITANT" and "Avoid contact with eyes".

Glyceryl thioglycollate in hair waving preparations except when labelled with directions for use that include the statement "Wear protective gloves when using. Keep out of eyes".

Glycolic acid (including its salts and esters) in cosmetic products or when packed and labelled for use as an agricultural chemical except—

(a) in cosmetic preparations for salon use only, when labelled in accordance with requirements under the Act;

(b) in preparations containing 5 per cent or less of glycolic acid; or

(c) in preparations containing 20 per cent or less of glycolic acid with a pH of 3.5 or greater.

Guanidine except—

(a) when included in Schedule 4; or

(b) in preparations containing 1 per cent or less of guanidine.

Guazatine.

Haloxon.

Haloxyfop.

Hc violet 1 except—

(a) in non-oxidative hair dye preparations containing 0.28 per cent or less of HC Violet 1 after mixing when the immediate container and primary pack are labelled with the following statements "KEEP OUT OF REACH OF CHILDREN" and "WARNING - This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use", written in letters not less than 1.5 mm in height; or

(b) in oxidative hair dye preparations containing 0.25 per cent or less of HC Violet 1 after mixing under oxidative conditions when the immediate container and primary pack are labelled with the following statements "KEEP OUT OF REACH OF CHILDREN" and "WARNING - This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye", written in letters not less than 1.5 mm in height.

Heptachlor.

Hexachlorophene—

(a) in preparations for the treatment of animals; or

(b) for cosmetic use.

Hexazinone except when included in Schedule 5.

Hexyloxyethanol except in preparations containing 10 per cent or less of hexyloxyethanol.

Hydramethylnon except when included in Schedule 5.

Hydrazine.

Hydrochloric acid (excluding its salts and derivatives) except—

(a) when included in Schedule 5;

(b) in preparations for therapeutic use; or

(c) in preparations containing 0.5 per cent or less of hydrochloric acid (HCl).

Hydrofluoric acid (excluding its salts and derivatives) and admixtures that generate hydrofluoric acid, in preparations containing 1 per cent or less of hydrogen fluoride except when included in Schedule 5.

Hydrogen peroxide (excluding its salts and derivatives) except—

(a) when included in Schedule 5;

(b) in hair dye preparations containing 6 per cent (20 volume) or less of hydrogen peroxide; or

(c) in other preparations containing 3 per cent (10 volume) or less of hydrogen peroxide.

Hydroquinone except—

(a) when included in schedules 2 or 4; or

(b) in preparations containing 10 per cent or less of hydroquinone.

Hydrosilicofluoric acid (excluding its salts and derivatives) in preparations containing 1 per cent or less of hydrosilicofluoric acid (H_2SiF_6) except when included in Schedule 5.

Hydroxyethyl-3,4-methylenedioxyaniline (including its salts) except in oxidative hair dye preparations containing 1.5 per cent or less of hydroxyethyl-3,4-methylenedioxyaniline after mixing under oxidative conditions when the immediate container and primary pack are labelled with the following statements "KEEP OUT OF REACH OF CHILDREN" and "WARNING - This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye", written in letters not less than 1.5 mm in height.

Imidacloprid except—

(a) when included in Schedule 5; or

(b) in preparations containing 5 per cent or less of imidacloprid.

Imidocarb.

Iminoctadine trialbesilate.

Imiprothrin except—

(a) when included in Schedule 5; or

(b) in preparations containing 10 per cent or less of imiprothrin.

Indaziflam.

Indoxacarb (includes the R and S enantiomers) except when included in Schedule 5.

Iodine (excluding its salts, derivatives and iodophors) except—

(a) when included in Schedule 2; or

(b) in solid or semi-solid preparations containing 2.5 per cent or less of available iodine.

Iodophors except in preparations containing 1.5 per cent or less of available iodine.

3-iodo-2-propynyl butyl carbamate (Iodocarb) except—

(a) when included in Schedule 5;

(b) in aqueous preparations not for cosmetic use containing 10 per cent or less of 3-iodo-2-propynyl butyl carbamate (Iodocarb); or

(c) in cosmetic preparations (other than aerosolised preparations) containing 0.1 per cent or less of 3-iodo-2-propynyl butyl carbamate.

Ioxynil.

Ipconazole except when included in Schedule 5.

Iron compounds (excluding up to 1 per cent of iron oxides when present as an excipient) for the treatment of animals except—

(a) when included in Schedule 5;

(b) in liquid or gel preparations containing 0.1 per cent or less of iron; or

(c) in animal feeds or feed premixes.

Isoconazole for the external treatment of animals.

Isocyanates, free organic, boiling below 300° C, except in—

(a) viscous polyurethane adhesives; or

(b) viscous polyurethane sealants,

containing not more than 0.7 per cent of free organic isocyanates boiling below 300°C.

Isoeugenol except—

(a) when included in Schedule 5;

(b) in preparations not intended for skin contact containing 10 per cent or less of isoeugenol; or

(c) in preparations intended for skin contact containing 0.02 per cent or less of isoeugenol.

Isopyrazam.

Lambda-cyhalothrin—

(a) in aqueous preparations containing 25 per cent or less of microencapsulated lambda-cyhalothrin;

(b) in emulsifiable granule formulations containing 25 per cent or less lambda-cyhalothrin; or

(c) in other preparations containing 1.6 per cent or less of lambda-cyhalothrin,

except when included in Schedule 5.

Lasalocid except in animal feeds containing 100 mg/kg or less of antibiotic substances.

Laureth carboxylic acids (excluding their salts and derivatives) except—

(a) in leave-on preparations containing 1.5 per cent or less of laureth carboxylic acids;

(b) in wash-off preparations containing 30 per cent or less of laureth carboxylic acids and, if containing more than 5 per cent of laureth carboxylic acids, when labelled with a warning to the following effect "IF IN EYES WASH OUT IMMEDIATELY WITH WATER"; or

(c) in other preparations containing 30 per cent or less of laureth carboxylic acids and, if containing more than 5 per cent of laureth carboxylic acids, when labelled with warnings to the following effect "IF IN EYES WASH OUT IMMEDIATELY WITH WATER" and "IF SKIN OR HAIR CONTACT OCCURS, REMOVE CONTAMINATED CLOTHING AND FLUSH SKIN AND HAIR WITH RUNNING WATER".

Lauryl isoquinolinium bromide.

Lauryl sulfate salts (excluding their derivatives) except—

(a) in wash-off preparations containing 30 per cent or less of lauryl sulfates and, if containing more than 5 per cent of lauryl sulfates, when labelled with a warning to the following effect "IF IN EYES WASH OUT IMMEDIATELY WITH WATER";

(b) in leave-on preparations containing 1.5 per cent or less of lauryl sulfates;

(c) in toothpaste and oral hygiene preparations containing 5 per cent or less of lauryl sulfates;

(d) in other preparations for animal use containing 2 per cent or less of lauryl sulfates; or

(e) in other preparations containing 30 per cent or less of lauryl sulfates and, if containing more than 5 per cent of lauryl sulfates, when labelled with warnings to the following effect "IF IN EYES WASH OUT IMMEDIATELY WITH WATER" and "IF SKIN OR HAIR CONTACT OCCURS, REMOVE CONTAMINATED CLOTHING AND FLUSH SKIN AND HAIR WITH RUNNING WATER".

Lead compounds except—

(a) when included in schedules 4 or 5;

(b) in paints, tinters, inks or ink additives;

(c) in preparations for cosmetic use containing 100 mg/kg or less of lead;

(d) in pencil cores, finger colours, showcard colours, pastels, crayons, poster paints/colours or coloured chalks containing 100 mg/kg or less of lead; or

(e) in ceramic glazes when labelled with the warning statement "CAUTION – Harmful if swallowed. Do not use on surfaces which contact food or drink", written in letters not less than 1.5 mm in height.

Leptospermum scoparium oil (manuka oil) except—

(a) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 ml or less fitted with a restricted flow insert and compliant with the labelling requirements under the Act;

(b) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 ml or less fitted with a restricted flow insert and a child-resistant closure and compliant with the labelling requirements under the Act;

(c) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 ml or less fitted with a restricted flow insert and labelled with the warnings "KEEP OUT OF REACH OF CHILDREN" and "NOT TO BE TAKEN";

(d) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 ml or less fitted with a restricted flow insert and a child-resistant closure and labelled with the warnings "KEEP OUT OF REACH OF CHILDREN" and "NOT TO BE TAKEN"; or

(e) in preparations containing 25 per cent or less of leptospermum scoparium oil.

Levamisole for the treatment of animals except—

(a) when included in schedules 4 or 5; or

(b) in preparations for the treatment of ornamental birds or ornamental fish, in packs containing 10 mg or less of levamisole.

Lindane except when included in schedules 2, 4 or 5.

Mafenide when packed and labelled for the treatment of ornamental fish only.

Malathion except—

(a) when included in Schedule 5;

(b) for human therapeutic use; or

(c) in dust preparations containing 2 per cent or less of malathion.

Mcpa except when included in Schedule 5.

Mcpb.

Mebendazole for the treatment of animals except when included in Schedule 5.

Mecoprop except when included in Schedule 5.

Mecoprop-*p*.

Mefluidide.

Melaleuca oil (tea tree oil) except—

(a) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 ml or less fitted with a restricted flow insert and compliant with the labelling requirements under the Act;

(b) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 ml or less fitted with a restricted flow insert and a child-resistant closure and compliant with the labelling requirements under the Act;

(c) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 ml or less fitted with a restricted flow insert and labelled with the warnings "KEEP OUT OF REACH OF CHILDREN" and "NOT TO BE TAKEN";

(d) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 ml or less fitted with a restricted flow insert and a child-resistant closure and labelled with the warnings "KEEP OUT OF REACH OF CHILDREN" and "NOT TO BE TAKEN"; or

(e) in preparations containing 25 per cent or less of melaleuca oil.

Melengestrol acetate when used as an animal feed additive.

Menazon.

Mercaptamine for cosmetic use except—

(a) when included in Schedule 5; or

(b) in preparations containing 1 per cent or less of mercaptamine.

Mercaptoacetic acid and its salts, but excluding its derivatives, in cosmetic preparations except—

(a) when included in Schedule 5; or

(b) in preparations containing 5 per cent or less of mercaptoacetic acid or its salts (as mercapturic acid).

2-mercaptoethanol in preparations for use as insect lures.

Mercuric oxide for the treatment of animals, in preparations for ocular use.

Mercurochrome for the treatment of animals, in preparations for topical use.

Metacresolsulphonic acid and formaldehyde condensation product for the treatment of animals.

Metalaxyl except when included in Schedule 5.

Metaldehyde except when included in Schedule 5.

Methacrifos in preparations containing 60 per cent or less of methacrifos.

Metham.

Metamitron.

Methanol (excluding its derivatives) except—

(a) when included in Schedule 5; or

(b) in preparations containing 2 per cent or less of methanol.

Methiocarb in preparations containing 20 per cent or less of methiocarb except when included in Schedule 5.

Methomyl in fly-baits containing 1 per cent or less of methomyl and not less than 0.002 per cent of denatonium benzoate as a bittering agent.

2-methoxy-5-nitrophenol.

Methylchloroisothiazolinone except—

(a) in rinse-off cosmetic preparations or therapeutic goods intended for topical rinse-off application containing 0.0015 per cent or less of methylchloroisothiazolinone and methylisothiazolinone in total; or

(b) in other preparations that are not intended for direct application to the skin containing 0.1 per cent or less of methylchloroisothiazolinone and methylisothiazolinone in total.

Methylcyclopentadienyl manganese tricarbonyl in preparations containing 10 per cent or less of methylcyclopentadienyl manganese tricarbonyl when fitted with a child-resistant closure.

Methyldibromo glutaronitrile except when in Schedule 10.

Methylene bisthiocyanate except in preparations containing 1 per cent or less of methylene bisthiocyanate.

Methyleugenol except in preparations containing 1 per cent or less of methyleugenol.

Methyl ethyl ketone oxime except—

(a) in viscous silicone adhesives or viscous silicone sealants containing 2.5 per cent or less of methyl ethyl ketone oxime; or

(b) in other preparations conting 1 per cent or less of methyl ethyl ketone oxime.

P-methylaminophenol except when used in hair dye and eyebrow/eyelash colouring products at a concentration of 1 per cent or less of *p*-methylaminophenol after mixing for use when the immediate container and primary pack are labelled with the following statements "KEEP OUT OF REACH OF CHILDREN" and "WARNING - This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use",written in letters not less than 1.5 mm in height.

Methyl isothiocyanate.

Methyl methacrylate (excluding its derivatives) except—

(a) for cosmetic use; or

(b) in preparations containing 1 per cent or less of methyl methacrylate as residual monomer in a polymer.

Methyl neodecanamide except in liquid preparations containing 2 per cent or less of methyl neodecanamide.

Methylisothiazolinone except—

(a) in rinse-off cosmetic preparations or therapeutic goods intended for topical rinse-off application containing 0.0015 per cent or less of methylisothiazolinone; or

(b) in other preparations that are not intended for direct application to the skin containing 0.1 per cent or less of methylisothiazolinone.

Methylnorbornylpyridine.

N-methyl-2-pyrrolidone except—

(a) when included in Schedule 5; or

(b) in preparations containing 25 per cent or less of designated solvents.

2-methylresorcinol except—

(a) in non-oxidative hair dye preparations containing 1.8 per cent or less of 2methylresorcinol when the immediate container and primary pack are labelled with the following statements "KEEP OUT OF REACH OF CHILDREN" and "WARNING – This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye", written in letters not less than 1.5 mm in height; or

(b) in oxidative hair dye preparations containing 1.8 per cent or less of 2-methylresorcinol after mixing under oxidative conditions when the immediate container and primary pack are labelled with the following statements "KEEP OUT OF REACH OF CHILDREN" and "WARNING – This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye", written in letter not less than 1.5 mm in height.

Methylrosanilinium chloride (formerly known as crystal violet CAS No. 548-62-9) and the following triarylmethane dyes—

(a) acid violet 49 (CAS No. 1694-09-3);

(b) ethyl violet (CAS No. 2390-59-2);

(c) basic blue 7 (CAS No. 2390-60-5); or

(d) methylium, 4-(dimethylamino)phenylbis4-(ethylamino)-3-methylphenyl-, acetate (CAS No. 72102-55-7),

except when included in schedules 4 or 10.

Methyl salicylate except—

(a) when included in Schedule 5;

(b) in preparations for therapeutic use; or

(c) in preparations containing 5 per cent or less of methyl salicylate.

Metofluthrin except when included in Schedule 5.

Metosulam.

Metrafenone except when included in Schedule 5.

Metribuzin.

Miconazole for the external treatment of animals.

Milbemectin except when included in Schedule 5.

Momfluorothrin except in preparations containing 0.2 per cent or less of momfluorothrin.

Monensin—

(a) in animal feed premixes containing 12.5 per cent or less of antibiotic substances; or

(b) in stockfeed supplements, blocks or licks containing 0.75 per cent or less of antibiotic substances.

Monoethanolamine (excluding its salts and derivatives) except—

(a) when included in schedules 4 or 5; or

(b) in preparations containing 5 per cent or less of monoethanolamine.

Morantel except—

(a) when included in Schedule 5; or

(b) in preparations containing 10 per cent or less of morantel.

Moxidectin—

(a) in preparations for external use containing 2.5 per cent or less of moxidectin when packed in single dose tubes for the treatment of cats and dogs;

(b) in preparations for external use containing 2 per cent or less of moxidectin for the treatment of animals; or

(c) in preparations for internal use containing 10 per cent or less of moxidectin for the treatment of sheep or cattle,

except when included in Schedule 5.

MSMA in herbicide or defoliant preparations containing 10 per cent or less of MSMA.

Naled except when included in Schedule 5.

Naphthalene (excluding its derivatives) except in liquid hydrocarbons.

1,5-naphthalenediol except—

(a) in non-oxidative hair dye preparations containing 1 per cent or less of 1,5-naphthalenediol when the immediate container and primary pack are labelled with the following statements "KEEP OUT OF REACH OF CHILDREN" and "WARNING - This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye", written in letters not less than 1.5 mm in height; or

(b) in oxidative hair dye preparations containing 1 per cent or less of 1,5-naphthalenediol after mixing under oxidative conditions when the immediate container and primary pack are labelled with the following statements "KEEP OUT OF REACH OF CHILDREN" and "WARNING - This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye", written in letters not less than 1.5 mm in height.

2,7-naphthalenediol except—

(a) in non-oxidative hair dye preparations containing 1 per cent or less of 2,7-naphthalenediol when the immediate container and primary pack are labelled with the following statements "KEEP OUT OF REACH OF CHILDREN" and "WARNING – This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye", written in letters not less than 1.5 mm in height; or

(b) in oxidative hair dye preparations containing 1 per cent or less of 2,7-naphthalenediol after mixing under oxidative conditions when the immediate container and primary pack are labelled with the following statements "KEEP OUT OF REACH OF CHILDREN" and "WARNING – This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye", written in letters not less than 1.5 mm in height.

1-naphthol except in hair dye preparations containing 1 per cent or less of 1-naphthol after mixing under oxidative conditions when the immediate container and primary pack are labelled with the following statements "KEEP OUT OF REACH OF CHILDREN" and "WARNING - This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye", written in letters not less than 1.5 mm in height.

Naphthalophos in preparations containing 80 per cent or less of naphthalophos.

Narasin in animal feed premixes containing 12 per cent or less of narasin.

Netobimin for the treatment of animals except when included in Schedule 5.

Nickel sulfate.

Nicotine in preparations containing 3 per cent or less of nicotine when labelled and packed for the treatment of animals.

Nimidane in preparations containing 25 per cent or less of nimidane.

Nitenpyram except in divided preparations containing 100 mg or less of nitenpyram.

Nitric acid (excluding its salts and derivatives) except—

(a) when included in Schedule 5; or

(b) in preparations containing 0.5 per cent or less of nitric acid (HNO_3).

Nitrobenzene except—

(a) in solid or semi-solid polishes;

(b) in soaps containing 1 per cent or less of nitrobenzene; or

(c) in other preparations containing 0.1 per cent or less of nitrobenzene.

3-nitro-*p*-hydroxyethylaminophenol except—

(a) in non-oxidative hair dye preparations containing 1.85 per cent or less of 3-nitro-p-hydroxyethylaminophenol after mixing when the immediate container and primary pack are labelled with the following statements "KEEP OUT OF REACH OF CHILDREN" and "WARNING - This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye", written in letters not less than 1.5 mm in height; or

(b) in oxidative hair dye preparations containing 3 per cent or less of 3-nitro-p-hydroxyethylaminophenol after mixing under oxidative conditions when the immediate container and primary pack are labelled with the following statements "KEEP OUT OF REACH OF CHILDREN" and "WARNING - This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye", written in letters not less than 1.5 mm in height.

Nitrophenols, ortho, meta and para, except when separately specified in the schedules to these Regulations.

Nitroprussides in preparations containing 2.5 per cent or less of nitroprussides except when included in Schedule 4.

Nitroxynil.

Nonoxinol 9 except—

(a) when included in Schedule 5;

(b) in preparations containing 25 per cent or less of nonoxinol 9 when labelled with the statements "IRRITANT" and "Avoid contact with eyes";

(c) in preparations containing 12.5 per cent or less of nonoxinol 9; or

(d) in preparations for human use.

1-octen-3-ol except in preparations containing 5 per cent or less of 1-octen-3-ol.

Octhilinone except in paints, jointing compounds and sealants containing 1 per cent or less of octhilinone calculated on the non-volatile content.

N-(*n*-octyl)-2-pyrrolidone except—

(a) when included in Schedule 5; or

(b) in preparations containing 25 per cent or less of designated solvents.

Olaquindox except in preparations containing 10 per cent or less of olaquindox.

N-oleyl-1,3-diaminopropane.

Omethoate in preparations containing 30 per cent or less of omethoate except when included in Schedule 5.

Oxadiazon.

Oxalic acid except—

(a) in dental care preparations, including mouthwashes, containing 3 per cent or less of soluble salts of oxalic acid; or

(b) its insoluble salts.

Oxyclozanide.

Paecilomyces lilacinus strain 251.

Paraformaldehyde (excluding its derivatives) in preparations containing 0.05 per cent or more of free formaldehyde except—

(a) for human therapeutic use;

(b) in oral hygiene preparations;

(c) in nail hardener cosmetic preparations containing 5 per cent or more of free formaldehyde;

(d) in nail hardener cosmetic preparations containing 0.2 per cent or less of free formaldehyde when labelled with the statement "PROTECT CUTICLES WITH GREASE OR OIL";

(e) in all other cosmetic preparations; or

(f) in other preparations containing 0.2 per cent or less of free formaldehyde when labelled with the warning statement "CONTAINS FORMALDEHYDE".

Parathion-methyl in aqueous preparations containing 45 per cent or less of microencapsulated parathion-methyl.

Parbendazole.

Pebulate.

Pennyroyal oil except—

(a) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 ml or less fitted with a restricted flow insert and a child-resistant closure and compliant with the labelling requirements under the Act;

(b) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 ml or less fitted with a restricted flow insert and a child-resistant closure and labelled with the warnings "KEEP OUT OF REACH OF CHILDREN" and "NOT TO BE TAKEN"; or

(c) in preparations containing 4 per cent or less of D-pulegone.

Pentachlorophenol in preparations containing 1.5 per cent or less of pentachlorophenol.

Peracetic acid except when included in Schedule 5.

Perfluidone.

Permanganates except potassium permanganate in aqueous solutions containing 1 per cent or less of potassium permanganate.

Permethrin except—

(a) when included in schedules 4 or 5;

(b) in preparations for human therapeutic use containing 5 per cent or less of permethrin; or

(c) in preparations containing 2 per cent or less of permethrin.

2-phenoxyethanol except—

(a) in cosmetic preparations containing 1 per cent or less of 2-phenoxyethanol; or

(b) in other preparations containing 15 per cent or less of 2-phenoxyethanol.

Phenol, including cresols and xylenols and any other homologue of phenol boiling below 220°C, except—

(a) when separately specified in the schedules to these Regulations; or

(b) in preparations containing 1 per cent or less of phenols, and in preparations containing 3 per cent or less of cresols and xylenols and other homologues of phenol.

Phenothiazine (excluding its derivatives) except in preparations containing 10 per cent or less of phenothiazine.

Phenoxymethyl oxirane.

Phenylenediamines including alkylated, arylated, halogenated and nitro derivatives not elsewhere specified in the schedules to these Regulations—

(a) in preparations packed and labelled for photographic purposes;

(b) in preparations packed and labelled for testing water except tablets containing 10 mg or less of diethyl-para-phenylenediamine or dimethyl-para-phenylenediamine in opaque strip packaging provided the directions for use include the statement, "Do not discard testing solutions into the pool";

(c) in hair dye preparations except when the immediate container and primary pack are labelled with the following statements "KEEP OUT OF REACH OF CHILDREN" and "WARNING — This product contains ingredients which may cause skin irritation to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye", written in letters not less than 1.5 mm in height; or

(d) in eyelash and eyebrow tinting products when the immediate container and primary pack are labelled with the following statement "WARNING— This product contains ingredients which may cause skin irritation to certain individuals, and when used for eyelash and eyebrow tinting may cause injury to the eye. A preliminary test according to the accompanying directions should be made before use", written in letters not less than 1.5 mm in height.

Phenyl methyl pyrazolone except when used in hair dye and eyebrow/eyelash preparations at a concentration of 0.25 per cent or less after mixing for use when the immediate container and primary pack are labelled with warning statements to the following effect "KEEP OUT OF REACH OF CHILDREN" and "WARNING – This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use", written in letters not less than 1.5 mm in height.

Phosalone.

Phosmet.

Phosphoric acid (excluding its salts and derivatives) except—

(a) when included in Schedule 5;

(b) in preparations containing 15 per cent or less of phosphoric acid (H_3PO_4);

(c) in solid or semi-solid preparations; or

(d) in professional dental kits.

Phoxim.

O-phthalaldehyde except when included in Schedule 5.

Pindone.

Pine oils when packed and labelled as a herbicide except when included in Schedule 5.

Pinoxaden except when included in Schedule 5.

Piperophos.

Pirimicarb except when included in Schedule 5.

Pirimiphos-ethyl.

Pirimiphos-methyl.

Polihexanide except—

(a) in cosmetic preparations containing 0.3 per cent or less of polihexanide;

(b) when packed and labelled for therapeutic use; or

(c) in other preparations containing 5 per cent or less of polihexanide.

Polixetonium salts except—

(a) when included in Schedule 5; or

(b) in preparations containing 1 per cent or less of polixetonium salts.

Potassium azeloyl diglycinate except in preparations for cosmetic use containing 1 per cent or less of potassium azeloyl diglycinate.

Potassium bromate except in preparations containing 0.5 per cent or less of potassium bromate.

Potassium cyanate.

Potassium hydroxide (excluding its salts and derivatives) except—

(a) when included in schedules 5 or 10;

(b) in preparations containing 5 per cent or less of potassium hydroxide being—

(i) solid preparations, the pH of which in a 10 g/l aqueous solution is 11.5 or less; or

(ii) liquid or semi-solid preparations, the pH of which is 11.5 or less.

Potassium nitrite in preparations containing 40 per cent or less of potassium nitrite except—

(a) when included in Schedule 5;

(b) in preparations containing 0.5 per cent or less of potassium nitrite;

(c) when present as an excipient in preparations for therapeutic use; or

(d) in aerosols containing 2 per cent or less of potassium nitrite.

Potassium peroxomonosulfate triple salt except—

(a) when included in Schedule 5;

(b) in solid orthodontic device cleaning preparations, the pH of which as an "in-use" aqueous solution is 2.5 or more, but not more than 11.5; or

(c) in preparations containing 5 per cent or less of potassium peroxomonosulfate triple salt being—

(i) solid preparations, the pH of which in a 10 g/l aqueous solution is 2.5 or more; or

(ii) liquid or semi-solid preparations, the pH of which is 2.5 or more.

Potassium persulfate in hair preparations.

Prallethrin (cis:trans=20:80) except—

(a) when included in Schedule 5; or

(b) in insecticidal mats containing 1 per cent or less of prallethrin.

Prochloraz.

Profenofos.

Promacyl.

Propachlor.

Propargite.

Propetamphos.

Propiconazole except when included in Schedule 5.

Propineb.

Propionic acid (excluding its salts and derivatives) except—

(a) when included in Schedule 5;

(b) in preparations containing 30 per cent or less of propionic acid; or

(c) for therapeutic use.

Propoxur except when included in Schedule 5.

N-propyl alcohol except—

(a) when included in Schedule 5;

(b) in preparations containing 5 per cent or less of n-propyl alcohol; or

(c) in preparations for cosmetic or therapeutic use other than in spray form.

Proquinazid.

Prosulfocarb.

Prosulfuron.

Prothiofos.

D-pulegone except in preparations containing 4 per cent or less of d-pulegone.

Pyraclofos.

Pyrazophos.

Pyridaben except when included in Schedule 5.

Pyridalyl.

Pyridate.

Pyriprole.

Pyrithione copper.

Pyrithione zinc except—

(a) when included in schedules 2 or 5;

(b) for human use in preparations for the treatment of the scalp containing 2 per cent or less of pyrithione zinc when compliant with the labelling requirements under the Act;

(c) in semi-solid hair preparations for animal use;

(d) in shampoos for animal use containing 2 per cent or less of pyrithione zinc when labelled with the statements "Keep out of eyes" and "If in eyes rinse well with water";

(e) when immobilised in solid preparations containing 0.5 per cent or less of pyrithione zinc; or

(f) in paints, jointing materials or sealants containing 0.1 per cent or less of pyrithione zinc calculated on the non-volatile content.

Pyriofenone except when included in Schedule 5.

Pyroxasulfone.

Pyroxsulam.

Quaternary ammonium compounds except—

(a) when separately specified in the schedules to these Regulations;

(b) when included in Schedule 5;

(c) dialkyl or dialkoyl quaternary ammonium compounds where the alkyl or alkoyl groups are derived from tallow or hydrogenated tallow or similar chain length (C16/C18) sources; or

(d) in preparations containing 5 per cent or less of such quaternary ammonium compounds.

Quinine in cosmetic preparations except—

(a) in rinse-off hair preparations containing 0.5 per cent or less of quinine calculated as free base; or

(b) in leave-on hair preparations containing 0.2 per cent or less of quinine calculated as free base.

Quinoline and its salts (excluding other derivatives).

Quizalofop ethyl.

Quizalofop-*p*-ethyl except when included in Schedule 5.

Quizalofop-*p*-tefuryl.

Resmethrin except when included in Schedule 5.

Resorcinol except—

(a) in preparations for human therapeutic use;

(b) in oxidative hair dye preparations containing 1.25 per cent or less of resorcinol after mixing for use when the immediate container and primary pack are labelled with the following statements "KEEP OUT OF REACH OF CHILDREN" and "WARNING - This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye", written in letters not less than 1.5 mm in height;

(c) in oxidative eyelash and eyebrow dye preparations containing 1.25 per cent or less of resorcinol after mixing for use when the immediate container and primary pack are labelled with the following statements "KEEP OUT OF REACH OF CHILDREN" and "WARNING - This product contains ingredients which may cause skin sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use",written in letters not less than 1.5 mm in height; or

(d) in hair lotions/shampoo products containing 0.5 per cent or less of resorcinol when the immediate container and primary pack are labelled with the following statement "WARNING – This product contains ingredients which may cause skin sensitisation to certain individuals", written in letters not less than 1.5 mm in height.

Rotenone except in solid or semi-solid preparations containing 2 per cent or less of rotenone.

Safrole except—

(a) for internal use; or

(b) in other preparations containing 1 per cent or less of safrole.

Sage oil (Dalmatian) except—

(a) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 ml or less fitted with a restricted flow insert and a child-resistant closure and compliant with the labelling requirements under the Act;

(b) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 15 ml or less fitted with a restricted flow insert and a child-resistant closure and labelled with the warnings "KEEP OUT OF REACH OF CHILDREN" and "NOT TO BE TAKEN"; or

(c) in preparations containing 4 per cent or less of thujone.

Salinomycin in animal feed premixes containing 12 per cent or less of antibiotic substances.

Sarolaner except when included in Schedule 5.

Sassafras oil except—

(a) for internal use; or

(b) in other preparations containing 1 per cent or less of safrole.

Selenium—

(a) in preparations containing 2.5 per cent or less of selenium when packed and labelled—

(i) for the blueing of gun barrels;

(ii) for photographic purposes; or

(iii) for the colouring of lead or lead alloys;

(b) in coated granules containing 1 per cent or less of selenium for application to pasture except in fertilisers containing 200 g/tonne or less of selenium; or

(c) for the treatment of animals—

(i) in a drench, injection, paste, stocklick, vaccine or horse feed supplement containing 0.5 per cent or less of selenium;

(ii) in animal feed premixes containing 2 per cent or less of selenium for the preparation of feeds containing 1 g/tonne or less of selenium;

(iii) in controlled release bolus preparations containing 25 mg or less of selenium with a release rate not greater than 0.25 mg/day; or

(iv) as barium selenate in preparations for injection containing 5 per cent or less of selenium.

Semduramicin in animal feed premixes for coccidiosis prevention containing 5 per cent or less of antibiotic substances.

Silicofluorides except—

(a) when included in Schedule 5; or

(b) in preparations containing 15 mg/kg or less of fluoride ion.

Silver nitrate except—

(a) when included in or expressly excluded from Schedule 2; or

(b) in preparations containing 1 per cent or less of silver.

Sinbioallethrin except—

(a) when included in Schedule 5; or

(b) in preparations containing 1 per cent or less of sinbioallethrin.

Sodium aluminate (excluding its salts and derivatives) except—

(a) in solid preparations, the pH of which in a 10 g/l aqueous solution is 11.5 or less; or

(b) in liquid preparations, the pH of which is 11.5 or less.

Sodium bromate except in preparations containing 0.5 per cent or less of sodium bromate.

Sodium hydroxide (excluding its salts and derivatives) except—

(a) when included in schedules 5 or 10;

(b) in preparations containing 5 per cent or less of sodium hydroxide being—

(i) solid preparations, the pH of which in a 10 g/l aqueous solution is 11.5 or less; or

(ii) liquid or semi-solid preparations, the pH of which is 11.5 or less.

Sodium nitrite in preparations containing 40 per cent or less of sodium nitrite except—

(a) when included in schedules 2 or 5;

(b) in preparations containing 0.5 per cent or less of sodium nitrite;

(c) when present as an excipient in preparations for therapeutic use; or

(d) in aerosols containing 2 per cent or less of sodium nitrite.

Sodium percarbonate (CAS No. 15630-89-4) except—

(a) when included in Schedule 5; or

(b) in preparations containing 15 per cent or less of sodium percarbonate.

Sodium persulfate—

(a) in hair preparations; or

(b) in products for the treatment of water for swimming pools and spas.

Sodium sulfide in preparations for use as insect lures.

Spiropidion.

Spirotetramat.

Spiroxamine.

Sulcofuron in preparations for the treatment of carpets during manufacture.

Sulfamic acid (excluding its salts and derivatives) except when included in Schedule 5.

Sulfluramid.

Sulfoxaflor except when included in Schedule 5.

Sulfuric acid (excluding its salts and derivatives) except—

(a) in fire extinguishers; or

(b) in preparations containing 0.5 per cent or less of sulfuric acid (H_2SO_4).

Sulfuryl fluoride.

Sulprofos.

2,4,5-t.

N-tallow alkyl-1,3-propanediamine diacetate and tallow.

Alkylamine acetates.

Tar acids distilling within the range 230-290°c inclusive.

Tcmtb (2-[thiocyanomethylthio]benzothiazole).

Tde (1,1-dichloro-2,2-bis[4-chlorophenyl]ethane) except when included in Schedule 5.

Tebufenpyrad.

Tebuthiuron.

Temephos except when in Schedule 5.

Terbuthylazine except in preparations containing 5 per cent or less of terbuthylazine.

Terpenes, chlorinated.

Testosterone in implant preparations for use in animals.

Tetrachloroethylene except—

(a) when included in schedules 2 or 5;

(b) in preparations containing 6 per cent or less of tetrachloroethylene when absorbed into an inert solid; or

(c) in preparations for the treatment of animals.

Tetraconazole except when included in Schedule 5.

Tetradifon.

2,2',6,6'-tetraisopropyl-diphenyl-carbodiimide in amitraz formulations containing 2 per cent or less of 2,2',6,6'-tetraisopropyl-diphenyl-carbodiimide.

Tetramisole in preparations for the treatment of animals.

Thiacloprid.

Thiamethoxam except when included in Schedule 5.

Thiazafluron.

Thiodicarb except when included in Schedule 5.

Thiometon.

Thiophanate-methyl except when included in Schedule 5.

Thiourea and alkyl thioureas except—

(a) when separately specified in the schedules to these Regulations; or

(b) for therapeutic use.

Thiram except in paint containing 0.5 per cent or less of thiram.

Thujone except in preparations containing 4 per cent or less of thujone.

Thymol when packed and labelled for use as a pesticide.

Toluene (excluding its derivatives) except in preparations containing 50 per cent or less of toluene or toluene and xylene.

Toluenediamine not elsewhere specified in the schedules to these Regulations—

(a) in hair dye preparations except when the immediate container and primary pack are labelled with the following statements "KEEP OUT OF REACH OF CHILDREN" and "WARNING – This product contains ingredients which may cause skin irritation to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye", written in letters not less than 1.5 mm in height;

(b) in eyelash and eyebrow tinting products when the immediate container and primary pack are labelled with the following statement "WARNING – This product contains ingredients which may cause skin irritation to certain individuals, and when used for eyelash and eyebrow tinting may cause injury to the eye. A preliminary test according to the accompanying directions should be made before use", written in letters not less than 1.5 mm in height; or

(c) in nail polish preparations containing 2,5-toluenediamine except when labelled "Avoid contact with skin".

Tolylfluanid.

Transfluthrin except—

(a) in preparations containing 1 per cent or less of transfluthrin; or

(b) in a cartridge for vaporiser use containing 600 mg or less of transfluthrin per cartridge.

Triadimefon except—

(a) when included in Schedule 5; or

(b) in fertilisers containing 5 g/kg or less of triadimefon.

Trichlorfon except metrifonate included in Schedule 4.

Trichloroacetic acid except—

(a) when included in schedules 4 or 5; or

(b) in human dermal preparations containing 12.5 per cent or less of trichloroacetic acid for the treatment of warts other than anogenital warts.

Trichloroethylene except when included in Schedule 4.

Trichlorophenol.

Triclabendazole except in preparations containing 20 per cent or less of triclabendazole.

Triclopyr.

Triclosan in cosmetic preparations for human use containing more than 0.3 per cent of triclosan.

Tridemorph.

Triethyl phosphate.

Trifluoromethanesulfonic acid.

Trinitrophenol (excluding its derivatives) except—

(a) in preparations for human therapeutic use; or

(b) in preparations containing 5 per cent or less of trinitrophenol.

Trisodium nitrilotriacetate except in preparations containing 20 per cent or less of trisodium nitrilotriacetate.

Vamidothion.

Vinyl acetate monomer (excluding its derivatives) except—

(a) in preparations for therapeutic use;

(b) in cosmetic preparations containing 0.01 per cent or less of vinyl acetate as residual monomer in a polymer; or

(c) in other preparations containing 1 per cent or less of vinyl acetate.

Warfarin except when included in schedules 4 or 5.

Xylene (excluding its derivatives) except in preparations containing 50 per cent or less of xylene or xylene and toluene.

Zeranol in ear implants for use as a growth promotant in steer cattle.

Zeta-cypermethrin in preparations containing 10 per cent or less of zeta-cypermethrin.

Zinc borate (excluding its derivatives) for use as an agricultural chemical.

Zinc chloride except—

(a) when included in Schedule 2; or

(b) in preparations containing 5 per cent or less of zinc chloride.

Zinc para-phenolsulfonate except in preparations containing 5 per cent or less of zinc para-phenolsulfonate.

Zinc lactate in toothpaste except in toothpaste preparations containing 2.5 per cent or less of zinc lactate and labelled with the statement "Not recommended for children under 12 years of age".

Zinc sulfate except—

(a) when included in or expressly excluded from Schedule 4; or

(b) in other preparations containing 5 per cent or less of zinc sulfate.

Ziram in granular preparations.

SCHEDULE 7
(Regulation 9)

DANGEROUS POISONS

Abamectin except when included in schedules 5 or 6.

Acibenzolar-*s*-methyl.

Acriflavinium chloride for veterinary use except when in Schedule 5.

Acrolein.

Acrylonitrile.

Alachlor.

Aldicarb.

Aldoxycarb.

Allyl alcohol except—

(a) in preparations containing 5 per cent or less of allyl esters with 0.1 per cent or less of free allyl alcohol by weight of allyl ester; or

(b) when separately specified in the schedules to these Regulations.

Alpha-cypermethrin except when included in schedules 5 or 6.

Aminoacridine for veterinary use except when included in Schedule 5.

Aminocarb except when included in Schedule 6.

4-aminopropiophenone.

4-aminopyridine except when included in Schedule 4.

Amiton.

Arprinocid.

Arsenic except—

(a) when separately specified in this schedule;

(b) when included in schedules 4 or 6;

(c) as selenium arsenide in photocopier drums;

(d) as 10,10'-oxydiphenoxarsine in silicone rubber mastic containing 120 mg/kg or less of arsenic;

(e) as 10,10'-oxydiphenoxarsine contained in polyvinyl chloride and polyurethane extruded and moulded articles containing 160 mg/kg or less of arsenic other than when included in articles—

(i) in contact with food stuffs, animal feeds or potable water;

(ii) of clothing and footwear in contact with the skin;

(iii) used as infant wear; or

(iv) intended for use as packaging materials;

(f) in animal feeds containing 75 g/tonne or less of arsenic; or

(g) in paints containing 0.1 per cent or less of arsenic calculated on the non-volatile content of the paint.

Azafenidin.

Azinphos-ethyl.

Azinphos-methyl.

Azocyclotin.

Azo dyes that are derivatives by diazotisation of any of the following substances—

(a) p-aminoazobenzene (CAS No. 60-09-3);

(b) o-aminoazotoluene (CAS No. 97-56-3);

(c) o-anisidine (CAS No. 90-04-0);

(d) p-chloroaniline (CAS No. 106-47-8);

(e) 4-chloro-o-toluidine (CAS No. 95-69-2);

(f) 6-methoxy-m-toluidine (p-cresidine) (CAS No. 120-71-8);

(g) 2-naphthylamine (CAS No. 91-59-8);

(h) 5-nitro-o-toluidine (CAS No. 99-55-8);

(i) 2,4-toluenediamine (CAS No. 95-80-7);

(j) o-toluidine (CAS No. 95-53-4); and

(k) 2,4,5-trimethylaniline (CAS No. 137-17-7),

except for basic red 76 (CAS No. 68391-30-0) when included in Schedule 6.

Bendiocarb except when included in schedules 5 or 6.

Benomyl except in paints containing 0.5 per cent or less of benomyl.

Benzene (excluding its derivatives) except—

(a) in preparations containing 15 ml/l or less of benzene; or

(b) in petrol containing 50 ml/l or less of benzene.

Benzidine-based azo dyes being—

(a) 2,2'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis[n-(4-chlorophenyl)-3-oxobutanamide] (CAS No. 94249-03-3);

(b) acid red 85 (acid fast red a);

(c) 1,3-naphthalenedisulfonic acid, 7-hydroxy-8-[[4'-[[4-[[(4-methylphenyl) sulfonyl]oxy]phenyl]azo][1,1'-biphenyl]-4-yl]azo]-, disodium salt (CAS No. 3567-65-5);

(d) c.i acid black 29 (CAS No. 12217-14-0);

(e) c.i direct orange 1 (CAS No. 54579-28-1);

(f) direct black 38;

(g) 2,7-naphthalenedisulfonic acid, 4-amino-3-[[4'-[(2,4-diaminophenyl)azo][1,1'-biphenyl]-4-yl]azo]-5-hydroxy-6-(phenylazo)-, disodium salt (CAS No. 1937-37-7);

(h) direct blue 2;

(i) 2,7-naphthalenedisulfonic acid, 5-amino-3-[[4'-[(7-amino-1-hydroxy-3-sulfo-2-naphthalenyl)azo][1,1'-biphenyl]-4-yl]azo]-4-hydroxy-, trisodium salt (CAS No. 2429-73-4);

(j) direct blue 6;

(k) 2,7-naphthalenedisulfonic acid, 3,3'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis[5-amino-4-hydroxy-, tetrasodium salt (CAS No. 2602-46-2);

(l) direct brown 2;

(m) 5-[[4'-[(7-amino-1-hydroxy-3-sulfo-2-naphthalenyl)azo][1,1'-biphenyl]-4-yl]azo]-2-hydroxy- benzoic acid disodium salt (CAS No. 2429-82-5);

(n) direct brown 95;

(o) cuprate(2-), [5-[[4'-[[2,6-dihydroxy-3-[(2-hydroxy-5-sulfophenyl)azo]phenyl]azo][1,1'-biphenyl]-4-yl]azo]-2-hydroxybenzoato(4-)]-, disodium salt (CAS No. 16071-86-6);

(p) direct green 1;

(q) 2,7-naphthalenedisulfonic acid, 4-amino-5-hydroxy-3-[[4'-[(4-hydroxyphenyl)azo][1,1'-biphenyl]-4-yl]azo]-6-(phenylazo)-, disodium salt (CAS No. 3626-28-6);

(r) direct green 6;

(s) 2,7-naphthalenedisulfonic acid, 4-amino-5-hydroxy-6-[[4'-[(4-hydroxyphenyl)azo][1,1'-biphenyl]-4-yl]azo]-3-[(4-nitrophenyl)azo]-, disodium salt (CAS No. 4335-09-5);

(t) direct red 28 (congo red);

(u) 1-naphthalenesulfonic acid, 3,3'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis[4-amino-, disodium salt (CAS No. 573-58-0);

(v) direct red 37; and

(w) 1,3-naphthalenedisulfonic acid, 8-[[4'-[(4-ethoxyphenyl)azo][1,1'-biphenyl]-4-yl]azo]-7-hydroxy-, disodium salt (CAS No. 3530-19-6).

Benzidine-congener (3,3'-disubstituted) azo dyes.

Betacyfluthrin except when included in schedules 5 or 6.

Bifenthrin except—

(a) when included in Schedule 6; or

(b) in preparations containing 0.5 per cent or less of bifenthrin.

Bifluorides (including ammonium, potassium and sodium salts) except when included in schedules 5 or 6.

Boron trifluoride except when included in schedules 5 or 6.

Brodifacoum except when included in Schedule 6.

Bromadiolone except when included in Schedule 6.

Bromethalin except when included in Schedule 6.

Bromine (excluding its salts and derivatives).

Brucine except in alcohol containing 0.02 per cent or less of brucine as a denaturant.

Cacodylic acid except—

(a) when included in Schedule 6; or

(b) in animal feeds containing 75 g/tonne or less of arsenic.

Cadusafos except when included in Schedule 6.

Calciferol for use as a rodenticide except when included in Schedule 6.

Captafol.

Carbadox.

Carbendazim except in paints, jointing compounds and sealants containing 0.1 per cent or less of carbendazim.

Carbofuran.

Carbon tetrachloride except in chlorinated rubber based paint containing 1 per cent or less of carbon tetrachloride.

Carbonyl sulfide when packed and labelled for use as a fumigant.

Carbophenothion.

Carbosulfan.

Chlordecone.

Chlordimeform.

Chlorfenapyr except when included in schedules 5 or 6.

Chlorfenvinphos.

Chlorine (excluding its salts and derivatives).

Chlorhexidine except—

(a) when included in schedules 5 or 6;

(b) in preparations containing 1 per cent or less of chlorhexidine; or

(c) in solid preparations.

Chloromethiuron.

5-chloro-3-methyl-4-nitropyrazole.

4-chloro-*o*-toluidine.

Chloropicrin except when included in Schedule 6.

Chlorthiophos.

Colecalciferol for use as a rodenticide.

Coumaphos except when included in Schedule 6.

Coumatetralyl except when included in schedules 5 or 6.

Creosote derived from coal.

Creosote derived from beechwood.

Cyanides, metallic except—

(a) ferricyanides;

(b) ferrocyanides; or

(c) when separately specified in the schedules to these Regulations.

Cyanogen.

Cyclosilazanes, di-me, me hydrogen, polymers with di-me, me hydrogen silazanes, reaction products with 3-(triethoxysilyl)-1-propanamine (CAS No. 475645-84-2) except when included in Schedule 6.

Cyhalothrin (aRS,1R,cis,Z):(aRS,1S,cis,Z) = 50:50.

Cyhexatin.

Deltamethrin except—

(a) when included in schedules 5 or 6;

(b) in factory prepared mosquito nets containing 1 per cent or less of deltamethrin; or

(c) in preparations containing 0.1 per cent or less of deltamethrin.

Demeton.

Demeton-*o*-methyl.

Demeton-*s*-methyl.

Dialifos.

4,4-diaminodiphenylmethane (methylene dianiline).

1,2-dibromo-3-chloropropane.

1,3-dichloropropene except in biocidal preparations containing 0.3 per cent or less of 1,3-dichloropropene.

Dichlorvos except when included in schedules 5 or 6.

Dicrotophos.

Difenacoum except when included in Schedule 6.

Difethialone except when included in Schedule 6.

Dimefox.

4-dimethylaminoazobenzene (*n*,*n*-dimethyl-4-[phenylazo]-benzenamine).

Dimethyl sulfate.

Dimetilan.

Dinitrocresols except when included in schedules 4 or 6.

Dinitrophenols except when included in schedules 4, 6 or 10.

Dinocap.

Dinoseb.

Diquat except when included in Schedule 6.

Disulfoton except when included in Schedule 6.

Doramectin except when included in schedules 5 or 6.

Dsma except when included in Schedule 6.

Emamectin except when included in schedules 5 or 6.

Endosulfan except when included in Schedule 6.

Endothal except when included in Schedule 6.

Endrin.

Epichlorohydrin.

Epidermal growth factor except in preparations for human therapeutic use.

Eprinomectin except when included in schedules 5 or 6.

Etaconazole.

Ethion.

Ethoprophos except when included in Schedule 6.

2-ethoxyethanol and its acetates except in preparations containing 0.5 per cent or less of 2-ethoxyethanol.

Ethylene dibromide.

Ethylene oxide.

Famphur except when included in Schedule 6.

Fenamiphos except when included in Schedule 6.

Fenoxacrim except—

(a) when included in Schedule 6; or

(b) in treated carpets.

Fensulfothion.

Fenthion except when included in schedules 5 or 6.

Fenthion-ethyl.

Flocoumafen except when included in Schedule 6.

Flucofuron except—

(a) when included in Schedule 6; or

(b) in treated carpets.

Flucythrinate.

Flumioxazin except when included in Schedule 6.

Fluoroacetamide.

Fluoroacetic acid.

Folpet.

Formetanate.

Fosthiazate.

Furathiocarb except when included in Schedule 5.

Gamma-cyhalothrin except when included in Schedule 5.

Halofuginone except when included in Schedule 4.

Halogenated dibenzodioxins and dibenzofurans.

Hcb.

Hydrocarbons liquid aromatic (including aromatic extract oils), any fraction of which boils above 350°C except—

(a) when in solid polymers;

(b) when containing 1 per cent or less of total polycyclic aromatic compounds as measured by IP 346; or

(c) when having a Mutagenicity Index of zero as measured by ASTM E1687-95.

Hydrocyanic acid except—

(a) when included in Schedule 4; or

(b) its salts and derivatives other than cyanides separately specified in this schedule.

Hydrofluoric acid (excluding its salts and derivatives) except when included in schedules 5 or 6.

Hydrogen sulfide.

Hydrosilicofluoric acid (excluding its salts and derivatives) except when included in schedules 5 or 6.

Iodomethane.

Isocarbophos.

Isofenphos.

Isoproturon.

Ivermectin except when included in schedules 4 or 5.

Lambda-cyhalothrin except when included in schedules 5 or 6.

Leptophos.

Lithium perfluorooctane sulfonate except in sealed bait stations containing 1 per cent or less of lithium perfluorooctane sulfonate.

Maduramicin except—

(a) when included in Schedule 5; or

(b) in animal feeds containing 5 mg/kg or less of antibiotic substances.

Malachite green for veterinary use except when included in Schedule 5.

Mazidox.

Mecarbam.

2-methoxyethanol and its acetates except in preparations containing 0.5 per cent or les of 2-methoxyethanol.

Mercuric chloride when prepared for use for agricultural, industrial, pastoral or horticultural purposes.

Mercury except—

(a) when separately specified in this schedule;

(b) when included in schedules 2, 4 or 6;

(c) in preparations containing 0.01 per cent or less of mercury in organic form as a preservative;

(d) mercury (metallic) in scientific instruments;

(e) dental amalgams; or

(f) in a sealed device, for therapeutic use, which prevents access to the mercury.

Methacrifos except when included in Schedule 6.

Methamidophos.

Methapyrilene.

Methazole.

Methidathion.

Methiocarb except when included in schedules 5 or 6.

Methomyl except when included in Schedule 6.

Methoxyethylmercuric acetate.

Methoxyethylmercuric chloride.

Methyl bromide.

Methylcyclopentadienyl manganese tricarbonyl except—

(a) when included in Schedule 6;

(b) when used in laboratory analysis; or

(c) when packed for industrial use in containers with a nominal capacity of 100 l or more.

4,4'-methylenebis[2-chloroaniline] (moca).

Methylene blue for veterinary use except when included in schedules 4 or 5.

Mevinphos.

Mipafox.

Mirex.

Molinate.

Monocrotophos.

Moxidectin except when included in schedules 4, 5 or 6.

Msma except when included in Schedule 6.

Naphthalophos except when included in Schedule 6.

Nicotine except—

(a) when included in Schedule 6;

(b) in preparations for human therapeutic use; or

(c) in tobacco prepared and packed for smoking.

Nimidane except when included in Schedule 6.

Nitrofen.

Nitroprussides except when included in schedules 4 or 6.

2-nitrotoluene.

Omethoate except when included in schedules 5 or 6.

Oxamyl.

Oxydemeton methyl.

Paraquat.

Parathion.

Parathion-methyl except when included in Schedule 6.

Pentachlorophenol except when included in Schedule 6.

Phenylmercuric acetate except in preparations containing 0.01 per cent or less of mercury as a preservative.

Phorate.

Phosfolan.

Phosphides, metallic.

Phosphine.

Phosphorus, yellow (excluding its salts and derivatives).

Potassium nitrite except—

(a) when included in schedules 5 or 6;

(b) in preparations containing 0.5 per cent or less of potassium nitrite;

(c) when present as an excipient in preparations for therapeutic use; or

(d) in aerosols containing 2 per cent or less of potassium nitrite.

Procymidone.

Propylene oxide.

Pyrinuron.

Quinine for veterinary use except when included in Schedule 5.

Saflufenacil except when included in Schedule 5.

Schradan.

Selenium except—

(a) when included in Schedule 6;

(b) as selenium arsenide in photocopier drums;

(c) in preparations for therapeutic use other than—

(i) drench concentrates containing 2.5 per cent or less of selenium; or

(ii) pour-on preparations containing 0.5 per cent or less of selenium;

(d) in paints or tinters containing 0.1 per cent or less of selenium calculated on the non-volatile content of the paint or tinter; or

(e) in fertilisers containing 200 g/tonne or less of selenium.

Semduramicin except—

(a) when included in Schedule 6; or

(b) in animal feeds containing 25 mg/kg or less of antibiotic substances.

Sodium nitrite except—

(a) when included in schedules 2, 5 or 6;

(b) in preparations containing 0.5 per cent or less of sodium nitrite;

(c) when present as an excipient in preparations for therapeutic use; or

(d) in aerosols containing 2 per cent or less of sodium nitrite.

Strychnine except when included in Schedule 4.

Sulcofuron except—

(a) when included in Schedule 6; or

(b in treated carpets.

Sulfentrazone.

Sulfotep.

Tefluthrin except when included in Schedule 5.

Tepp.

Terbufos.

Tetrachloroethane.

2,2',6,6'-tetraisopropyl-diphenyl-carbodiimide except when included in Schedule 6.

Thallium.

Thiofanox.

Tin organic compounds, being dialkyl, trialkyl and triphenyl tin compounds where the alkyl group is methyl, ethyl, propyl or butyl except—

(a) when separately specified in this schedule;

(b) in plastics;

(c) in semi-solid sealants, adhesives or elastomers containing 1 per cent or less of the dialkyl, trialkyl or triphenyl tin component; or

(d) in paint containing 1 per cent or less of such compounds calculated as tin in the non-volatile content of the paint.

O-tolidine except in solid-state diagnostic therapeutic reagents.

Triamiphos.

Triazbutil.

Tribufos (s,s,s-tributylphosphorotrithioate).

Vinclozolin.

Vinyl chloride.

Zeta-cypermethrin except when included in Schedule 6.

Ziram except when included in Schedule 6.

SCHEDULE 8

(Regulation 10)

DANGEROUS DRUGS

Acetyldihydrocodeine.

Acetylmethadol.

Acetylmorphines.

Alfentanil.

Alphacetylmethadol.

Alphaprodine.

Amfetamine also known as amphetamine.

Amobarbital except when included in Schedule 4.

Anileridine.

Benzylmorphine.

Bezitramide.

Buprenorphine.

Butobarbital.

Butorphanol.

Cocaine.

Codeine except when included in Schedule 4.

Codeine-*n*-oxide.

Concentrate of poppy straw (the material arising when poppy straw has entered into a process for concentration of its alkaloids).

4-cyano-1-methyl-4-phenylpiperidine (pethidine intermediate a).

Cyclobarbital.

Dexamfetamine.

Dextromoramide.

dextropropoxyphene except when included in Schedule 4.

Difenoxin except when included in Schedule 4.

Dihydrocodeine except when included in schedules 3 or 4.

Dihydromorphine.

Diphenoxylate except when included in schedules 3 or 4.

Dipipanone.

Dronabinol (delta-9-tetrahydrocannabinol) when prepared and packed for therapeutic use.

Drotebanol.

Ethylamfetamine.

Ethylmorphine fentanyl.

Hydrocodone.

Hydromorphinol.

Hydromorphone.

Levamfetamine.

Levomethamfetamine.

Levomoramide.

Levorphanol (excluding its stereoisomers).

Lisdexamfetamine.

Methadone.

Metamfetamine (or methamphetamine).

Methyldihydromorphine.

Methylphenidate.

1-methyl-4-phenylpiperidine-4-carboxylic acid (pethidine intermediate c).

Morphine.

Morphine methobromide.

Morphine-n-oxide.

Nabilone.

Norcodeine.

Normethadone.

Oxycodone.

Oxymorphone.

Pentazocine.

Pentobarbital except when included in Schedule 4.

Pethidine.

Phendimetrazine.

Phenmetrazine.

Phenoperidine.

4-phenylpiperidine-4-carboxylic acid ethyl ester (pethidine intermediate b).

Pholcodine except when included in schedules 2 or 4.

Piritramide.

Propiram.

Racemoramide.

Remifentanil.

Secbutobarbital.

Secobarbital.

Sodium oxybate for human therapeutic use.

Sufentanil.

Tapentadol.

Thebacon.

Thebaine.

Tilidine.

All narcotic drugs under the International Control (Singler Convention on Narcotic Drugs, 1961)

SCHEDULE 9
(Regulation 11)

PROHIBITED SUBSTANCES

Acetorphine.

Acetyl-alpha-methylfentanyl.

Alkoxyamfetamines and substituted alkoxyamfetamines except when separately specified in the schedules to these Regulations.

Alkoxyphenylethylamines and substituted alkoxyphenylethylamines except when separately specified in the schedules to these Regulations.

Alkylthioamfetamines and substituted alkylthioamfetamines except when separately specified in the schedules to these Regulations.

Allylprodine.

Alphameprodine.

Alpha-methylfentanyl.

Alpha-methylthiofentanyl.

Alphamethadol.

Alpha-pyrrolidinovalerophenone *(alpha-pvp).

2-amino-1-(2,5-dimethoxy-4-methyl)phenylpropane *(stp or dom).

5-(2-aminopropyl)indan and substituted 5-(2-aminopropyl)indans except when separately specified in the schedules to these Regulations.

Benzethidine.

Benzoylindoles except when separately specified in the schedules to these Regulations.

Benzylpiperazine *(bzp).

Betacetylmethadol.

Beta-hydroxyfentanyl.

Beta-hydroxy-3-methylfentanyl.

Betameprodine.

Betamethadol.

Betaprodine.

1-(8-bromobenzo[1,2-b;4,5-b]difuran-4-yl)-2-aminopropane *(bromo-dragonfly).

4-bromo-2,5-dimethoxyphenethylamine *(bdmpea).

Bufotenine.

Cannabis (including seeds, extracts, resins, tinctures and the plant and any part of the plant whether fresh, dried or otherwise).

Carfentanyl.

Cathinones except when separately specified in the schedules to these Regulations.

Clonazolam.

Clonitazene.

Coca leaf.

Codoxime.

4-cyano-2-dimethylamino-4,4'-diphenylbutane.

Cyclohexylphenols except—

(a) when separately specified in the schedules to these Regulations; or

(b) in preparations containing 0.5 per cent or less of cyclohexylphenols.

Deschloroetizolam.

Desomorphine.

N,*n*-dialkylaminocyclohexyl alkyl benzamides except when separately specified in the schedules to these Regulations.

N,*n*-dialkylaminocyclohexylmethyl alkyl benzamides except when separately specified in the schedules to these Regulations.

Diampromide.

Dibenzopyrans except when separately specified in the schedules to these Regulations.

3,4-dichloro-n-[(1r,2r)-2-(dimethylamino)cyclohexyl]-*n*-methylbenzamide (u-47700).

3,4-dichloro-n-{[1- (dimethylamino)cyclohexyl]methyl}benzamide *(ah-7921).

Diclazepam.

Diethylthiambutene.

N,n-diethyltryptamine *(det).

Dimenoxadol.

Dimepheptanol.

2,5-dimethoxyamfetamine *(dma).

2,5-dimethoxy-4-bromoamfetamine *(dob).

2,5-dimethoxy-4-ethyl-*a*-amfetamine *(doet).

2,5-dimethoxy-4-ethylthiophenethylamine *(2c-t-2).

2,5-dimethoxy-4-iodophenethylamine *(2c-i).

2,5-dimethoxy-4-(*n*)-propylthiophenethylamine *(2c-t-7).

3-(2-dimethylaminoethyl)-4-hydroxyindole *(psilocine or psilotsin).

3-(1,2-dimethylheptyl)-1-hydroxy-7,8,9,10-tetrahydro-6,6,9-trimethyl-6h-dibenzo (b,d) pyran *(dmhp).

N, α -dimethyl-3,4-(methylenedioxy)phenylethylamine *(mdma).

N,*n*-dimethylamfetamine (dimetamfetamine).

Dimethylthiambutene.

N,*n*-dimethyltryptamine *(dmt).

Dioxaphetyl butyrate.

Ecgonine.

N-ethyl-α-methyl-3,4-(methylenedioxy)phenethylamine *(*n*-ethyl mda).

Ethylmethylthiambutene.

Eticyclidine *(pce).

Etonitazene.

Etorphine.

Etoxeridine.

Fenetylline.

4-fluoro-*n*-methylamfetamine.

Flubromazepam.

Flubromazolam.

1-(5-fluoropentyl)-3-(2-iodobenzoyl)indole *(am-694).

Furethidine.

Harmala alkaloids except in herbs, or preparations, for therapeutic use—

(a) containing 0.1 per cent or less of harmala alkaloids; or

(b) in divided preparations containing 2 mg or less of harmala alkaloids per recommended daily dose.

Heroin.

3-hexyl-1-hydroxy-7,8,9,10-tetrahydro-6,6,9-trimethyl-6h-dibenzo (b,d) pyran *(parahexyl).

4-hydroxybutanoic acid and its salts except for sodium oxybate when in Schedule 8. *(gamma hydroxybutyrate (ghb)).

2-[(1*r*,3*s*)-3-hydroxycyclohexyl]-5-(2-methylnonan-2-yl)phenol *(cannabicyclohexanol or cp 47,497 c8 homologue).

2-[(1*r*,3*s*)-3-hydroxycyclohexyl]-5-(2-methyloctan-2-yl)phenol *(cp 47,497).

Hydroxypethidine.

Isomethadone.

Ketobemidone.

Levomethorphan (excluding its stereoisomers).

Levophenacylmorphan.

Lysergic acid.

Lysergide.

Meclonazepam.

Mecloqualone.

Metazocine.

Methaqualone.

Methcathinone.

5-methoxy- α –methyltryptamine *(5-meo-amt).

5-methoxy-3,4-methylenedioxyamfetamine *(mmda).

4-methoxy- α –methylphenylethylamine *(pma).

2-(2-methoxyphenyl)-1-(1-pentylindol-3-yl)ethanone *(jwh-250).

Methyl (2*s*, 4a*r*, 6a*r*, 7*r*, 9*s*, 10a*s*, 10b*r*)-9-acetoxy-6a,10b-dimethyl-4,10-dioxo-dodecahydro-2-(3-furyl)-2h-naphtho[2,1-c]pyran-7-carboxylate *(salvinorin a).

4-methylaminorex.

Methyldesorphine.

3,4-methylenedioxyamfetamine *(mda).

3,4-methylenedioxypyrovalerone *(mdpv).

3-methylfentanyl.

4-methylmethcathinone *(mephedrone).

N- α -[methyl-3,4-(methylenedioxy)phenethyl]hydroxylamine *(*n*-hydroxy mda).

N-methyl-1-(3,4-methylenedioxyphenyl)-2-butanamine *(mbdb).

2-methyl-3-morpholino-1, 1-diphenylpropane carboxylic acid (moramide intermediate).

Methylone *(mdmc).

1-methyl-4-phenyl-4-piperidinol propionate *(mppp).

4-methylthioamfetamine.

3-methylthiofentanyl.

Metopon.

Mitragyna speciosa.

Mitragynine.

Morpheridine.

(1-(2-morpholin-4-ylethyl)indol-3-yl)-napthalen-1-ylmethanone *(jwh-200).

Muscimol.

Myrophine.

Naphthoylindoles except when separately specified in the schedules to these Regulations.

Naphthylmethylindoles except when separately specified in the schedules to these Regulations.

Naphthoylpyrroles except when separately specified in the schedules to these Regulations.

Naphthylmethylindenes except when separately specified in the schedules to these Regulations.

Naphthalen-1-yl-(1-butylindol-3-yl)methanone *(jwh-073).

Nicocodine.

Nicodicodine.

Nicomorphine.

Nifoxipam.

Noracymethadol.

Norlevorphanol.

Normorphine.

Norpipanone.

Opium.

Para-fluorofentanyl.

1-pentyl-3-(4-methyl-1-napthoyl)indole. *(jwh-122).

1-pentyl-3-(1-naphthoyl)indole *(jwh-018).

Phenadoxone.

Phenampromide.

Phenazocine.

Phencyclidine *(pcp).

Phenibut.

N-phenethyl-4-piperidone.

Phenomorphan.

Phenylacetylindoles except when separately specified in the schedules to these Regulations.

1-phenylethyl-4-phenyl-4-piperidinol acetate *(pepap).

Piminodine.

Proheptazine.

Properidine.

Psilocybine.

Pyrazolam.

Racemethorphan.

Racemorphan.

Rolicyclidine *(php or pcpy).

Salvia divinorum.

Synthetic cannabinomimetics except when separately specified in the schedules to these Regulations.

Tenocyclidine *(tcp).

Tetrahydrocannabinols and their alkyl homologues, except—

(a) when included in schedules 4 or 8;

(b) processed hemp fibre containing 0.1 per cent or less of tetrahydrocannabinols, and hemp fibre products manufactured from such fibre; or

(c) in hemp seed oil for purposes other than internal human use containing 50 mg/kg or less of total cannabinoids, including 20 mg/kg or less of tetrahydrocannabinols, when labelled with either of the following warning statements "Not for internal use" or "Not to be taken".

Thiofentanyl.

1-(3-trifluoromethylphenyl)piperazine *(tfmpp).

Trimeperidine.

3,4,5-trimethoxy- α –methylphenylethylamine *(tma).

3,4,5-trimethoxyphenethylamine (mescaline) and other substances structurally derived from methoxy-phenylethylamine except—

(a) methoxyphenamine; or

(b) when separately specified in this schedule.

1-(3,4,5-trimethoxyphenyl)-2-aminobutane.

SCHEDULE 10
(Regulation 12)

PROHIBITED POISONS

Abrus precatorius (jequirity) seed or root for therapeutic use.

Acorus calamus (calamus) for human therapeutic use.

Alkaline salts, being the carbonate, silicate or phosphate salts of sodium or potassium alone or in any combination for domestic use—

(a) in liquid or semi-solid food additive preparations, the pH of which is more than 11.5;

(b) in solid automatic dishwashing preparations, the pH of which in a 500 g/l aqueous solution or mixture is more than 12.5; or

(c) in liquid or semi-solid automatic dishwashing preparations, the pH of which is more than 12.5.

Alkylamines with stimulant properties except when separately specified in the schedules to these Regulations.

Allylisopropylacetylurea for therapeutic use.

Aminophenazone (amidopyrine) and its derivatives for human therapeutic use.

Amygdalin for therapeutic use.

Anchusa officinalis for therapeutic use.

O-anisidine (excluding its derivatives) in preparations for skin colouration (including tattooing) and dyeing of hair, eyelashes or eyebrows except in preparations containing 0.001 per cent or less of *o*-anisidine.

Aristolochia spp. for therapeutic use.

Aristolochic acid for human therapeutic use.

Asarum spp. containing aristolochic acid for human therapeutic use.

Azadirachta indica (neem) including its extracts and derivatives, in preparations for human internal use except 'debitterised neem seed oil'.

Basic orange 31 (2-[(4-aminophenyl)azo]-1,3-dimethyl-1H-imidazolium chloride) in preparations for skin colouration and dyeing of eyelashes or eyebrows.

1,2-benzenediamine in preparations for cosmetic use and skin colouration (including tattooing).

1,3-benzenediamine in preparations for cosmetic use and skin colouration (including tattooing).

Bithionol for human therapeutic use.

Borago officinalis (borage) for therapeutic use except the fixed oil derived from the seeds of borago officinalis.

Bragantia spp. containing aristolochic acid for human therapeutic use.

Buclosamide for therapeutic use.

Buniodyl sodium for therapeutic use.

1,4-butanediol (excluding its derivatives) in non-polymerised form in preparations for domestic use.

Butyl benzyl phthalate for cosmetic use.

Cacalia spp. for therapeutic use.

Carbamide peroxide (excluding its salts and derivatives) in teeth whitening preparations containing more than 18 per cent of carbamide peroxide except in preparations manufactured for, and supplied solely by, registered dental practitioners as part of their dental practice.

Cardarine.

Chrysoidine base in preparations for use in hair dyes.

Cinchophen and its derivatives for therapeutic use.

Clioquinol and other halogenated derivatives of oxyquinoline for human internal use.

Coal tar for cosmetic use other than in therapeutic goods.

Conium maculatum (coniine) for therapeutic use.

Cotarnine for therapeutic use.

Crotalaria spp. for therapeutic use.

Croton tiglium for therapeutic use.

Cynoglossum spp. for therapeutic use.

Dibutylphthalate for cosmetic use.

Dicophane (ddt) for therapeutic use.

Diethylene glycol for use in toothpastes or mouthwashes except in preparations containing 0.25 per cent or less of diethylene glycol.

Diethylene glycol monomethyl ether for cosmetic use.

Diethylhexyl phthalate for cosmetic use.

Diethylphthalate in sunscreens, personal insect repellents or body lotion preparations for human use except in preparations containing 0.5 per cent or less of diethylphthalate.

5,6-dihydroxyindoline for cosmetic use in preparations containing more than 2 per cent of 5,6-dihydroxyindoline.

Diiodohydroxyquinoline (iodoquinol) for human internal use.

Diisobutyl phthalate for cosmetic use.

1,3-dimethylamylamine (dmaa).

1,3-dimethylbutylamine (dmba) except when separately specified in the schedules to these Regulations.

1-(1,1-dimethylethyl)-2-methoxy-4-methyl-3,5-dinitrobenzene (musk ambrette).

1,5-dimethylhexylamine (dmha) except when separately specified in the schedules to these Regulations.

1,4-dimethylpentylamine (dmpa).

Dimethylphthalate in sunscreens, personal insect repellents or body lotion preparations for human use except in preparations containing 0.5 per cent or less of dimethylphthalate.

Di(methyloxyethyl) phthalate for cosmetic use.

2,4-dinitrophenol for human use.

Disperse yellow 3 for use in hair dyes.

Dulcin for therapeutic use.

Ethylene glycol for use in toothpastes or mouthwashes except in preparations containing 0.25 per cent or less of ethylene glycol.

Eupatorium cannabinum (hemp agrimony) for therapeutic use.

Farfugium japonicum for therapeutic use.

Formaldehyde (excluding its derivatives)—

(a) in oral hygiene preparations containing more than 0.1 per cent of free formaldehyde;

(b) in aerosol sprays for cosmetic use containing 0.005 per cent or more of free formaldehyde;

(c) in nail hardener cosmetic preparations containing 5 per cent or more of free formaldehyde; or

(d) in all other cosmetic preparations containing 0.05 per cent or more of free formaldehyde except in preparations containing 0.2 per cent or less of free formaldehyde when labelled with the warning statement "CONTAINS FORMALDEHYDE".

Gamma butyrolactone (excluding its derivatives) in non-polymerised form in preparations for domestic and cosmetic use.

Heliotropium spp. for therapeutic use.

Hydrogen peroxide (excluding its salts and derivatives) in teeth whitening preparations containing more than 6 per cent (20 volume) of hydrogen peroxide except in preparations manufactured for, and supplied solely by, registered dental practitioners as part of their dental practice.

Isopropyl nitrite.

Juniperus sabine [savin(e)] for therapeutic use.

Lead compounds in paints, tinters, inks or ink additives except in preparations containing 0.1 per cent or less of lead calculated on the non-volatile content of the paint, tinter, ink or ink additive.

Ligularia dentata for therapeutic use.

Melia azedarach including its extracts and derivatives.

Methyldibromo glutaronitrile in preparations intended to be in contact with the skin, including cosmetic use.

Methyl methacrylate for cosmetic use except in preparations containing 1 per cent or less of methyl methacrylate as residual monomer in a polymer.

Methylrosanilinium chloride (formerly known as crystal violet CAS No. 548-62-9) and the following triarylmethane dyes – for use in hair dyes—

(a) acid violet 49 (CAS No. 1694-09-3);

(b) ethyl violet (CAS No. 2390-59-2);

(c) basic blue 7 (CAS No. 2390-60-5); and

(d) basic blue 26 (ci 44045) (CAS No. 2580-56-5).

Naphthalene (excluding derivatives) in preparations in block, ball, disc, pellet or flake form for domestic use except when enclosed in a device which, in normal use, prevents removal or ingestion of its contents.

Oxyphenisatin for therapeutic use.

Paraformaldehyde (excluding its derivatives)—

(a) in oral hygiene preparations containing more than 0.1 per cent of free formaldehyde;

(b) in aerosol sprays for cosmetic use containing 0.005 per cent or more of free formaldehyde;

(c) in nail hardener cosmetic preparations containing 5 per cent or more of free formaldehyde; and

(d) in all other cosmetic preparations containing 0.05 per cent or more of free formaldehyde except in preparations containing 0.2 per cent or less of free formaldehyde when labelled with the warning statement "CONTAINS FORMALDEHYDE".

Petasites spp. for therapeutic use.

Phenpromethamine.

Phenylenediamines, including alkylated, arylated, halogenated and nitro derivatives, in preparations for skin colouration, tattooing and dyeing of eyelashes or eyebrows except when included in Schedule 6.

Potassium hydroxide (excluding its salts and derivatives), in liquid or semi-solid food additive preparations, for domestic use, the pH of which is more than 11.5.

N-propyl nitrite.

Pteridium spp. for therapeutic use.

Pulmonaria spp. for therapeutic use.

Safrole for internal therapeutic use except in preparations containing 0.1 per cent or less of safrole.

Sanguinaria canadensis (bloodroot) in preparations for human use except in preparations containing 0.01 per cent or less of sanguinarine.

Senecio spp. for therapeutic use.

Silicones for injection or implantation except when included in Schedule 4.

Sodium hydroxide (excluding its salts and derivatives), in liquid or semi-solid food additive preparations, for domestic use, the pH of which is more than 11.5.

Symphytum spp. (comfrey) in preparations for human or animal use except when in Schedule 5.

2,4-toluenediamine in preparations for skin colouration (including tattooing) and dyeing of hair, eyelashes or eyebrows.

Toluenediamines in preparations for skin colouration (including tattooing) and dyeing of eyelashes or eyebrows except when included in Schedule 6.

O-toluidine (excluding its derivatives) in preparations for skin colouration (including tattooing) and dyeing of hair, eyelashes or eyebrows except in preparations containing 0.001 per cent or less of *o*-toluidine.

1,1,1-trichloroethane in pressurised spray packs for therapeutic use.

Trichodesma africana for therapeutic use.

Triparanol for therapeutic use.

Tussilago farfara for therapeutic use.

SCHEDULE 11
(Regulation 13)

GENERAL EXEMPTIONS

Bacterial culture media.

Ceramics.

Chemistry sets.

Copper compounds in paints.

Electrical accumulators, batteries, components or lamps.

Electronic components.

Enhancing agents for use in ultrasonic and magnetic resonance imaging.

Explosives.

Food except—

(a) food additives before incorporation into food; or

(b) when used as a means of administering a controlled substance for therapeutic use.

Fritted glazing or enamelling preparations in which the poison is confined as a non-migratory component or glassy solid flakes or granules.

Glass, including crystal ware.

Glazed pottery.

In vitro diagnostic and analytical preparations containing 0.001 per cent or less of any substances included in schedules 1 to 10.

Intraocular viscoelastic products.

Lubricants except soluble oils and solvent-deposited lubricating agents.

Matches.

Medical and veterinary adhesives, glues and cements.

Motor, heating or furnace fuels except—

(a) when the contrary appears in schedules 1 to 10;

(b) when containing methanol;

(c) toy or hobby fuels; or

(d) petrol or kerosene when packed in containers having a capacity of 20 litres or less.

Nutrition replacement preparations for parenteral administration.

Paper except—

(a) when prepared for pesticidal use; or

(b) when containing a dangerous drug or a prohibited substance.

Photographic paper or film.

Pigments when immobilised in a polymer.

Porcelain.

Printing inks or ink additives except when containing a pesticide.

Radiographic contrast media (radiopaques) for therapeutic use.

Radioisotopes for therapeutic use.

Seeds treated with seed protectants.

Termite barriers consisting of a registered termiticide, other than arsenic, laminated between impervious sheeting.

Timber and wallboard.

Vitreous enamels.

Writing correction pens that do not allow ingestion of the contents and do not contain—

(a) acetone;

(b) dimethylformamide;

(c) N-(N-dodecyl)-2-pyrrolidone;

(d) hydrocarbons (liquid);

(e) methanol;

(f) methyl ethyl ketone;

(g) methyl isoamyl ketone;

(h) methyl isobutyl ketone;

(i) N-methyl-2-pyrrolidone;

(j) N-(N-octyl)-2-pyrrolidone;

(k) phenyl methyl ketone;

(l) styrene;

(m) tetrachlorethylene; or

(n) 1,1,1-trochloroethane.