



Therapeutic Goods (Permissible Ingredients) Amendment (2016 Measures No. 1) Determination 2016

I, Dr Mayada Kayali, as delegate of the Minister for Health and Aged Care, make the following determination.

Dated 30 September 2016

Dr Mayada Kayali
Acting Assistant Secretary
Complementary & OTC Medicines Branch
Medicines Regulation Division
Department of Health

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1 Name

This instrument is the *Therapeutic Goods (Permissible Ingredients) Amendment (2016 Measures No. 1) Determination 2016*.

2 Commencement

- (1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. The whole of this instrument	The day after this instrument is registered.	6 October 2016

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

- (2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under section 26BC of the *Therapeutic Goods Act 1989*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

Therapeutic Goods (Permissible Ingredients) Determination No. 2 of 2016

1 Table 1 in Part 2 of Schedule 1 (after table item 56)

Insert:

56A	2-BUTYL-4,4,6-TRIMETHYL-1,3-DIOXANE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
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2 Table 1 in Part 2 of Schedule 1 (after table item 91)

Insert:

91A	2-METHYL-4-(2,2,3-TRIMETHYL-3-CYCLOPENTENYL)-2-BUTEN-1-OL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. Only for use in topical medicines for dermal application.
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3 Table 1 in Part 2 of Schedule 1 (after table item 92)

Insert:

92A	2-METHYL-4-(CAMPHENYL-8)-CYCLOHEXANONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
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4 Table 1 in Part 2 of Schedule 1 (after table item 127)

Insert:

127A	2,2-DIMETHYL-3-(3-METHYL-2,4-PENTADIENYL)-OXIRANE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
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5 Table 1 in Part 2 of Schedule 1 (after table item 236)

Insert:

236A	4,5-DIMETHYL-3-HYDROXY-2(5H)FURANONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
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6 Table 1 in Part 2 of Schedule 1 (after table item 252)

Insert:

252A	6-BUTYL-3,6-DIHYDRO-O-2,4-DIMETHYL-2H-PYRAN	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
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7 Table 1 in Part 2 of Schedule 1 (cell at table item 754, column 4)

Repeal the cell, substitute:

When for oral ingestion, the maximum recommended daily dose must not provide more than 383.5 milligrams of behenic acid.

8 Table 1 in Part 2 of Schedule 1 (cell at table item 796, column 4)

Repeal the cell, substitute:

When for internal use oxedrine is a mandatory component of bergamot oil coldpressed.

The maximum recommended daily dose must provide no more than 30 milligrams of oxedrine.

The warning statement (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect) must be included on the medicine label unless the medicine is:

- a) for internal use; or
- b) in preparations containing 0.4 per cent or less of bergamot oil coldpressed; or
- c) for use in soaps or bath or shower gels that are washed off the skin.

9 Table 1 in Part 2 of Schedule 1 (after table item 1007)

Insert:

1007A	CALCIFIED LITHOTHAMNION SPECIES	A	Only for use in oral medicines.
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10 Table 1 in Part 2 of Schedule 1 (after table item 1008)

Insert:

1008A	CALCIUM ALGINATE	E	
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11 Table 1 in Part 2 of Schedule 1 (cell at table item 1024, column 4)

Repeal the cell, substitute:

Folinic acid is a mandatory component of calcium folinate.

The maximum daily dose must provide no more than 500 micrograms of folinic acid.

When folic acid, folinic acid, levomefolate salts and/or their derivatives are used in combination, the medicine provides not more than a total of 500 micrograms of folic acid, folinic

acid, levomefolate salts and/or their derivatives in total per daily dose.

The following indications are only permitted when the medicine is for oral and sublingual use:

- (OSPOR1) 'Source of calcium. May assist in the prevention and/or treatment of osteoporosis.'

- (OSPOR2) 'Source of calcium. Women's calcium requirements are increased after menopause. Calcium supplementation may be of assistance in the prevention and/or treatment of osteoporosis.'

- (CALC1) 'Source of calcium. Women's calcium requirements are increased after menopause.'

- (CALC2) 'Source of calcium. A calcium supplement formulated to strengthen bone and tissue in growing and mature users.' OR 'Source of calcium. A calcium supplement formulated to strengthen bone and tissue for children and older adults.'

- (CALC3) 'Source of calcium. Adequate dietary calcium in our youth and throughout life is required to maximise bone.'

- (CALC4) 'Source of calcium. A diet deficient in calcium can lead to osteoporosis in later life.'

The indication 'For mineral [may state the mineral] supplementation' is only permitted for use when the medicine is for oral or sublingual use.

When used as an active ingredient and the route of administration is oral or sublingual, the medicine requires the following warning statement on the

medicine label:

- (VIT) 'Vitamins can only be of assistance if the dietary vitamin intake is inadequate.' OR 'Vitamin supplements should not replace a balanced diet.'

12 Table 1 in Part 2 of Schedule 1 (cell at table item 1083, column 4)

Repeal the cell, substitute:

In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%.

In liquid preparations other than essential oils, the concentration of camphor must be no more than 2.5%.

In essential oil preparations, if the concentration of camphor is more than 2.5% but less than or equal to 10%, and the nominal capacity of the container is less than 25 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label:

- (CHILD) 'Keep out of reach of children' (or words to that effect); and
- (NTAKEN) 'Not to be taken'.

In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is less than 15 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label:

- (CHILD) 'Keep out of reach of children' (or words to that effect); and
- (NTAKEN) 'Not to be taken'.

In essential oil preparations, if the

concentration of camphor is more than 10%, and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a restricted flow insert and child resistant closure fitted on the container and include the following warning statements on the medicine label:

- (CHILD) 'Keep out of reach of children' (or words to that effect); and
- (NTAKEN) 'Not to be taken'.

13 Table 1 in Part 2 of Schedule 1 (cell at table item 1085, column 4)

Repeal the cell, substitute:

Camphor, cineole and saffrole are mandatory components of Camphor oil brown.

In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%.

In liquid preparations other than essential oils, the concentration of camphor must be no more than 2.5%.

In essential oil preparations, if the concentration of camphor is more than 2.5% but less than or equal to 10%, and the nominal capacity of the container is less than 25 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label:

- (CHILD) 'Keep out of reach of children' (or words to that effect); and
- (NTAKEN) 'Not to be taken'.

In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the

preparation is more than 25% and the nominal capacity of the container is no more than 15 millilitres, the medicine must have the restricted flow insert fitted on the container and include the following warning statements on the medicine label:

- (CHILD) 'Keep out of reach of children' (or words to that effect); and

- (NTAKEN) 'Not to be taken'.

When for internal use then the concentration of safrole in a medicine must be no more than 0.1%.

When for topical use then the concentration of safrole in a medicine must be no more than 1.0%.

14 Table 1 in Part 2 of Schedule 1 (cell at table item 1086, column 4)

Repeal the cell, substitute:

Camphor and safrole are mandatory components of camphor oil white.

In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%.

In liquid preparations other than essential oils, the concentration of camphor must be no more than 2.5%.

In essential oil preparations, if the concentration of camphor is more than 2.5% but less than or equal to 10%, and the nominal capacity of the container is less than 25 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label:

- (CHILD) 'Keep out of reach of children' (or words to that effect); and

- (NTAKEN) 'Not to be taken'.

In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is less than 15 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label:

- (CHILD) 'Keep out of reach of children' (or words to that effect); and

- (NTAKEN) 'Not to be taken'.

In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a restricted flow insert and child resistant closure fitted on the container and include the following warning statements on the medicine label:

- (CHILD) 'Keep out of reach of children' (or words to that effect); and

- (NTAKEN) 'Not to be taken'.

When for internal use then the concentration of safrole in a medicine must be no more than 0.1%.

When for topical use then the concentration of safrole in a medicine must be no more than 1.0%.

15 Table 1 in Part 2 of Schedule 1 (cell at table item 1349, column 4)

Repeal the cell, substitute:

Camphor, cineole and safrole are mandatory components of Cinnamomum camphora.

In solid and semi solid preparations, the

concentration of camphor must be no more than 12.5%.

In liquid preparations other than essential oils, the concentration of camphor must be no more than 2.5%.

In essential oil preparations, if the concentration of camphor is more than 2.5% but less than or equal to 10%, and the nominal capacity of the container is less than 25 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label:

- (CHILD) 'Keep out of reach of children' (or words to that effect); and
- (NTAKEN) 'Not to be taken'.

In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is less than 15 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label:

- (CHILD) 'Keep out of reach of children' (or words to that effect); and
- (NTAKEN) 'Not to be taken'.

In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a restricted flow insert and child resistant closure fitted on the container and include the following warning statements on the medicine label:

- (CHILD) 'Keep out of reach of

children' (or words to that effect); and

- (NTAKEN) 'Not to be taken'.

When the concentration of cineole in the preparation is more than 25%, the nominal capacity of the container must not be more than 25 millilitres.

When the concentration of cineole in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a child resistant closure and restricted flow insert fitted on the container and include the following warning statements on the medicine label:

- (CHILD) 'Keep out of reach of children' (or words to that effect); and

- (NTAKEN) 'Not to be taken'.

When the concentration of cineole in the preparation is more than 25% and the nominal capacity of the container is no more than 15 millilitres, the medicine must have the restricted flow insert fitted on the container and include the following warning statements on the medicine label:

- (CHILD) 'Keep out of reach of children' (or words to that effect); and

- (NTAKEN) 'Not to be taken'.

When for internal use then the concentration of safrole in a medicine must be no more than 0.1%.

When for topical use then the concentration of safole in a medicine must be no more than 1.0%.

When used as an active ingredient, the maximum daily dose of the medicine

must contain no more than 0.001% of coumarin.

16 Table 1 in Part 2 of Schedule 1 (cell at table item 1385, column 4)

Repeal the cell.

17 Table 1 in Part 2 of Schedule 1 (cell at table item 1386, column 4)

Repeal the cell.

18 Table 1 in Part 2 of Schedule 1 (cell at table item 1617, column 4)

Repeal the cell, substitute:

When for excipient use, only permitted for use as a colour in topical and oral medicines.

19 Table 1 in Part 2 of Schedule 1 (cell at table item 1700, column 4)

Repeal the cell, substitute:

Medicines that contain 'deer velvet antler powder' as the therapeutically active ingredient are subject to the following conditions:

- a) the medicines are for oral use only;
- b) the antlers (including the velvet) are sourced only from red deer (*Cervus elaphus*), elk/wapiti (*Cervus canadensis*), or a crossbreed of these species;
- c) the deer are sourced only from farmed stock bred and raised in New Zealand;
- d) the deer are sourced only from herds farmed for food in accordance with the Animal Products Act 1999 (New Zealand) and the regulations made under that Act, as in force or existing from time to time;
- e) the antlers are removed from the deer only according to the Animal Welfare Act 1999 (New Zealand) and the

regulations made under that Act, as in force or existing from time to time.

20 Table 1 in Part 2 of Schedule 1 (cell at table item 1701, column 4)

Repeal the cell, substitute:

Medicines that contain 'deer velvet antler slice' as the therapeutically active ingredient are subject to the following conditions:

- a) the medicines are for oral use only;
- b) the antlers (including the velvet) are sourced only from red deer (*Cervus elaphus*), elk/wapiti (*Cervus canadensis*), or a crossbreed of these species;
- c) the deer are sourced only from farmed stock bred and raised in New Zealand;
- d) the deer are sourced only from herds farmed for food in accordance with the Animal Products Act 1999 (New Zealand) and the regulations made under that Act, as in force or existing from time to time;
- e) the antlers are removed from the deer only according to the Animal Welfare Act 1999 (New Zealand) and the regulations made under that Act, as in force or existing from time to time.

21 Table 1 in Part 2 of Schedule 1 (cell at table item 1821, column 4)

Repeal the cell, substitute:

Only for use in oral and topical medicines.

22 Table 1 in Part 2 of Schedule 1 (cell at table item 1864, column 4)

Repeal the cell, substitute:

Only for use as an active ingredient in sunscreens for dermal application.

The concentration in a medicine must be no more than 3%.

When used in primary sunscreen products, the medicine requires the following warning statements on the label:

- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and

- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).

23 Table 1 in Part 2 of Schedule 1 (cell at table item 1890, column 4)

Repeal the cell, substitute:

Only for use as an active ingredient in sunscreens for dermal application.

The concentration in a medicine must be no more than 10%.

When used in primary sunscreen products, the medicine requires the following warning statements on the label:

- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and

- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).

24 Table 1 in Part 2 of Schedule 1 (cell at table item 1920, column 4)

Repeal the cell, substitute:

Only for use as an active ingredient in sunscreens for dermal application.

The concentration in a medicine must be no more than 10%.

When used in primary sunscreen products, the medicine requires the following warning statements on the label:

- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and

- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).

25 Table 1 in Part 2 of Schedule 1 (after table item 1931)

Insert:

1931A	DUPICAL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
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26 Table 1 in Part 2 of Schedule 1 (cell at table item 1935, column 4)

Repeal the cell, substitute:

Only for use as an active ingredient in sunscreens for dermal application.

The concentration in a medicine must be no more than 10%.

When used in primary sunscreen products, the medicine requires the following warning statements on the label:

- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and

- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this

effect).

27 Table 1 in Part 2 of Schedule 1 (table item 2022)

Repeal the item.

28 Table 1 in Part 2 of Schedule 1 (cell at table item 2328, column 4)

Repeal the cell, substitute:

Only for use when the dosage form is
'chewing gum'.

Must comply with:

a) the Glycerol Ester of Partially
Hydrogenated Gum Rosin monograph
in the Food Chemicals Codex published
by the United States Pharmacopeial
Convention, as in force or existing from
time to time; and

b) the requirements for residual solvents
and catalysts in the British
Pharmacopeia or the United States
Pharmacopeia-National Formulary.

29 Table 1 in Part 2 of Schedule 1 (cell at table item 2329, column 4)

Repeal the cell, substitute:

Behenic acid is a mandatory component
of calcium behenate.

When for oral ingestion, the maximum
recommended daily dose must not
provide more than 383.5 milligrams of
behenic acid.

In medicines for topical use, the
concentration of glyceryl behenate must
be no more than 5%.

30 Table 1 in Part 2 of Schedule 1 (cell at table item 2349, column 4)

Repeal the cell, substitute:

Only for use when the dosage form is
'chewing gum'.

Must comply with:

- a) the Glycerol Ester of Gum Rosin monograph in the Food Chemicals Codex published by the United States Pharmacopeial Convention, as in force or existing from time to time; and
- b) the requirements for residual solvents and catalysts in the British Pharmacopeia or the United States Pharmacopeia-National Formulary.

31 Table 1 in Part 2 of Schedule 1 (after table item 2355)

Insert:

2355A	GLYCERYL UNDECYLENATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration of glyceryl undecylenate in a medicine must be no more than 3%.
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32 Table 1 in Part 2 of Schedule 1 (cell at table item 2874, column 4)

Repeal the cell, substitute:

Camphor is a mandatory component of *Lavandula angustifolia*.

In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%.

In liquid preparations other than essential oils, the concentration of camphor must be no more than 2.5%.

In essential oil preparations, if the concentration of camphor is more than 2.5% but less than or equal to 10%, and the nominal capacity of the container is less than 25 millilitres, the medicine must have a restricted flow insert fitted on the container and include the

following warning statements on the medicine label:

- (CHILD) 'Keep out of reach of children' (or words to that effect); and
- (NTAKEN) 'Not to be taken'.

In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is less than 15 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label:

- (CHILD) 'Keep out of reach of children' (or words to that effect); and
- (NTAKEN) 'Not to be taken'.

In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a restricted flow insert and child resistant closure fitted on the container and include the following warning statements on the medicine label:

- (CHILD) 'Keep out of reach of children' (or words to that effect); and
- (NTAKEN) 'Not to be taken'.

33 Table 1 in Part 2 of Schedule 1 (cell at table item 2876, column 4)

Repeal the cell, substitute:

Camphor is a mandatory component of *Lavandula x intermedia*.

In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%.

34 Table 1 in Part 2 of Schedule 1 (cell at table item 2877, column 4)

Repeal the cell, substitute:

Camphor is a mandatory component of lavender oil.

In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%.

In liquid preparations other than essential oils, the concentration of camphor must be no more than 2.5%.

In essential oil preparations, if the concentration of camphor is more than 2.5% but less than or equal to 10%, and the nominal capacity of the container is less than 25 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label:

- (CHILD) 'Keep out of reach of children' (or words to that effect); and

- (NTAKEN) 'Not to be taken'.

In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is less than 15 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label:

- (CHILD) 'Keep out of reach of children' (or words to that effect); and

- (NTAKEN) 'Not to be taken'.

In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the

medicine must have a restricted flow insert and child resistant closure fitted on the container and include the following warning statements on the medicine label:

- (CHILD) 'Keep out of reach of children' (or words to that effect); and
- (NTAKEN) 'Not to be taken'.

35 Table 1 in Part 2 of Schedule 1 (cell at table item 2891, column 4)

Repeal the cell, substitute:

When used internally, oxedrine is a mandatory component of lemon.

The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.

36 Table 1 in Part 2 of Schedule 1 (cell at table item 2894, column 4)

Repeal the cell, substitute:

When used internally, oxedrine is a mandatory component of lemon oil.

The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.

The warning statement (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect) must be included on the medicine label unless the medicine is:

- a) steam distilled or rectified; or
- b) for internal use; or
- c) contains 0.05% or less of lemon oil;
or
- d) for use in soaps or bath or shower
gels that are washed off the skin.

37 Table 1 in Part 2 of Schedule 1 (cell at table item 2895, column 4)

Repeal the cell, substitute:

When used internally, oxedrine is a mandatory component of lemon oil distilled.

The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.

38 Table 1 in Part 2 of Schedule 1 (cell at table item 2896, column 4)

Repeal the cell, substitute:

When used internally, oxedrine is a mandatory component of lemon oil terpeneless.

The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.

39 Table 1 in Part 2 of Schedule 1 (cell at table item 2898, column 4)

Repeal the cell, substitute:

When used internally, oxedrine is a mandatory component of lemon peel dried.

The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.

40 Table 1 in Part 2 of Schedule 1 (cell at table item 2933, column 4)

Repeal the cell, substitute:

The warning statement (SENS)
'Application to skin may increase sensitivity to sunlight' (or words to that effect) must be included on the medicine label unless the medicine is:

a) for internal use; or

b) contains 0.5% or less of lime oil

coldpressed; or

c) for use in soaps or bath or shower gels that are washed off the skin.

41 Table 1 in Part 2 of Schedule 1 (cell at table item 3111, column 4)

Repeal the cell, substitute:

When used internally, oxdrine is a mandatory component of mandarin oil coldpressed.

The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.

42 Table 1 in Part 2 of Schedule 1 (cell at table item 3434, column 4)

Repeal the cell, substitute:

Camphor is a mandatory component of *Ocimum kilimandscharicum*.

In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%.

In liquid preparations other than essential oils, the concentration of camphor must be no more than 2.5%.

In essential oil preparations, if the concentration of camphor is more than 2.5% but less than or equal to 10%, and the nominal capacity of the container is less than 25 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label:

- (CHILD) 'Keep out of reach of children' (or words to that effect); and

- (NTAKEN) 'Not to be taken'.

In essential oil preparations, if the concentration of camphor is more than

10%, and the nominal capacity of the container is less than 15 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label:

- (CHILD) 'Keep out of reach of children' (or words to that effect); and
- (NTAKEN) 'Not to be taken'.

In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a restricted flow insert and child resistant closure fitted on the container and include the following warning statements on the medicine label:

- (CHILD) 'Keep out of reach of children' (or words to that effect); and
- (NTAKEN) 'Not to be taken'.

When the plant preparation is oil, Methyl chavicol is a mandatory component of *Ocimum kilimandscharicum*.

When the concentration of Methyl chavicol in a medicine is more than 5% and the nominal capacity of the container is 25 millilitres or less, a restricted flow insert must be fitted on the container, and the medicine requires the following warning statement on the medicine label:

- (CHILD) 'Keep out of reach of children' (or words to that effect).

43 Table 1 in Part 2 of Schedule 1 (cell at table item 3497, column 4)

Repeal the cell, substitute:

When used internally, oxdrine is a mandatory component of orange flower oil.

The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.

44 Table 1 in Part 2 of Schedule 1 (cell at table item 3500, column 4)

Repeal the cell, substitute:

When used internally, oxedrine is a mandatory component of orange oil.

The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.

45 Table 1 in Part 2 of Schedule 1 (cell at table item 3502, column 4)

Repeal the cell, substitute:

When used internally, oxdrine is a mandatory component of orange oil bitter coldpressed.

The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.

The warning statement (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect) must be included on the medicine label unless the medicine is:

- a) for internal use; or
- b) in preparations containing 1.4% or less of orange oil bitter coldpressed; or
- c) for use in soaps or bath or shower gels that are washed off the skin.

46 Table 1 in Part 2 of Schedule 1 (cell at table item 3504, column 4)

Repeal the cell, substitute:

When used internally, oxedrine is a mandatory component of orange oil distilled.

The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.

47 Table 1 in Part 2 of Schedule 1 (cell at table item 3506, column 4)

Repeal the cell, substitute:

When used internally, oxedrine is a mandatory component of orange oil terpeneless.

The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.

48 Table 1 in Part 2 of Schedule 1 (cell at table item 3508, column 4)

Repeal the cell, substitute:

When used internally, oxedrine is a mandatory component of orange peel dried bitter.

The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.

49 Table 1 in Part 2 of Schedule 1 (cell at table item 3713, column 4)

Repeal the cell, substitute:

When used internally, oxedrine is a mandatory component of petitgrain oil paraguay.

The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.

50 Table 1 in Part 2 of Schedule 1 (after table item 3866)

Insert:

3866A	POLIGLUSAM DERIVED FROM ASPERGILLUS NIGER	A,E	When for oral use, the medicine must provide no more than 2000 milligrams of Poliglusam derived from <i>Aspergillus niger</i> per maximum recommended daily dose and requires the following warning statement on the medicine label: - (CHITO) 'Poliglusam should be taken at least one hour after any other medication as it may reduce the effect of other medication' (or words to that effect). If the medicine is a powdered dosage form, the medicine also requires the following warning statement on the medicine label: - 'Do not take powder alone. Mix with food or fluid.' When used as an excipient, Poliglusam derived from <i>Aspergillus niger</i> is only permitted for use in topical medicines for dermal application.
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51 Table 1 in Part 2 of Schedule 1 (cell at table item 3892, column 4)

Repeal the cell, substitute:

Except when used in a medicine containing only homoeopathic preparations, a child resistant closure and restricted flow insert must be fitted onto the container.

52 Table 1 in Part 2 of Schedule 1 (cell at table item 3921, column 4)

Repeal the cell, substitute:

Only for use when the dosage form is 'chewing gum'.

Must comply with:

a) the Polyisobutylene monograph in the

Food Chemicals Codex published by the United States Pharmacopeial Convention, as in force or existing from time to time; and

b) the requirements for residual solvents and catalysts in the British Pharmacopeia or the United States Pharmacopeia-National Formulary.

53 Table 1 in Part 2 of Schedule 1 (table item 3992)

Repeal the item, substitute:

3992	POTASSIUM IODATE	A,H	Iodine is a mandatory component of potassium iodate. The percentage of iodine from potassium iodate should be calculated based on the molecular weight of potassium iodate. When for use in adults, the medicine must contain a daily dose of no more than 505 micrograms of potassium iodate. When for use in children aged 1-3 years, the medicine must contain a daily dose of no more than 337 micrograms of potassium iodate.
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54 Table 1 in Part 2 of Schedule 1 (cell at table item 4156, column 4)

Repeal the cell, substitute:

Only for use as an active homoeopathic or excipient ingredient.

In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%.

In liquid preparations other than essential oils, the concentration of camphor must be no more than 2.5%.

In essential oil preparations, if the concentration of camphor is more than

2.5% but less than or equal to 10%, and the nominal capacity of the container is less than 25 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label:

- (CHILD) 'Keep out of reach of children' (or words to that effect); and

- (NTAKEN) 'Not to be taken'.

In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is less than 15 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label:

- (CHILD) 'Keep out of reach of children' (or words to that effect); and

- (NTAKEN) 'Not to be taken'.

In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a restricted flow insert and child resistant closure fitted on the container and include the following warning statements on the medicine label:

- (CHILD) 'Keep out of reach of children' (or words to that effect); and

- (NTAKEN) 'Not to be taken'.

55 Table 1 in Part 2 of Schedule 1 (cell at table item 4251, column 4)

Repeal the cell, substitute:

Camphor and cineole are mandatory

components of *Rosmarinus officinalis*.

In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%.

In liquid preparations other than essential oils, the concentration of camphor must be no more than 2.5%.

In essential oil preparations, if the concentration of camphor is more than 2.5% but less than or equal to 10%, and the nominal capacity of the container is less than 25 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label:

- (CHILD) 'Keep out of reach of children' (or words to that effect); and

- (NTAKEN) 'Not to be taken'.

In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is less than 15 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label:

- (CHILD) 'Keep out of reach of children' (or words to that effect); and

- (NTAKEN) 'Not to be taken'.

In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a restricted flow insert and child resistant closure fitted on the container and include the following warning statements on the

medicine label:

- (CHILD) 'Keep out of reach of children' (or words to that effect); and

- (NTAKEN) 'Not to be taken'.

When the concentration of cineole in the preparation is more than 25%, the nominal capacity of the container must not be more than 25 millilitres.

When the concentration of cineole in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a child resistant closure and restricted flow insert fitted on the container and include the following warning statements on the medicine label:

- (CHILD) 'Keep out of reach of children' (or words to that effect); and

- (NTAKEN) 'Not to be taken'.

When the concentration of cineole in the preparation is more than 25% and the nominal capacity of the container is no more than 15 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label:

- (CHILD) 'Keep out of reach of children' (or words to that effect); and

- (NTAKEN) 'Not to be taken'.

56 Table 1 in Part 2 of Schedule 1 (after table item 4401)

Insert:

4401A	SILICIFIED MICROCRYSTALLINE	E	Only for use when the route of administration is other than
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	CELLULOSE		inhalation.
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57 Table 1 in Part 2 of Schedule 1 (cell at table item 4580, column 4)

Repeal the cell, substitute:

Camphor is a mandatory component of spike lavender oil.

In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%.

In liquid preparations other than essential oils, the concentration of camphor must be no more than 2.5%.

In essential oil preparations, if the concentration of camphor is more than 2.5% but less than or equal to 10%, and the nominal capacity of the container is less than 25 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label:

- (CHILD) 'Keep out of reach of children' (or words to that effect); and

- (NTAKEN) 'Not to be taken'.

In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is less than 15 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label:

- (CHILD) 'Keep out of reach of children' (or words to that effect); and

- (NTAKEN) 'Not to be taken'.

In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the

container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a restricted flow insert and child resistant closure fitted on the container and include the following warning statements on the medicine label:

- (CHILD) 'Keep out of reach of children' (or words to that effect); and
- (NTAKEN) 'Not to be taken'.

58 Table 1 in Part 2 of Schedule 1 (cell at table item 4734, column 4)

Repeal the cell, substitute:

When used internally, oxdrine is a mandatory component of tangerine oil coldpressed.

The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.

59 Table 1 in Part 2 of Schedule 1 (cell at table item 4951, column 4)

Repeal the cell, substitute:

When used as an excipient, the route of administration must be topical.

Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.

When used as an excipient, the concentration in a medicine must be no more than 0.05%.

The maximum recommended daily dose must provide no more than 300 milligrams of ubidecarenone.

When used in combination with Ubiquinol-10, the maximum recommended daily dose must provide no more than 300 milligrams of

ubiquinol-10 and ubidecarenone
combined.

The medicine requires the following
warning statement on the medicine
label:

- (WARF) 'Do not take while on
warfarin therapy without medical
advice.'

60 Table 1 in Part 2 of Schedule 1 (cell at table item 5145, column 4)

Repeal the cell, substitute:

When used internally, zinc is a
mandatory component of zinc oxide.

The percentage of zinc from zinc oxide
should be calculated based on the
molecular weight of zinc oxide.

The indication 'For mineral (may state
the mineral) supplementation' is only
permitted when the medicine is for oral
or sublingual use.