Public Submissions on the Proposed Amendments to the Poisons Standard

Notice under subsections 42ZCZL of the Therapeutic Goods Regulations 1990 (the Regulations)

A delegate of the Secretary to the Department of Health publishes herein all valid public submissions made in response to the invitation for public submission on the proposed amendments to the Poisons Standard (commonly referred to as the *Standard for the Uniform Scheduling of Medicines and Poisons* - SUSMP). These submissions were considered by the Advisory Committee on Chemicals Scheduling (ACCS) #10 (March 2014 meeting).

In accordance with the requirements of subsection 42ZCZL of the Regulations these submissions have had confidential information removed.

Material claimed to be commercial-in-confidence was considered against the guidelines for the use and release of confidential information set out in Chapter 6 of the Scheduling Policy Framework (SPF), issued by the National Coordinating Committee on Therapeutic Goods. The SPF is accessible at www.tga.gov.au/industry/scheduling-spf.htm.

Discrete submissions have been grouped by substance. Four submitters provided submissions that related to multiple substances and these have been separately grouped.

List of Submissions

Substance	Total number of public submissions
1-Butanol	4 submissions under 'submissions on multiple substances'
1-Propanol	4 submissions under 'submissions on multiple substances'
1,3,5,7-Tetraazatricyclo [3.3.1.13] decane	2 submissions under 'submissions on multiple substances'
2,4-Diaminophenoxy ethanol sulfate	2 submissions under 'submissions on multiple substances'
Benzoic acid, 2-hydroxy-, (3Z)-1-methyl-3-hexen-1-YL ester	2 submissions under 'submissions on multiple substances'
Dibutyl phthalate	2 submissions under 'submissions on multiple substances'
Diethylene glygol monoethyl ether	3 submissions under 'submissions on multiple substances'. [**Note:** This substance was not considered at the March 2014 ACCS meeting and will be considered at the July 2014 meeting.]

Substance	Total number of public submissions
Ethanol, 2-phenoxy-	3 (2 submissions under ‘submissions on multiple substances’)
Hexanoic acid, 2-ethyl-, 2-ethylhexyl ester	2 submissions under ‘submissions on multiple substances’
Lambda-cyhalothrin	1 submission under ‘submissions on multiple substances’
Methylated spirits	3* (2 submissions under ‘submissions on multiple substances’)
Methyl isobutyl ketone	2 submissions under ‘submissions on multiple substances’
Oxalic acid	4 submissions under ‘submissions on multiple substances’
Ppg-1-peg-9 lauryl glycol ether	2 submissions under ‘submissions on multiple substances’
Tillenal	2 submissions under ‘submissions on multiple substances’

*One of the public submissions on methylated spirit was received after the closing date.

Submissions on Multiple Substances

One submission was on 1-butanol, 1-propanol, 1,3,5,7-tetraazatricyclo [3.3.1.13] decane, 2,4-diaminophenoxy ethanol sulfate, benzoic acid, 2-hydroxy-, (3Z)-1-methyl-3-hexen-1-YL ester, dibutyl phthalate, diethylene glygol monoethyl ether, ethanol, 2-phenoxy-, hexanoic acid, 2-ethyl-, 2-ethylhexyl ester, lambda-cyhalothrin, methylated spirits, methyl isobutyl ketone, oxalic acid, Ppg-1-peg-9 lauryl glycol ether and tillenal.

One submission was on 1-butanol, 1-propanol, 1,3,5,7-tetraazatricyclo [3.3.1.13] decane, 2,4-diaminophenoxy ethanol sulfate, benzoic acid, 2-hydroxy-, (3Z)-1-methyl-3-hexen-1-YL ester, dibutyl phthalate, diethylene glygol monoethyl ether, ethanol, 2-phenoxy-, hexanoic acid, 2-ethyl-, 2-ethylhexyl ester, methylated spirits, methyl isobutyl ketone, oxalic acid, Ppg-1-peg-9 lauryl glycol ether and tillenal.

One submission was on 1-butanol, 1-propanol, diethylene glygol monoethyl ether and oxalic acid.

One submission was on 1-butanol, 1-propanol, ethanol, 2-phenoxy- and oxalic acid.

thefire company

e-NRG Bioethanol Safety Warnings

The Secretary
Medicines & Poisons Scheduling
Office of Chemical Safety (MDP 88)
GPO Box 9848
CANBERRA ACT 2601

EMAIL: SMP@health.gov.au

To whom it may concern,

RE: Notice inviting public submissions under Regulation 42ZCZK of the Therapeutic Goods Regulations 1990.
Warning on methylated spirits containers.

As the manufacturer of the globally distributed EcoSmart Fire brand of bioethanol fires, The Fire Company would like to express our full support for the introduction of standardised safety markings and warnings on bioethanol fires and the fuel used in bioethanol burners. We also thank you for the opportunity to be involved in the process. We have a lot of experience to offer as a result of our involvement with Standards in other countries over the last 10 years.

In reference to the proposed new warnings on Methylated Spirits containers I'd like to provide you with a bit of information on how the industry terminology has evolved and how the fuel is referenced globally:

EARLY REFERENCE: Denatured Ethanol / Denatured Alcohol (also known as Methylated Spirits).
INDUSTRY/REGULATORY BODY/ STANDARDS FUEL REFERENCE: Bioethanol

The appliances themselves have never been referenced as having a 'methylated spirits burner' and therefore perhaps referring to it in this manner may create confusion or inadequately manage the opportunity for change in line with industry standards and the continuing stable growth of the category. It is absolutely beneficial to both consumers and the category to have appropriately and adequately labeled fuel available as apposed to unlabeled methylated spirits bottles.

The Fire Company markets and sells its own brand of bioethanol fuel (e-NRG Bioethanol), in a few markets around the world including USA, Germany, Australia. We did this for a number of reasons:

1. Some Global Standards make you nominate a fuel brand e.g DIN-4734 (German Norm) that the European Norm is proposed to closely follow.
2. Variation in fuel quality and insufficient warnings in relation to the specific product category / fuel use
3. Customer Service - customers calling fuel manufacturers don't get the information that is relevant to their use of the fuel as they are not related to the core product.
4. Overall it enabled us to extend on our commitment to safety and further support the safety warnings that appear *in* our technical and marketing materials and physically *on* our product.

On the following pages you will see examples of what the e-NRG packaging and materials currently include in reference to safety messages/devises which you may find useful in how you reword the label on Methylated Spirits Containers.


1)


2)

For your reference, these are the pictograms provided by industry regulators (specifically TUEV in Germany) to highlight the primary safety messages this relabelling topic is addressing:
1) Do not fill while hot **2) Do not fill while operating**

If you have any questions, please do not hesitate to contact me personally.
Kind regards

[redacted]

thefire company

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tel +61 2 9997 3050 fax +61 2 9997 6050
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e-NRG Bioethanol Safety Warnings

CARTON PACKAGING

Artwork at 30% final size

Artwork created: 27.11.12

Font size of warning: 30pt
Colour: Black

FRONT

SIDE

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e-NRG Bioethanol Safety Warnings

BOTTLE LABEL

Artwork at 70% final size

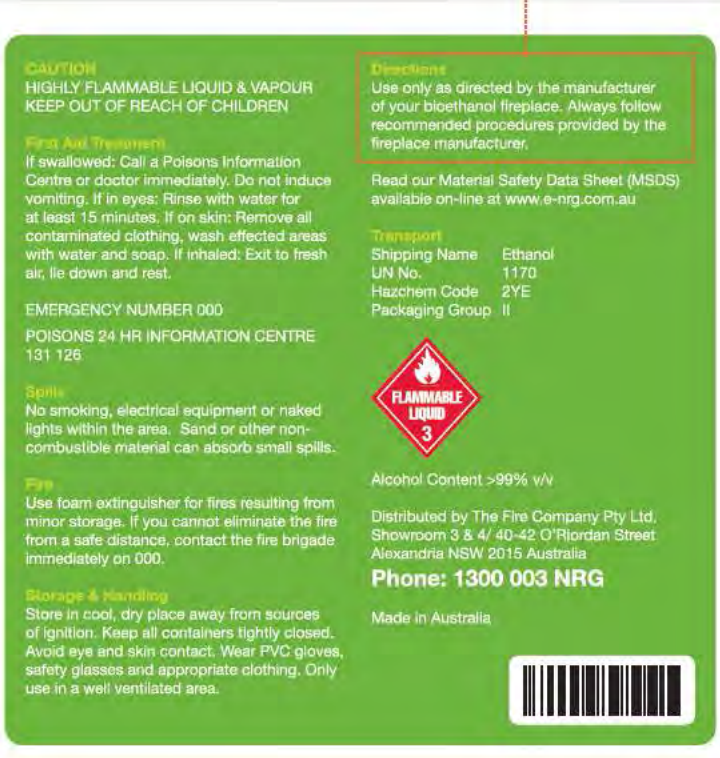
Artwork created: 07.11.12

Font size of warning: 8pt
Colour: Black

Warning Location:

FRONT

BACK



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e-NRG Bioethanol Safety Warnings

WEBSITE LEARN SECTION

Font size of warning: 14pt
Colour: Black

Warning Location: Learn Page
www.e-nrg.com.au/learn

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e-NRG Bioethanol Safety Warnings

PROMOTIONAL POSTCARD
Artwork at 80% final size

Artwork created: 16.12.13

Font size of wa ning 6 5pt
Colour: PMS 369

Warning Location:

Your safety is our number one priority. Here are some important safety reminders: 1. USE ONLY for Ventless Fireplaces. NEVER use for any other product or appliance. 2. NEVER allow e-NRG to be poured onto an open flame. Misuse can be dangerous. Serious harm can arise. 3. Before using e-NRG, please carefully read the e-NRG label on the box and bottle, as well as the included MSDS. (The MSDS sheet can be found on our website www.e-nrg.com.au) 4. Always use e-NRG in accordance with the operating instructions provided by the manufacturer of your Ventless Fireplace. 5. Only use e-NRG with operating accessories supplied with your ventless fireplace. Additional or replacement operating accessories such as Jerry Cans, Lighting Rods and Lighters can be purchased, call 1300 003 NRG. 6. And please remember to keep this product away from children at all times.

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e-NRG Bioethanol Safety Warnings

DIRECT MAIL
Artwork at 50% final size

Artwork created: 31.10.13

Font size of warning: 8pt
Colour: White

Warning Location:

Front

Inside

thefire company

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Alexandria NSW 2015 Australia
tel +61 2 9997 3050 fax +61 2 9997 6050
e info@thefirecompany.com.au

e-NRG Bioethanol Safety Warnings

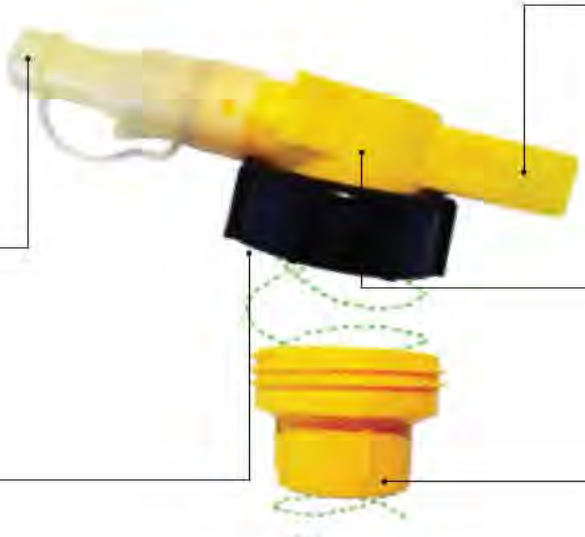
SAFETY SPOUT /ADAPTER

EcoSmart Fire bioethanol fires are accompanied by a series of accessories that cover the operational procedures to reduce risk - this includes a Jerry Can that features a safety spout with built-in flame arrester (Refer to image below).

To eliminate the need to decant the fuel from one container to another before filling the burner an Adapter is included in e-NRG packaging.

FEATURES OF THE SPOUT

There are many features of this spout that make this component the most important safety device used within our operational system.



Child Lock

A spring loaded 'active push' button that requires significant strength to start flow and stops automatically when thumb is released

End Cap

Prevents drips when bottle is being relocated

Flame Arrester

Prevents a flame from traveling back into the fuel bottle.

Self Vented

Prevents overfilling the burner. (Auto Stops when burner is full)

Adaptor

Eliminates the need for the decanting process

thefire company

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e-NRG Bioethanol Safety Warnings

We also have available the following operational accessories which come as standard with all EcoSmart Fire models and are available to e-NRG customers.

JERRY CAN

Artwork at 80% final size

Font size of warning: 7pt
Colour: Black and PMS WG10

LIGHTING ROD

Artwo k a 70% final size

Font siz
Colour:

ecosmart Fire
www.ecosmartfire.com

WARNING **Improper use can cause uncontrolled fire. To reduce fire risk:** Never use any fuel other than bioethanol (also known as denatured ethanol or denatured alcohol) in the appliance - we recommend E-NRG where available (www.e-nrg.com). Never re-use original packaged fuel container. Always store fuel at room temperature in another location separate from the appliance and away from other fuel containers. Never fuel the appliance while it is operating or hot. Always let the combustion chamber cool in accordance with the manufacturer's instructions. **If fire occurs:** Exit quickly and warn others, call the Fire Department. Do not: Try to move appliance, try to smother fire, or put water on the fire. Hot Surfaces – Keep Children Away – Do not operate without a protective guard.

ecosmart Fire
www.ecosmartfire.com

CAUTION **Improper use can cause pollution and health problems.** To reduce fire risk: Never use any fuel other than bioethanol (also known as denatured ethanol or denatured alcohol) in the appliance - we recommend E-NRG where available (www.e-nrg.com). Operate according to manufacturers instructions. Keep the appliance clean - refer to Operating Manual for instructions. Do not operate at lower than minimum setting. Always operate with the doors of the room open. Follow all applicable code requirements when using this appliance. Keep Instruction Manual.

LIGHTER

[redacted]

Australian Competition & Consumer Commission

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19 February 2014

The Secretary
Medicines & Poisons Scheduling
Office of Chemical Safety (MDP 88)
GPO Box 9848
CANBERRA ACT 2601

By email: SMP@health.gov.au

To the Secretary Medicines & Poisons Scheduling,

Re: Re: Application for methylated spirit scheduling, invitation for public comment - ACCS, ACMS and joint ACCS/ACMS meetings, March 2014

The ACCC applied to the Scheduling Secretariat in November 2013, seeking an amendment to the *Poisons Standard* to include a new warning for methylated spirits, alerting users to the dangers of refuelling spirit burners when lit or still warm.

I therefore welcome the opportunity to now write in response to the Scheduling advisory committee's invitation for public comment (posted on the TGA website 30 January 2014) on the ACCC proposal.

The Committee is asked to consider the following:

The warning should be applied nationally

The original application sought an amendment to the Schedule 5 entry for methylated spirits. A copy of the original application (redacted for privacy reasons) is attached for reference (Attachment 1).

The delegate has proposed to instead include a new entry for methylated spirit in Appendix F to require a label warning statement such as: 'WARNING: do NOT attempt to refill methylate spirit burner while it is in use or still warm; it could lead to serious burn injury or death'.

However, the ACCC is concerned that Appendix F is not adopted across all jurisdictions and may therefore not be the most appropriate mechanism for ensuring the warning is adopted nationally. The scheduling committee is therefore asked to consider the best option for achieving nationally adopted consistent warnings for methylated spirits, perhaps for example, via an amendment to Part 2.

Utilising an amendment to Part 2 would mean that those jurisdictions that have not adopted Appendix F would not need to replicate the provision in their own legislation, which would be inefficient and a duplication of effort for stakeholders.

The warning should apply to all methylated spirits supplied to consumers

Methylated spirits products are marketed to consumers for use as fuel for burners under a range of names including methylated spirits, bio-fuel and bio-ethanol. The ACCC is concerned that the proposed warning statement should apply to all such methylated spirits products, irrespective of how the product is named or marketed and regardless of whether it is marketed specifically as a fuel.

The proposed warning

The original ACCC application stated:

'The warning must be printed in capital letter in text at least 5mm high for a container having a nominal capacity of 2 litres or less and in text at least 10mm high for a container having a nominal capacity of 2 litres or more.'

However, this should have read:

'The word 'WARNING' must be printed in capital letters in text at least 5mm high for a container having a nominal capacity of less than 2 litres and in text at least 10mm high for a container having a nominal capacity of 2 litres or more. The remaining words should be in small capitals. The warning should be in a prominent position on the methylated spirits' label.'

The ACCC is pleased to support the proposed warning:

WARNING

DO NOT ATTEMPT TO REFILL A METHYLATED SPIRIT BURNER WHILE IT IS IN USE OR STILL WARM; IT COULD LEAD TO SERIOUS BURN INJURY OR DEATH

Ongoing injury

The ACCC is aware of injuries still occurring during the fuelling and ignition of ethanol burners. There are likely to be many other cases that are not reported to the ACCC. Samples of patients' narratives illustrating the severe consequences of these injuries are attached for reference (Attachment 2).

The proposed amendment to the *Poisons Standard* to require a warning on methylated spirit containers supplied to consumers, will serve to reduce burn injuries associated with the use of methylated spirits as a fuel for burners, and address gaps in consumer knowledge regarding its safe use.

[redacted]

Yours sincerely,

[redacted]

Attachment 1: Application - Proposed warning on methylated spirits on its use as fuel burner

Methylated spirits is ethanol that has additives to make it poisonous, extremely bad tasting, foul smelling or nauseating, to discourage recreational consumption. Methanol is commonly used additive because its boiling point is close to that of ethanol and because it is toxic. Methylated spirits is also known as denatured ethanol, ethanol, denatured alcohol, and many other names.

Methylated spirits is classified as Schedule 5 poisons; the products' label includes the signal word "CAUTION". It is available from supermarkets, hardware stores and camping/outdoors stores.

Methylated spirits is classified as hazardous according to criteria of Worksafe Australia and as dangerous goods according to the criteria of the Australian Dangerous Goods (ADG) Code. The products' label includes the following information:

- "Highly Flammable" symbol and risk phrase
- "Keep out of reach of children", "Keep container tightly closed" and "Keep away from ignition source – No smoking" safety phrases

According to Part 2 Poisons Standard 2012, methylated spirits sold or supplied in a container having a nominal capacity of 5 litres or less, it must be closed with a child-resistant closure.

Generally, methylated spirits is used as cleaning solvent. Labels on all products available in Australia indicate product use for cleaning.

Since the introduction of ethanol burners into the Australian market, methylated spirits has also been used as a common fuel for these products. As shown in Figures 2, though it is not prominent, the label indicates the product is suitable to use as "burner fuel" and provides instructions of use of filling the product into the burners. However, the labels of other brands do not have this information.

Figure1: Ethanol burners

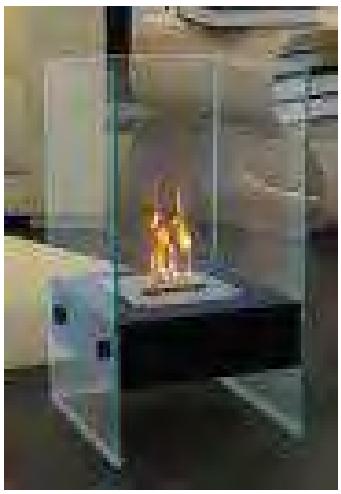
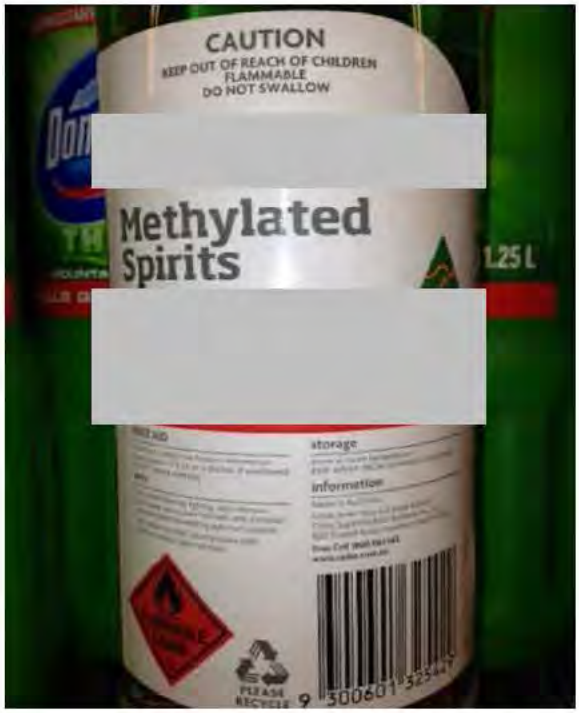


Figure2: Label of product providing instructions of use of filling the product into the burners

Figure3: Label of product not providing instructions of use of filling the product into the burners



From May 2010 until now, the ACCC is aware of twenty-seven incidents relating to ethanol burners, in which twenty-two resulted in burn injuries ranging from minor burns and up to serious burns to 55% of the body. Most of the injuries required hospitalisation. Five of the reported incidents resulted in injuries to child and elderly bystanders.

The majority (64%) of burn injuries reported occurred during the refilling of the burner while it was still lit or warm. The number and severity of injuries related to ethanol burners suggest that ethanol burners pose a hazard to the Australian consumers due to the following reasons:

- Lack of safety warnings on fuel packaging
- Lack of safety warnings on burners and burners' packaging

This application proposes to amend the Schedule 5 entry for methylated spirit products. This application proposes that a prominent warning of filling the fuel into the burners is printed on labels of methylated spirits: "NEVER REFILL METHYLATED SPIRITS BURNER WHILE STILL IN USE OR STILL WARM; IT COULD LEAD TO SERIOUS BURN OR DEATH". The warning must be printed in capital letter in text at least 5mm high for a container having a nominal capacity of 2 litres or less and in text at least 10mm high for a container having a nominal capacity of 2 litres or more.

Attachment 2: Samples of burns patients' narratives from hospital records

The consequences associated with refuelling burners while still warm are illustrated in the following examples of the narratives of recent burns victims:

1. A young boy was burned when his older 10 year old brother was showing his younger brother what he had learned from Scout Camp and refuelled a methylated spirits burner whilst still lit. The younger brother's clothing caught alight, resulting in a long admission to an Intensive Care Unit and ongoing scar management.

2. The Brisbane News, Editor's letter from 23-29 May 2012 cites the story of nine year old Adin Thompson who was burned after a methylated spirits fuelled cooker exploded during dinner. Adin sustained third degree burns to half of his body, requiring skin grafts and up to 10 years ongoing painful treatment and rehabilitation. He narrowly escaped losing his sight and the medication he is taking causes vomiting.

3. Two young men were admitted with burns after pouring methylated spirits into an ornamental bowl light. The fuel exploded into a fireball which engulfed both the young men, setting their clothes on fire. Their pet dog was also set afire. One patient was admitted for pain relief and the other spent over two weeks in the burns unit, and required skin grafts.

4. An adult female was lighting a small table ornament, which she had used many times before, but this time, when she refuelled it and lit it, the fuel exploded, setting fire to her clothes and causing serious burns to her upper body and thighs. She spent two weeks in the burns unit and required skin grafts.

5. One adult patient, burnt at the end of 2010, has had 11 readmissions for scar review.

MIGHTY HELPFUL
MITRE 10

Support Centre

12 Dansu Court Hallam Vic 3803 Australia
Locked Bag 10 Doveton Vic 3177 Australia
Tel 61 3 9703 4200 Fax 61 3 9703 4222

Mitre 10 Australia Pty Ltd ABN 98 009 713 704

The Secretary
Medicines & Poisons Scheduling
Office of Chemical Safety (MDP 88)
GPO Box 9848
CANBERRA ACT 2601

By email transmission only:
SMP@health.gov.au

Dear Secretary

RE SAFETY WARNINGS FOR ETHANOL BURNERS AND METHYLATED SPIRITS

We refer to the letter from John Jamieson dated 13 February 2014 inviting comments from suppliers of ethanol fuel or methylated spirits on the Australian market for an additional warning on containers.

Mitre 10 notes that methylated spirits has multiple uses of which only one is for use in burners. For example, it is also applied for disinfecting and cleaning which does not result in it being heated.

Mitre 10 submits that it may be more appropriate to apply the proposed warning statement to the appliance or burner itself, particularly considering such appliances may also have alternate fuel options (which may not contain the proposed warning if such warning is only applied to methylated spirit containers).

[redacted]

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[redacted]

20 February 2014

The Secretary
Medicines & Poisons Scheduling
Office of Chemical Safety (MDP 88)
GPO Box 9848
CANBERRA ACT 2601

Re: INVITATION FOR PUBLIC SUBMISSIONS ON PROPOSALS REFERRED TO THE SCHEDULING EXPERT ADVISORY COMMITTEE(S) MARCH 2014 MEETINGS

Dear Secretary,

We wish to comment on the following proposal in regard to Ethanol, 2-phenoxy-. In response to issues raised in a NICNAS IMAP report No. 529, the scheduling proposal under consideration is to create a new Schedule 5 entry for cosmetic preparations containing more than 1% of ethanol, 2-phenoxy-.

[redacted] a large number of cosmetic products, for a large number of customers, which contain up to a maximum of 1.00% w/w of Ethanol, 2-phenoxy- as preservative. These products would appear not to be affected by the proposal to create a new Schedule 5 entry for cosmetic preparations containing more than 1% of ethanol, 2-phenoxy-. However, we have some concerns as to how this threshold is defined. If it is defined as 1% w/w we don't have a problem, but if it is defined as 1.00% w/v, and we have a product with a density of greater than 1.00 g/mL, we may exceed the threshold. For example, if a product contains 1.00% w/w of Ethanol, 2-phenoxy- and has a density of 1.04 g/mL, it will contain 1.04% w/v (1.04 g/100 mL) of Ethanol, 2-phenoxy- and will exceed the threshold. But if rounding off is allowed then 1.04% w/v rounds off to 1% w/v and it does not exceed the threshold.

It is our understanding that internationally, the generally accepted threshold for safe use in cosmetics is 1.0% of Ethanol, 2-phenoxy- as preservative, but it is not clear whether this is 1.0% w/w or 1.0% w/v or both.

We understand that an interim decision will be published and will be open for further public submission from applicants and those persons who made a submission in response to the original invitation and which were received on or before the closing date for public submissions of 20 February 2014. Therefore, we reserve the right to make a further submission at that time.

[redacted]

[redacted]

[redacted]

Yours faithfully

[redacted]

The Secretary
Scheduling Secretariat
GPO Box 9848
CANBERRA ACT 2601

Email: SMP@health.gov.au

Dear Sir/Madam

Public Comment Submission to the March 2014 meeting of the Advisory Committee on Chemicals Scheduling (ACCS)

We refer to the notice published on 30 January 2014 inviting public submissions, with respect to certain substances, addressing a matter raised in s.52E of the *Therapeutic Goods Act 1989.*

Accord Australasia Limited is the peak national industry association that represents the hygiene, cosmetic & specialty products industry.

Accord wishes to provide information on:

- **1-butanol;**
- **1-propanol;**
- **1,3,5,7-tetraazatricyclo [3.3.1.13] decane;**
- **2,4-diaminophenoxy ethanol sulfate;**
- **Benzoic acid, 2-hydroxy-, (3Z)-1-methyl-3-hexen-1-yl ester;**
- **Dibutyl phthalate;**
- **Diethylene glycol monoethyl ether;**
- **Ethanol, 2-phenoxy-;**
- **Hexanoic acid, 2-ethyl-, 2-ethylhexyl ester;**
- **Methylated spirits;**
- **Methyl isobutyl ketone;**
- **Oxalic acid;**
- **PPG-1-PEG-9-lauryl glycol ether; and**
- **Tillenal**

for consideration at the March 2014 meeting of the ACCS.

Please see attached submission for details.

Accord is an interested party and stakeholder with regard to the nominated substances and would appreciate being advised of the Committee's considerations and the Delegate's interim decision, with the opportunity for further submission, if appropriate.

We look forward to further advice from the ACCS and the Delegate. Should the Committee or the Delegate require any additional information from Accord at this stage please do not hesitate to contact me on [redacted]

Accord Australasia Limited ACN 117 659 168 ABN 83 205 141 267
Fusion C4.02, 22 – 36 Mountain Street, Ultimo NSW 2007
PO Box 290 BROADWAY NSW 2007

Tel: 61 2 9281 2322 **Fax:** 61 2 9281 0366 **Website:** www.accord.asn.au

Yours faithfully

[unsigned for electronic submission]

[redacted]

20 February 2014

ACCS meeting: March 2014

1-butanol

Accord notes that based on the NICNAS IMAP report on 1-butanol, the recommendation for scheduling appears to have arisen from potential irritation concerns, particularly eye irritation which can be severe.

Based on information from Members, the most common cosmetic use of 1-butanol is in nail products including in nail polish and in nail fortifiers as a solvent (up to 15%). Members also reported the use of 1-butanol in aerosol propellants in low concentrations in both cosmetic and therapeutic products. It is also expected that 1-butanol may be present in small quantities in other cosmetics and consumer products.

We understand that there is no restriction on the use of 1-butanol in cosmetics in the EU. Also, the US-based Cosmetic Ingredient Review (CIR) Ingredient Status Report notes that 1-butanol is safe in all cosmetic product categories in their current use.

We do not believe that NICNAS has presented any new information that supports placing restrictions on 1-butanol when there are no international restrictions in place.

Accord does not support scheduling of 1-butanol. However, if 1-butanol is considered for inclusion in the Poisons Standard, Accord suggests a joint ACMS/ACCS consideration to ensure that therapeutic use of 1-butanol is not inadvertently affected (1-butanol is listed on the ARTG), and suggests excluding all current uses of 1-butanol in cosmetics as they have been found to be safe by the US CIR.

ACCS meeting: March 2014

1-propanol

Accord notes that based on the NICNAS IMAP report on 1-propanol, the recommendation for scheduling of 1-propanol in cosmetics and consumer products appears to have arisen from potential eye irritation concerns.

While NICNAS notes in its report that 1-propanol is used in a range of cosmetic products overseas at concentrations up to 60%, it does not discuss whether there have been any concerns raised with this use in overseas jurisdictions. As far as we are aware, no concerns have been raised with the current uses of 1-propanol and there are no restrictions in the EU or the US on the use of 1-propanol in cosmetics or consumer products.

While 1-propanol is not used as commonly as ethanol or isopropanol as a solvent in cosmetics and consumer products due to its cost being much higher, ethanol, isopropanol and 1-pronanol are considered to provide comparable efficacy and safety in a range of applications, most notably in alcohol-based hand-rubs.

We note that NICNAS does not appear to have presented any evidence to suggest that current uses of 1-propanol at up to 60% in some products are causing public health and safety concerns.

Accord does not support scheduling of 1-propanol. However, if scheduling of 1-propanol is considered appropriate, Accord suggests a joint ACMS/ACCS deliberation to ensure that therapeutic uses of 1-propanol are not inadvertently captured (1-propanol is listed on the ARTG).

ACCS meeting: March 2014

1,3,5,7-tetraazatricyclo [3.3.1.13] decane (hexamine or methenamine)

Accord notes that the proposal for the scheduling of methenamine and a 0.15% cut-off from scheduling appears to be based on the European Cosmetics Directive cut-off for the use of methenamine as a preservative in cosmetics. To date, Accord has not received any comments on the use of methenamine in any Member products and therefore currently is not opposed to the scheduling of methenamine in cosmetics on the basis of international harmonisation. However, we are unsure whether inclusion of methenamine in Schedule 5 for all other purposes is appropriate.

Accord notes that the best known use of methenamine is as a camp stove fuel tablet (hexamine tablets). Any scheduling decision should understand the impact on this and other potential sectors. While the NICNAS IMAP report lists other uses of methenamine including in fuel tablets, NICNAS does not appear to have considered the public health and safety impact of methenamine in any uses other than in cosmetics and has ignored the potential impact of scheduling on non-cosmetic uses.

Accord also notes that there have been no concerns raised with the use of methenamine in the Australian context to date – the NICNAS IMAP report appears mainly to be an assessment of hazards and comparison between Australian and other regulatory (particularly the EU Cosmetic) controls.

ACCS meeting: March 2014

2,4-diaminophenoxyethanol sulfate

Accord notes that while 2,4-diaminophenoxyethanol sulfate is not listed by a specific schedule entry in the Poisons Standard, we believe that the Schedule entry for phenylenediamine extends to 2,4-diaminophenoxyethanol sulfate.

Phenylenediamine is included in Appendix C when in preparations for skin colouration and dyeing of eyelashes or eyebrows **except** when included in Schedule 6.

Schedule 6 entry for phenylenediamine reads:

> *PHENYLENEDIAMINES and alkylated phenylenediamines not elsewhere specified in these schedules:*
>
> *(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 diethylpara-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.*

In the EU Cosmetics Directive, 2,4-diaminophenoxyethanol sulfate is restricted in hair dyes to 2% on-head concentration i.e. the pre-mix product can contain higher levels of 2,4-diaminophenoxyethanol sulfate provided that the pre-mix is diluted before use.

Accord does not believe that there is a need for further scheduling, as we believe that the schedule entry for phenylenediamine adequately address the risks of 2,4-diaminophenoxyethanol sulfate.

However, if the Delegate believes there is a need to separately schedule 2,4-diaminophenoxyethanol sulfate, the wording of the new schedule entry should clearly indicate

that the limitations imposed relate to the on-head concentration of the mixture containing 2,4-diaminophenoxyethanol, not the product containing the substance.

ACCS meeting: March 2014

Benzoic acid, 2-hydroxy-, (3Z)-1-methyl-3-hexen-1-yl ester

Based on the information in the NICNAS Full Public Report, this substance appears to be a fragrance material. While the Scheduling notice did not suggest any scheduling cut-offs, the NICNAS Public Report appears to place restrictions on the use of the substance.

Accord notes that the Notifier of the substance has requested that NICNAS consider the following concentrations of the substance in a range of uses. They are:

- 0.96% in deodorants,
- 4.8% in fine fragrances,
- 0.96% in other leave-on cosmetics, and
- 0.96% in rinse-off cosmetics, fabric care and household cleaning products.

Accord also notes that after its assessment and consideration, NICNAS reduced this to:

- 0.2% in deodorants,
- 0.37% in fine fragrances,
- 0.51% in other leave-on cosmetic products, and
- 0.96% in rinse-off cosmetics, fabric care and household cleaning products.

As far as we are aware, currently in Australia, benzoic acid, 2-hydroxy-, (3Z)-1-methyl-3-hexen-1-yl ester cannot be used at higher concentrations than the levels set by NICNAS.

Based on the summary provided in the NICNAS assessment report (page 9 of the Full Public Report), this substance has low toxicity, a low irritation potential, and is non-mutagenic and non-genotoxic. While the animal sensitisation studies showed evidence of sensitisation, the skin sensitisation test with human volunteers (repeat insult patch test) showed that the substance was not sensitising at concentrations up to 15%.

We are therefore unsure of the basis for NICNAS restrictions on the use of the substance, and we believe their conclusion that the substance is a skin sensitiser ignores the evidence to the contrary.

Accord does not support scheduling of this substance based on the evidence provided by the Notifier of the substance available in the NICNAS Full Public Report.

ACCS meeting: March 2014

Dibutyl phthalate

As far as we are aware, none of our Members are marketing products containing dibutyl phthalate. Accord notes that dibutyl phthalate is listed in Annex II (substances banned in cosmetics) of the EU Cosmetics Directive.

Therefore, Accord currently has no objections to the inclusion of dibutyl phthalate in Appendix C for cosmetic use.

ACCS meeting: March 2014

Diethylene glycol monoethyl ether (ethoxydiglycol)

Accord is unsure of the basis for the scheduling proposal for diethylene glycol monoethyl ether (ethoxydiglycol).

For the November 2013 meeting of the ACCS, the Scheduling Secretariat sought comments on ethylene glycol monomethyl ether. Accord sought clarification from the Scheduling Committee and the Delegate whether the schedule entry for ethylene glycol monoalkyl ether also applies to diethylene glycol monoalkyl ethers, as we believe that the proposal was put forward based on the IMAP report on diethylene glycol monomethyl ether.

While we suspected that diethylene glycol monomethyl ether is not used in cosmetics (as it is also on the prohibited list in the EU Cosmetics Directive), Accord respectfully suggested that if diethylene glycol monomethyl ether is captured by the ethylene glycol monomethyl ether entry, that this be made clear in the Delegate's Interim Decisions as a minimum to allow comments from companies that are potentially impacted.

We note that unlike diethylene glycol monomethyl ether, ethoxydiglycol is not on the prohibited list in the EU Directive. While there are a number of opinions on ethoxydiglycol from the Scientific Committee on Consumer Safety (SCCS)[1], no limitations are currently imposed in the EU.

We also note that in the US, up to 80% ethoxydiglycol in cosmetic products was considered acceptable by the Cosmetics Ingredient review (CIR) panel – ethoxydiglycol is used in a large number of cosmetic products (over 1000 different products counted in the US) including nail care products, shower gels, foundations and eye creams as humectants, perfumes or solvents.

Accord would appreciate a further opportunity to better understand the basis and the specific details of this scheduling proposal (e.g. any cut-offs for exemption from scheduling, suggested restrictions when used in cosmetics) so that the impact on our Members can be better assessed.

**Note: As there are a number of similar chemicals with similar chemical names, we have tried to improve readability by colour coding different chemical names.*

- Diethylene glycol monoethyl ether (ethoxydiglycol) – Substances proposed for scheduling
- Diethylene glycol monomethyl ether – NICNAS IMAP report suggests control through scheduling
- Ethylene glycol monomethyl ether – Scheduling secretariat sought comments for the November 2013 meeting schedulign proposal
- Ethylene glycol monoalkyl ether – currently scheduled
- Diethylene glycol monoalkyl ether – no specific scheduling

[1] The latest SCCS opinion on ethoxydiglycol is available from: http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_119.pdf.

ACCS meeting: March 2014

Ethanol, 2-phenoxy- (2-phenoxyethanol)

Accord notes that the proposal to schedule 2-phenoxyethanol when used in cosmetics is based on the EU Cosmetics Directive restriction on the use of 2-phenoxyethanol, which allows up to 1% as a preservative in cosmetics.

Comments received from Members to date indicate that 2-phenoxyethanol is used in cosmetics in concentration of 1% or less. On this basis, Accord has no objections to scheduling of 2-phenoxyethanol when used in cosmetic formulation, with an exemption from scheduling for products containing 1% or less 2-phenoxyethanol.

ACCS meeting: March 2014

Hexanoic acid, 2-ethyl-, 2-ethylhexyl ester (ethylhexyl ethylhexanoate)

Accord notes that the NICNAS recommendation to schedule ethylhexyl ethylhexanoate arises from the classification of the substance as a category 3 reproductive toxicant. Accord also notes that while the EU classifies the substance as a category 3 reproductive toxicant, there are no restrictions placed on the use of the substance in cosmetics.

The Cosmetic Ingredient Review (CIR) report on alkyl ethylhexanoate use in cosmetics[2] (including ethylhexyl ethylhexanoate) concluded that the current use of alkyl ethylhexanoates in cosmetics is safe when formulated to be non-irritating.

Given that both the EU and the USA have considered the use of this substance in cosmetics in depth including its reproductive toxicant potential, and have concluded there was no reason to place restrictions on its use, we are unsure why NICNAS believes there is a need to place controls on the substance when no new data appears to have been considered.

Based on the lack of controls in the EU and the USA after extensive consideration of the risk posed by the substance, we do not believe that there is a need to schedule ethylhexyl ethylhexanoate.

[2] http://www.cir-safety.org/sites/default/files/ethylh_032013_build.pdf.

ACCS meeting: March 2014

Methylated spirits

Currently methylated spirits require two first aid statements (standard statements A and G3). The words “FLAMMABLE LIQUID” is also required on the label, unless the label meets the *Australian Code for the Transport of Dangerous Goods by Road and Rail* (ADG Code) requirements (includes a flammable “pictogram”).

Accord notes that the proposal to include a warning statement on methylated spirits arises from the recent rise in incidents relating to alcohol burners used in the home – 22 incidents of burns (some severe) over four year period.

As the methylated spirits label already carries information on flammability, we note that the additional warning statement is not to warn of the flammability, but to warn of the dangers of re-filling methylated spirit burners when the burner is still warm or still lit.

While we agree that there is a concern with the rise in the number of incidents with the use of methylated spirit burners, we are unsure whether a warning label on the methylated spirit bottles is the best way to address the issue. We believe a better method may be to include a warning label on the methylated spirit burner itself that it is not to be refuelled while it is still lit or hot.

Contact of any highly flammable liquid with any hot surface or with any flame is highly risky and should be discouraged, whether it is methylated spirit on methylated spirit burners or petrol on coal-fired barbecues. We are simply concerned that a warning label on all solvents that may potentially be used for fires, in addition to the flammability information already on the label, may not be the best method to discourage the practice, noting that a cluttered label becomes more difficult to read and understand.

However, if the ACCS and the Delegate believe that there is a need for additional warning labels on methylated spirits, Accord requests that the ACCS and the Delegate allow enough time for companies to amend the label and transition to the newly labelled product. We believe that a minimum of two years should be allowed for the transition.

ACCS meeting: March 2014

Methyl isobutyl ketone (MIBK)

Accord notes that the NICNAS recommendation to up-schedule MIBK appears to be on the basis of the substance potentially being a category 3 carcinogen (or IARC group 2B carcinogen). We note that this information is not new i.e. both the USA and the EU should also be aware of this information. We also note that there are no restrictions in the EU or the USA on the use of this substance in cosmetics. Further NICNAS has not provided any evidence that the current scheduling control of MIBK has failed or is inadequate.

MIBK is used in cosmetics as a denaturant, fragrance ingredient and solvent. According to the International Cosmetic Ingredient Dictionary and Handbook, MIBK is mainly used in nail products. MIBK has other uses in industry, notably as a denaturant in ethanol. We also understand that MIBK has a therapeutic use and is listed on the ARTG.

MIBK is currently included in Schedule 5 as follows:

> *METHYL ISOBUTYL KETONE* ***except*** *in preparations containing 25 per cent or less of designated solvents.*

That is, MIBK is unscheduled unless it is in a preparation in which the combined designated solvent total is greater than 25%.

Accord does not believe that there is a demonstrated need to up-schedule MIBK or to remove the exemption from scheduling currently provided in the Poisons Standard. We therefore do not support the proposal.

ACCS meeting: March 2014

Oxalic acid

Accord supports the proposed exemption from scheduling of oxalic acid in domestic cleaning preparations containing 8% or less oxalic acid. We also request that the ACCS and the Delegate consider exemption for dental products including mouthwashes containing 3% or less of soluble salts of oxalic acid.

While the exemption could be limited to therapeutic dental products, if the use of up to 3% soluble salts of oxalic acid is considered acceptable in therapeutic dental products, the same should apply to non-therapeutic dental products. Further, if a company markets products to treat tooth sensitivity, the product would automatically become therapeutic.

Potassium oxalate is currently in products used to treat dental sensitivity marketed in the UK, and its use for this purpose is also permitted in the United States. The oxalate ion works by combining with calcium ions in the oral cavity to form insoluble calcium oxalate crystals which block the dentinal tubules.

According to the SCCS notes of guidance for the testing of cosmetic ingredients and their safety evaluation, 7th revision[3], approximately 10% mouthwash is expected to be retained in the oral cavity after use (conservatively estimating). The intended dose of the mouthwash is between 10-20ml. This equates to maximum absorption of approximately 30mg of oxalate ion.

Oxalic acid is a naturally occurring substance found in common foods such as coffee, spinach, carrots, lettuce and chocolate.

Based on information on average quantities of oxalic acid in foods from the United States Department of Agriculture (USDA)[4], more than 10 times the amount of oxalic acid retained from a mouthwash can be consumed from eating one medium sized carrot (carrots contain approximately 0.5g (500mg) oxalic acid per 100g – an average carrot weighs approximately 70g).

We therefore request that the following scheduling proposal be considered:

Schedule 6

OXALIC ACID except:

a) its derivatives and insoluble salts,

b) in household and domestic cleaning preparations containing 8 per cent or less oxalic acid or its soluble salts, and

c) in dental care preparations including mouthwashes containing 3 per cent or less oxalic acid or its soluble salts.

[3] http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_s_004.pdf.
[4] http://www.ars.usda.gov/Services/docs htm?docid=9444

Accord notes that NICNAS restricts the use of this surfactant in rinse-off cosmetic preparations to 3% and leave-on cosmetics to 2%. Accord questions the basis for NICNAS' restrictions.

Dermal absorption

The dermal absorption data was provided by the Notifier of the substance for the analogue polymer of PPG-1-PEG-9 lauryl glycol ether – approximately 1% in rinse-off products and approximately 3-5% in leave-on products. While Accord cannot confirm that the analogue polymer is a relevant analogue for this purpose, we would assume that both the Notifier and NICNAS agreed this was the case. As such, the maximum dermal absorption rate should be taken to be 5%. This would seem a reasonably conservative estimate noting that the molecular weight of this polymer is > 500 Da.

NICNAS however appears to have used a dermal absorption value of 15.6%. While the information available on the modelling method is patchy, it appears that NICNAS has relied on the modelled concentration of the notified chemical in the *stratum corneum* after 24 hours (page 10 of the NICNAS Full Public Report for LTD/1616). We are unsure why NICNAS has opted to use modelled data on concentration in the *stratum corneum* when animal test data was available.

Daily use of products containing PPG-1-PEG-9 lauryl glycol ether

In calculating the maximum allowable concentration in cosmetics, NICNAS has assumed that a single person will use all of the following products containing PPG-1-PEG-9 lauryl glycol ether (page 9 of the NICNAS Full Public Report for LTD/1616):

- Body lotion,
- Face cream,
- Hand cream,
- Deodorant,
- Fragrances,
- Shower gel,
- Hand wash soap,
- Shampoo,
- Hair conditioner, and
- Hair styling products.

NICNAS has also assumed that all products will contain PPG-1-PEG-9 lauryl glycol ether at 10%, even though the Notifier has specified that the typical use concentration is 2-3%.

It is highly unlikely that a single person will use all of these products containing PPG-1-PEG-9 lauryl glycol ether daily. NICNAS notes in its report that this is the worst case calculation.

We do not believe that this worst case estimation is warranted, as the NICNAS assessment for the substance was for Limited Notification i.e. no more than 1000kg of the substance is imported into Australia per year i.e. using the NICNAS worst case scenario, this is equivalent to use by a maximum of 387 people (1000kg ÷ (sum(daily amount)/10 x 365)). Given that the Australian population is currently approximately 22.5 million, we assume that PPG-1-PEG-9 lauryl glycol ether is not widely used and/or used in fairly small volumes by most individuals.

Conclusion

Accord does not believe that there is a need to schedule this substance as we do not believe that the toxicity profile and its use pattern warrants scheduling, particularly when only a maximum of 1000kg of the polymer is allowed in Australia per year.

If scheduling is deemed necessary, we believe it should align with other already scheduled surfactants such as sodium lauryl sulfate.

Tillenal

Accord notes the restrictions on the use of Tillenal in the NICNAS Full Public Report for Tillenal (LTD/1617) and questions the basis of the conclusions derived.

Similar to PPG-1-PEG-9 lauryl glycol ether, Accord questions the dermal absorption value used in the assessment of Tillenal – 100% dermal absorption was assumed by NICNAS. We also question the use of the worst case scenario i.e. the use of Tillenal by a single person in maximum concentrations in 10 product types (body lotion, face cream, hand cream, fine fragrances, deodorant spray, shampoo, conditioner, shower gel, hand soap and hair styling products). Tillenal is only allowed to be imported at a maximum volume of 1000kg per year into Australia.

We also question the use of 300 as the acceptable Margin of Exposure (MoE) value for Tillenal when 100 was used for PPG-1-PEG-9 lauryl glycol ether. For both substances, the NOAEL value was derived from rat, repeat dose oral gavage study (90 days for PPG-1-PEG-9 lauryl glycol ether, 28 days for Tillenal). It does not appear to make sense that an MoE value of 100 is deemed acceptable for one of the substances but not for the other particularly when for both substances NICNAS reports state that the acceptable MoE value accounts for inter and intra-species differences.

Accord defers to the expertise of the ACCS and the Delegate to determine whether the methods and data used by NICNAS to derive the acceptable use pattern of Tillenal are appropriate.

If the ACCS and the Delegate consider it is necessary to schedule Tillenal, we believe a consultation which includes the proposed exemption cut-off from scheduling should take place – we note that the scheduling notice did not include the exemption cut-off values.

Australian Self-Medication Industry Inc
[redacted]

19 February 2014

The Secretary
Scheduling Secretariat
GPO Box 9848
Canberra ACT 2601

Dear Sir or Madam,

Re: Invitation for public comment – ACCS, ACMS and joint ACCS / ACMS meetings, March 2014
ASMI Comment – ACCS meeting

We refer to the notice inviting public comment under Regulation 42ZCZK of the Therapeutic Goods Regulations and would like to provide comment on the scheduling proposals that are to be considered by the ACCS and the joint ACCS/ACMS meetings in March 2014. The comments submitted below address matters raised in section 52E of the *Therapeutic Goods Act 1989*, and are in relation to the proposed amendments referred by the delegate for scheduling advice for consideration by the ACCS.

ASMI (Australian Self Medication Industry) is the peak body representing companies involved in the manufacture and distribution of consumer healthcare products (non-prescription medicines) in Australia. ASMI also represents related businesses providing support services to manufacturers, including advertising, public relations, legal, statistical and regulatory consultants.

For ease of reference, the comments are in the same order as the proposals in the consultation document.

ACCS Agenda – General comments

ASMI notes the many proposals for the amendment of schedule entries for various substances in the poisons standard, to be considered by the ACCS. The proposals for consideration appear to pertain mainly to the use of the chemicals in cosmetic products and some industrial chemicals, however ASMI notes that there is insufficient detail in the proposals to allow an adequate assessment of impact on the therapeutic goods industry.

Some of the proposals on the agenda appear to follow the NICNAS IMAP review process and recommendations, however we are concerned that the possible impact on ingredients entered in the ARTG for use in therapeutic goods may not have been fully considered. ASMI urges the Scheduling Secretariat to ensure that there has been adequate co-ordination between the relevant agencies (NICNAS, TGA, APVMA and ANZFA) prior to the publication of the agenda, and greater detail and transparency on the rationale behind the proposals on the agenda to enable industry to assess the proposals adequately and comment appropriately.

We have reviewed the entire agenda and to the extent possible, have commented on any specific items which are relevant to our members. Some agenda items are clearly not relevant, however given the ambiguity and lack of detail in the agenda (for example, cut-off concentrations are not nominated), ASMI cannot be certain that all relevant sections and matters in the agenda have been identified. For this reason, our general comments below that relate to the impact on therapeutic goods, should be considered as comments in relation to each agenda item for the purposes of providing a post-meeting response.

Some of the proposals do not appear to be relevant to the therapeutic goods industry. However given the limited information provided, the complexity of nomenclature and the large number of possible salts and derivatives, we cannot be certain that no impact exists and we would appreciate the opportunity to provide further comment on any of the agenda items should possible impact be identified following the release of the Delegate's interim decisions.

Proposed scheduling amendments and ASMI comment

Substance	Proposal
1-Butanol	In response to issues raised in IMAP Report No. 85 – To create new S5 and/or S6 entries with appropriate concentration cut-offs and associated warning statements

Comment:
1-Butanol is identified in the relevant IMAP report as being present in cosmetic products as a component of fragrances and as a denaturant. It also has commercial and industrial uses.

A search of the TGA e-BS site shows that 1-Butanol is entered in the ARTG ingredient list as n-butyl alcohol BP, indicating that it may have uses in therapeutic goods, although specific uses are not defined. ASMI understands that this ingredient may have use as a propellant in certain aerosol dosage forms for medicines.

The proposed Schedule 5 or 6 entry is not restricted to cosmetic or industrial products, and no cut-off is proposed. ASMI is concerned about the possibility that there may be some impact on therapeutic goods, and consideration should be given to drafting the entry so that therapeutic goods are excluded. It would be inappropriate to capture therapeutic goods as part of any proposed Schedule 5 or Schedule 6 entry.

Substance	Proposal
1-Propanol	In response to issues raised in IMAP Report No. 47 – To create new S5 and/or S6 entries with appropriate concentration cut-offs and associated warning statements

Comment:
1-Propanol is identified in the relevant IMAP report as being present in cosmetics as a perfume substrate / solvent, as well as in a range of other domestic, commercial and industrial products. The report also states that 1-propanol is used in pharmaceuticals, although no specific description of its use in pharmaceuticals has been stated. ASMI understand that it may be used in trace amounts, as solvents for printing inks on coated tablets and similar uses.

A search of the TGA e-BS site shows that 1-propanol is entered in the ARTG as propan-1-ol BP, and is allowed in therapeutic goods in products for dermal use up to a maximum concentration of 18% w/v.

The proposed Schedule 5 or 6 entry is not restricted to cosmetic or industrial products, and no cut-off is proposed. ASMI is concerned about the possibility that there may be some impact on therapeutic goods, and consideration should be given to drafting the entry so that therapeutic goods are excluded. It would be inappropriate to capture therapeutic goods as part of any proposed Schedule 5 or 6 entries.

Substance	Proposal
1,3,5,7-Tetraazatricyclo[3.3.1.13] decane	In response to issues raised in IMAP Report No. 119 – To create a new S5 and/or S6 entry for 1,3,5,7- Tetraazatricyclo[3.3.1.13] decane with a 0.15% concentration cut-off.

Comment:
ASMI notes that the IMAP report No. 119 also refers to 1,3,5,7- Tetraazatricyclo [3.3.1.13] decane as methenamine, hexamine and urotropine (as synonyms). The report also states that the substance has uses in pharmaceutical products.

We also note that the proposal refers to a cut-off concentration of 0.15%, but does not specify commercial, industrial or cosmetic uses, so that the proposal (as written) would capture therapeutic goods.

A search of the TGA e-BS site and the ARTG indicates that hexamine (synonym methenamine, CAS 100-97-0) is entered in the ARTG ingredient list. Hexamine hippurate is also an active ingredient in an OTC medicine widely used to treat urinary tract infection (hexamine hippurate 1g tablets), and this substance could be regarded as a salt or derivative of hexamine.

The scheduling proposal as written would therefore capture a marketed therapeutic product, registered by the TGA. ASMI suggests that the wording of any proposed entry should be carefully drafted so that therapeutic goods are specifically excluded and consideration should be given as to whether salts and derivatives should also be excluded from any proposed Schedule 5 or 6 entry.

Substance	Proposal
2,4-Diaminophenoxy ethanol sulfate	In response to issues raised in NICNAS new chemical report No. LTD/1528 – To include 2,4-Diaminophenoxy ethanol sulfate in Schedule 6 and Appendix F, with appropriate cut-off to exempt for preparations with low concentrations.

Comment:
The information provided in the scheduling consultation and in the NICNAS new chemical report No. TD/1528 is not sufficiently clear as to whether this ingredient is used in any therapeutic goods, as the report pertains to its use in hair dyes.

ASMI therefore reserves the right to comment at the post-meeting comment stage, should it become evident that there may be an impact on therapeutic goods. In addition, any scheduling proposals should be carefully drafted to exclude therapeutic goods.

Substance	Proposal
Benzoic acid, 2-hydroxy-,(3Z)-1-methyl-3-hexeh-1-YL ester	In response to issues raised in NICNAS new chemical report No. LTD/1582 – To include Benzoic acid, 2-hydroxy-,(3Z)-1-methyl-3-hexeh-1-YL ester in Schedule 6 and Appendix F, with appropriate cut-off to exempt for preparations with low concentrations.

Comment:
The information provided in the scheduling consultation and in the NICNAS new chemical report No. LTD/1582 is not sufficiently clear as to whether this ingredient is used in any therapeutic goods, as the report pertains to its use in fragrances.

ASMI therefore reserves the right to comment at the post-meeting comment stage, should it become evident that there is an impact on therapeutic goods. In addition, any scheduling proposals should be carefully drafted to exclude therapeutic goods.

Substance	Proposal
Dibutyl phthalate	In response to issues raised in NICNAS Priority Existing Chemical Report No. 36: To include cosmetic and personal care preparations containing dibutyl phthalate in Appendix C with appropriate concentration cut-offs.

Comment:
The NICNAS Priority Existing Chemical Report No. 36 refers to the use of dibutyl phthalate in cosmetics and personal care products.

A search of the TGA e-BS site shows an entry for dibutyl phthalate, with use as an active ingredient restricted to topical prescription products, and use allowed as an excipient in registered and listed medicines. ASMI supports the wording of the scheduling proposal, namely that it specifically applies to cosmetic and personal care products, and requests that the wording of the schedule and cut-off is carefully drafted so that therapeutic goods are not affected.

Substance	Proposal
Diethylene glycol monoethyl ether	Proposal to develop a separate listing of diethylene glycol monoethyl ether in Schedule 6 to complement the current generic listing of ethylene glycol monoalkyl ethers and to consider restrictions on use in cosmetic preparations

Comment:
The information provided in the scheduling consultation is not detailed, and not linked to any NICNAS assessment. Diethylene glycol monoethyl ether is used in industrial cleaners, wood stains, paints, inks and coatings in the printing and dyeing process. It does not appear to be in the TGA's ingredient list and it is unclear whether the substance is used in any therapeutic goods.

ASMI therefore reserves the right to comment at the post-meeting comment stage, should it become evident that there is any impact on therapeutic goods. In addition, any scheduling proposals should be carefully drafted to exclude therapeutic goods.

Substance	Proposal
Ethanol, 2-phenoxy-	In response to issues raised in NICNAS IMAP report No. 529: To create a new Schedule 5 entry for cosmetic preparations containing more than 1% of ethanol,2-phenoxy-

Comment:
ASMI notes that there is a TGA e-BS entry for phenoxyethanol (CAS 122-99-6) which according to NICNAS IMAP Report No. 529 is a synonym for ethanol, 2-phenoxy-. The wording of the scheduling proposal clearly refers to cosmetic products, and ASMI supports the clear distinction between cosmetics/personal care products and therapeutic goods in the drafting of scheduling proposals.

As proposed in the above wording, impact on therapeutic goods is unlikely, however ASMI reserves the right to provide comment at the post-meeting comment stage, if it becomes evident that there may be an impact on therapeutic goods.

Substance	Proposal
Hexanoic acid, 2-ethyl-,2-ethylhexyl ester	In response to issues raised in NICNAS IMAP report No. 827: To create a new Schedule 6 entry with appropriate low concentration exemption cut-off for hexanoic acid,2-ethyl-2-ethylhexyl ester

Comment:
The information provided in NICNAS IMAP Report No. 827 indicates that hexanoic acid,2-ethyl-2-ethylhexyl ester is used as an emollient, and in cleaning/washings agents, lubricants and additives.

There does not appear to be an entry in TGA e-BS, and it is unclear from the information provided whether there may be any impact on therapeutic goods, noting that the wording of the scheduling proposal does not exclude therapeutic goods.

ASMI therefore reserves the right to comment at the post-meeting comment stage, should it become evident that there may be an impact on therapeutic goods. In addition, any scheduling proposals should be carefully drafted to exclude therapeutic goods.

Substance	Proposal
Lambda-cyhalothrin	Proposal to amend the Schedule 6 entry for lambda-cyhalothrin to increase the concentration cut-off for (b) other preparations containing lambda-cyhalothrin for 1% or less to 1.6% or less of lambda-cyhalothrin.

Comment:
Although not stated in the scheduling proposal, lambda-cyhalothrin appears to be used as an insecticide therefore it is unlikely that there will be an impact on therapeutic goods.

Substance	Proposal
Methylated spirits	Proposal to include a new entry for methylated spirits in Appendix F to require a label warning statement such as : "WARNING: Do not attempt to refill a methylate spirit burner while it is still in use or still warm; it could lead to serious burn injury or death.

Comment:
ASMI does not object to the addition of this warning statement to labelling of methylated spirits.

Substance	Proposal
Methyl isobutyl ketone	In response to issues raised in NICNAS IMAP Report No. 88 the proposal is to: • Delete the current Schedule 5 entry for methyl isobutyl ketone; and • Include methyl isobutyl ketone in Schedule 6 • Consider listing methyl isobutyl ketone in Appendix I (Uniform Paint Standard)

Comment:
A search of the TGA e-BS website contains an ARTG ingredient listing for methyl isobutyl ketone USP NF, with the use not specified.

ASMI suggests that the wording of any proposed Schedule 6 entry should be consistent with the existing Schedule 5 entry, which states: "Methyl isobutyl ketone except in preparations containing 25 per cent or less of designated solvents."

This wording would exclude therapeutic goods from Schedule 5 or 6, as per the existing entry.

Substance	Proposal
Oxalic acid	Proposal to amend the Schedule 6 oxalic acid entry to exempt from scheduling household and domestic cleaning preparations containing 8% or less of oxalic acid or to list such products in Schedule 5.

Comment:
ASMI does not object to the above proposal in principle. However, ASMI suggests that the substance description of the oxalic acid Schedule 5 entry should remain the same (i.e. "oxalic acid except its derivatives and insoluble salts") so that it excludes the oxalate salt of some registered medicines, such as escalitopram oxalate (which is in Schedule 4).

Substance	Proposal
Ppg-1-peg-9 lauryl glycol ether	In response to issues raised in NICNAS new chemical report No. LTD/1616: Proposal to include Ppg-1-peg-9 lauryl glycol ether in Schedule 5 and Appendix F with appropriate cut-off to exempt for preparations with low concentrations

Comment:
Ppg-1-peg-9 lauryl glycol ether is an ingredient which is entered in TGA eBS website, with the synonym Eumulgin LG. The compound is also found in the International Cosmetic Ingredient Dictionary; its stated uses are as an emulsifying agent / surfactant. The TGA e-BS website information states that the concentration of this ingredient is not to exceed 5% in the final finished product and is not to be included in topical products intended for use on the eye.

ASMI suggests that the ACCS also consider the uses of this substance in medicines and any scheduling amendments should be drafted so that there is no impact on its use in therapeutic goods.

Substance	Proposal
Tillenal	In response to issues raised in NICNAS new chemical report No. LTD/1617: To include tillenal in Schedule 6 and Appendix F, with appropriate cut-off to exempt for preparations with low concentrations

Comment:
ASMI understands that tillenal is used as a fragrance in cosmetic and household products.

The substance does not appear to be on the ingredient list of the ARTG, however ASMI would like the opportunity to comment if further information suggests that therapeutic goods will be impacted by the proposal.

Conclusion

ASMI supports co-ordination between the various agencies to minimise the impact of scheduling changes proposed for cosmetics, personal care products, commercial and industrial products on products such as therapeutic goods, foods and veterinary products.

ASMI requests the ACCS to carefully consider the possible impact of the scheduling proposals on therapeutic goods, and care should be taken to ensure that any amendments are clearly and carefully drafted to exclude any impact on these products.

The ACCS should also allow sponsors adequate time to make changes to formulations and/or labelling if needed; adequate transition times are important to industry, as is the need to allow existing stock in market to be sold through.

As an industry representative, ASMI is a key stakeholder in scheduling matters and we are keen to provide further input as required. We look forward to the Delegate's interim decisions and greater detail on the final scheduling proposals.

Please contact me should you require any further clarification relating to this submission.

Yours sincerely,

[redacted]

Australian Food and Grocery Council

SUBMISSION

20 FEBRUARY 2014

TO:
THERAPEUTIC GOODS ADMINISTRATION

IN RESPONSE TO:
INVITATION FOR PUBLIC SUBMISSIONS UNDER REGULATION 42ZCZK OF THE THERAPEUTIC GOODS REGULATIONS 1990

Australian Food and Grocery Council

Australian Food and Grocery Council

1. OVERVIEW

The Australian Food and Grocery Council (AFGC) welcome the opportunity to provide comment to the Therapeutic Goods Administration (TGA) in response to the invitation for public submissions under Regulation 42ZCZK of the Therapeutic Goods Regulations.

The AFGC has developed this response in consultation with its membership of manufacturers and brand owners, specifically those member companies who are impacted by, or have an interest in, the changes proposed under this regulation.

The AFGC supports and co-ordination between the different agencies involved to ensure the impact of scheduling changes proposed for cosmetics, personal care products, commercial and industrial products is minimised for products such as foods, veterinary products and therapeutics.

The AFGC has had the opportunity to review the submission from ASMI and we support the general comments made in relation to the ACCS agenda and in particular, the concern that the possible impact on ingredients entered in the ARTG for use in therapeutic goods may not have been fully considered.

2. SPECIFIC COMMENTS

[2.1] 1-butanol and 1-propoanol

AFGC is not aware of any issues using 1-butanol and 1-propanol in aerosol products intended for cosmetic or therapeutic use and propose that these types of product be exempted from the proposed Schedule 5 and 6 scheduling.

1-butanol

Proposal: to create new Schedule 5 and/or 6 entries with appropriate concentration cut-offs and associates warning statements.

This ingredient is currently used in therapeutic (as part of the propellant in aerosol dose products) and cosmetic products. AFGC agrees that this ingredient should be considered by both the ACCS and ACMS. Based on the CIR Ingredient Status Report and publically available data, 1-butanol has been classified as safe for use in various cosmetic products as currently used (1).

1-propanol

Proposal: to create new Schedule 5 and/or 6 entries with appropriate concentration cut-offs and associates warning statements.

This ingredient is currently used in therapeutic and cosmetic products. In a member's therapeutic product (tablet), it is found in trace amounts and is used as a solvent in the printing ink. AFGC believes that this ingredient should be considered by both the ACCS and ACMS. Based on the CIR Ingredient Status Report and publically available data, 1-propanol (synonym propyl alcohol) has been considered safe for use in various cosmetic products as currently used (2).

[2.2] Diethylene glycol monoethyl ether

Proposal: to develop a separate listing of diethyl (sic) glycol monoethyl ether in Schedule 6 to complement the current generic entry listing of ethylene glycol monoalkyl ethers and to consider restrictions on use in cosmetic preparations.

This ingredient is currently used in cosmetic products. If a separate listing of diethylene glycol monoethyl ether in Schedule 6 is required to complement the current generic entry listing of ethylene glycol monoalkyl ethers, the conditions of ethylene glycol monoalkyl ethers should apply.

AFGC propose the following:

Schedule 6
DIETHYLENE GLYCOL MONOETHYL ETHER except:
(a) when separately specified in these Schedules; or
(b) in preparations containing 10 per cent or less of such substances.

Should it be considered necessary to restrict the use in cosmetic products international considerations should be taken into account; such as The European Commission's 'Scientific Committee on Consumer Safety' (SCCS) review which concluded that "the use of Diethylene glycol monoethyl ether at a maximum concentration of 2.6% in cosmetic products taking into account the other uses previously assessed (10% in rinse-off products, 7.0% in oxidative and 5% in non-oxidative hair dye formulation) does not pose a risk to the health of the consumer" (3).

It is noted however that there are currently no restrictions for the use of the ingredient in cosmetics in Europe. If a restriction for cosmetic preparations is to be proposed by the ACCS, the cut off should be at a concentration of at least 2.6%.

[2.3] Methylated spirits

Proposal: to include a new entry for methylated spirits in Appendix F to require a label warning statement such as : 'WARNING: do NOT attempt to refill methylated spirit burner while it is in use or still warm; it could lead to serious burn injury or death'.

AFGC question why the current flammability warning is *not* considered effective, and if it is not, why a new warning *would* be considered to be effective. Labelling proposals need to be demonstrated to be effective before they are imposed.

[2.4]. Oxalic acid

Proposal: to amend the Schedule 6 oxalic acid entry to exempt from scheduling household and domestic cleaning preparations containing 8% or less of oxalic acid or to list such products in Schedule 5.

AFGC request that consideration of this proposal be broadened to also exclude therapeutic mouthwash containing not more than 3% potassium oxalate.

Oxalic acid is an organic acid that occurs naturally in regularly consumed plants (eg spinach, rhubarb, coffee, chocolate, tea) and is also produced endogenously in the normal human body as an end product of the metabolism of glycine, glycolate and ascorbic acid (4).

Oral LD50 values of 300 and 7500 mg/kg have been reported in gravid rats and rats respectively (5).

Potassium oxalate is an effective option for the treatment of dental sensitivity that is captured under the current scheduling for Oxalic acid as it is a soluble oxalic acid salt. Mouthwash containing potassium oxalate is currently marketed in the UK for this purpose and its use is also permitted in the United States.

In the aqueous environment of saliva, potassium oxalate dissociates into potassium cations and oxalate anions. The oxalate then combines with calcium ions in the oral environment to form water insoluble calcium oxalate crystals which block the dentinal tubules. Calcium oxalate being an insoluble oxalic acid salt is currently exempt from scheduling.

The intended use of mouthwash is to rinse the oral cavity with a measured quantity (10-20 mL) and expel. Approximately 10% of each dose of mouthwash is retained in the oral cavity (6). This combined with the formation of calcium oxalate crystals in the mouth will result in a very low exposure to oxalic acid as the result of using a potassium oxalate mouthwash. Should the mouthwash be unintentionally swallowed absorption of oxalate will also be low as studies from the literature show that absorption of oxalate from the diet ranges 2-14% (7, 8).

A 10 mL dose of mouthwash containing potassium oxalate 3% would contain approximately 30 mg potassium oxalate/15mg oxalic acid (assuming 10% retention), whereas the average western diet is estimated to contain 70mg to greater than 200mg oxalic acid/day (9, 10). Given the relatively poor absorption of oxalate from the gastrointestinal tract this would suggest that accidental ingestion of a dose of such a mouthwash would not be clinically significant in healthy individuals.

AFGC therefore request the scheduling proposal be broadened to:

Schedule 6: OXALIC ACID except

(a) its derivatives and insoluble salts;

(b) household and domestic cleaning preparations containing 8% or less of oxalic acid; and

(c) mouthwash containing not more than 3% potassium oxalate.

3. SUMMARY

The AFGC –

- agrees that 1-butanol and 1-propoanol should be considered by both the ACCS and ACMS.
- requests that if a separate listing of diethylene glycol monoethyl ether in Schedule 6 is required to complement the current generic entry listing of ethylene glycol monoalkyl ethers, the conditions of ethylene glycol monoalkyl ethers should apply.
- question why the current flammability warning is *not* considered effective, and if it is not, why a new warning *would* be considered to be effective.
- requests that consideration of the proposal for oxalic acid be broadened to also exclude therapeutic mouthwash containing not more than 3% potassium oxalate.

[redacted]

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(1) Final Report of the Addendum to the Safety Assessment of n-Butyl Alcohol as Used in Cosmetics. Int J Tox. 2008 27(Suppl 2):53-69

(2) Heldreth B et al. Final Report of the Cosmetic Ingredient Review Panel on the Safety Assessment of Methyl Acetate. 2012 Int J Toxicol. 31 (Suppl 1) 11225-1365

(3) Scientific Committee on Consumer Safety .Opinion on Diethylene Glycol Monoethyl Ether (Degee) Scientific Committee on Consumer Safety 2013 SCCS/1507/13

(4) Noonan SC, Savage GP. Oxalate content of foods and its effect on humans Asia Pacific J Clin Nutr. 1999; 8(1): 64-74

(5) United States EPA Reassessment of One Exemption from the Requirements of a Tolerance for Oxalic acid. 2005 September

(6) Scientific Committee on Consumer Safety (SCCS). The SCCS's notes of guidance for the testing of cosmetic ingredients and their safety evaluation, 7th revision SCCS/1416/11

(7) Hodgkinson A, zarembski PM. Oxalic acid metabolism in man: a review. Calcif Tissue Res. 1968 Oct 21;2(2): 115-32

(8) Holmes RP, Assimos DG. The impact of dietary oxalate on kidney stone formation. Urol Res. 2004 Oct;32(5):311-6

(9) Zarembski PM, Hodgkinson A. The oxalic content of English diets. Br J Nutr. 1962;16:627-34

(10) Holmes RP, Kennedy M. Estimation of the oxalate content of foods and daily oxalate intake. Kidney Int. 2000 Apr; 57(4):1662-7

Johnson & Johnson Pacific

The Secretary
Scheduling Secretariat
GPO Box 9848
CANBERRA ACT
2601

20 February 2014

Dear Sir/Madam,

RE: Comments on Proposed amendments referred by the Delegate for scheduling advice for consideration by the Advisory Committee on Chemicals Scheduling (ACCS)

Johnson & Johnson Pacific Pty Ltd (JJP) would like to provide comments on a number of the proposed amendments referred by the Delegate to the Committee of Chemicals Scheduling (ACCS).

1-Butanol

Proposal to create new Schedules 5 and/or 6 entries with appropriate concentration cut-offs and associated warning statements.

1-Butanol is used in very low concentrations in a number of JJP products which include therapeutic and cosmetic products and we are not aware of any issues relating to the ingredient.

As 1-Butanol is an ingredient which can found in therapeutic goods, the scheduling proposal should be considered by the ACCS and the Advisory Committee on Medicines Scheduling (ACMS) to ensure the cut-off limit, route of administration, function of the ingredient and possible impact on the therapeutic goods have been considered.

Publically available data has shown that 1-Butanol is recognized as safe for use in cosmetic products. Additionally it is noted that no other market restricts the use of 1-Butanol in cosmetic products. The Cosmetic Ingredient Review (CIR) Expert Panel had reviewed the safety of 1-Butanol in 1987. At that point in time, the only reported uses of the ingredient as a cosmetic were in nail care products. Since the original safety assessment, new safety data have become available for products which included eye make-up, personal hygiene and shaving products. In 2008, the CIR Expert Panel assessed the safety profile of the ingredient in the different products. The concentration of 1-Butanol ranged from a low of 0.000007% in bath soaps and detergents to a high of 15% in nail care products. The CIR Expert Panel concluded that the ingredient was considered safe in all the cosmetic categories it was used in.

If a Schedule 5 and/or Schedule 6 entry is adopted, we strongly urge the Committee and the Delegate to exempt cosmetic and therapeutic products containing 1-Butanol from the scheduling. If a concentration cut-off is applied, the cut-off should be set at a concentration where current cosmetic and therapeutic products in the market will not be impacted

1-Propanol

Proposal to create new Schedules 5 and/or 6 entries with appropriate concentration cut-offs and associated warning statements.

1-Propanol is used in low concentrations in a number of JJP products which include therapeutic and cosmetic products and we are not aware of any issues relating to the ingredient. In our therapeutic products, the ingredient is found in trace amounts as a solvent.

As 1-Propanol is an ingredient which can found in therapeutic goods, the scheduling proposal should be considered by the ACCS and the ACMS to ensure the cut-off limit, route of administration, function of the ingredient and possible impact on the therapeutic goods have been considered.

The safety profile of 1-Propanol when used in cosmetics had been reviewed by the CIR Expert Panel in 2012. Various product categories were assessed and the concentrations of the ingredient ranged from 0.002% to 100%. The CIR Expert Panel concluded that 1-Propanol were safe in the all the cosmetic product categories that were assessed. Additionally, it is noted no other market restricts the use of 1-Propanol in cosmetic products.

If a Schedule 5 and/or Schedule 6 entry is adopted, we strongly urge the Committee and the Delegate to exempt cosmetic and therapeutic products containing 1-Propanol from the scheduling. If a concentration cut-off is applied, the cut-off should be set at a concentration where current cosmetic and therapeutic products in the market will not be impacted

Diethylene glygol monoethyl ether

Proposal to develop a separate listing of diethyl glycol monoethyl ether in Schedule 6 to complement the current generic listing of ethylene glycol monoalkyl ethers and to consider restrictions on use in cosmetic preparations.

This ingredient is currently used in our cosmetic products at low concentrations. If a separate listing of diethylene glycol monoethyl ether in Schedule 6 is required to complement the current generic entry listing of ethylene glycol monoalkyl ethers, the conditions of ethylene glycol monoalkyl ethers should apply.

JJP proposes the following:

Schedule 6
DIETHYLENE GLYCOL MONOETHYL ETHER except:
(a) when separately specified in these Schedules; or
(b) in preparations containing 10 per cent or less of such substances; or

It is noted that there are currently no restrictions in other markets for the use of the ingredient in cosmetics. If a restriction for cosmetic preparations is to be proposed by the ACCS, the cut off the cut-off should be set at a concentration where current cosmetic in the market will not be impacted. Additionally, the opinions of the European Commission's 'Scientific Committee on Consumer Safety' (SCCS) should be considered.

In 2013, the SCCS performed a review of the ingredient and they are of the opinion that *the use of Diethylene glycol monoethyl ether at a maximum concentration of 2.6% in cosmetic products taking into account the other uses previously assessed (10% in rinse-off products, 7.0% in oxidative and 5% in non-oxidative hair dye formulation) does not pose a risk to the health of the consumer.*

JJP proposes a cut-off concentration of at least 2.6% for cosmetic preparations.

Oxalic Acid

We provide the following comment in regard to the proposed scheduling change for oxalic acid **From**:

Schedule 6: OXALIC ACID except its derivatives and insoluble salts

To:

Schedule 6: OXALIC ACID except:
a) its derivatives and insoluble salts.
b) household and domestic cleaning preparations containing 8% or less of oxalic acid

We provide the following information for consideration of this proposal be broadened to include therapeutic mouthwash containing not more than 3% potassium oxalate.

Oxalic acid
Oxalic acid (CAS # 144-62-7; $C_2H_2O_4$) is an organic acid that is slightly soluble in water and occurs naturally in regularly consumed plants (eg spinach, rhubarb, coffee, chocolate, tea). It is also produced endogenously in the normal human body as an end product of the metabolism of glycine, glycolate and ascorbic acid [1].

Therapeutic purpose
Potassium oxalate is an effective option for the treatment of dental sensitivity that is captured under the current scheduling for Oxalic acid as it is a soluble oxalic acid salt. The primary population that experiences dental sensitivity is adults 20-40 years. Use in children is considered unlikely due to the taste profile of the ingredient in a mouthwash.

In the aqueous environment of saliva potassium oxalate dissociates into potassium cations and oxalate anions. The oxalate then combines with calcium ions in the oral environment to form water insoluble calcium oxalate crystals which block the dentinal tubules. Calcium oxalate being an insoluble oxalic acid salt is currently exempt from scheduling.

Mouthwash containing potassium oxalate is currently marketed in the UK for dental sensitivity and it is a permitted active ingredient in the United States.

Pharmacology
Absorption of oxalic acid can occur all along the intestinal tract but is predominately absorbed in the upper intestine [8]. Only a small proportion of the oxalate from the diet is absorbed (range: 2-14%) [3, 4]. There is no evidence that oxalate is used/metabolised by the human tissues [3, 9] and the primary route of excretion is via the kidneys. Normal excretion is approximately 40 mg/day in adults [3].

Toxicology
The acute LD50 is reported as 300 mg/kg in gravid rats and 7500 mg/kg in rats [7]. A single subchronic toxicity study in rats fed diets with 2.5% or 5% oxalic acid (equivalent to 1250-1500 and 2500-3000 mg/kg/day) showed decreased body weights and restricted growth in both sexes, and disrupted oestrous cycles in females. The lowest observed adverse effect level (LOAEL) was 1250 mg/kg/day[7].

Safety
Toxicological studies of oxalate in animals have reported the formation of renal cysts, hypothyroidism, weight loss and reproductive effects however findings in animals are not always translatable to man.
In the case of humans none of these effects have been noted in the general clinical literature on chronic oxalate toxicity however extra renal effects secondary to chronic oxalate exposure have been reported in the rare condition of primary hyperoxaluria [10]. In these cases the oxalosis relates to very high systemic oxalate, as opposed to intake of exogenous oxalate.

The contribution of oxalate from retained from a dose of mouthwash containing up to 3% potassium oxalate is approximately 13.7 mg oxalic acid which is substantially less than the amount of oxalate included in the normal average diet (the average western diet is estimated to contain 70mg to greater than 200mg oxalic acid/day [5, 6]).

Chronic oxalate ingestion from long term use of a potassium oxalate mouthwash used as per the label directions is expected not to present a significant clinical risk in the normal healthy population.

A possible safety concern arising with the use of potassium oxalate in a mouthwash is in adults predisposed to kidney stone formations and/with existing kidney disease. Calcium oxalate is the most common chemical compound in kidney stones however kidney stone formation is a multifactorial process of which one of the factors is calcium/oxalic acid ratio in the diet.

It would be prudent to recommend to these consumers that they do not use potassium oxalate containing products.

Dosage
The intended use of mouthwash is to rinse the oral cavity with a measured quantity (10-20 mL) and expel. Approximately 10% of each dose of mouthwash is retained in the oral cavity [2]. This combined with the formation of calcium oxalate crystals in the mouth will result in a very low exposure to oxalic acid as the result of using a potassium oxalate mouthwash. Should the mouthwash be unintentionally swallowed absorption of oxalate will also be low as studies from the literature show that absorption of oxalate from the diet ranges 2-14% [3, 4].

Accidental misuse
A 10 mL dose of mouthwash containing potassium oxalate 3% would contain approximately 30 mg potassium oxalate/15mg oxalic acid (assuming 10% retention), whereas the average western diet is estimated to contain 70mg to greater than 200mg oxalic acid/day [5, 6]. Given the relatively poor absorption of oxalate from the gastrointestinal tract this would suggest that accidental ingestion of a dose of such a mouthwash would not be clinically significant in healthy individuals.

Abuse potential
The potential for abuse of mouthwash containing this ingredient is low as the chemical is not addictive and the labelling and advertising will be aimed at persons with tooth sensitivity.

We therefore request the scheduling proposal be broadened to:

Schedule 6: OXALIC ACID except

a) its derivatives and insoluble salts.
b) household and domestic cleaning preparations containing 8% or less of oxalic acid
c) mouthwash containing not more than 3% potassium oxalate

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Conclusion

In summary, JJP proposes that the scheduling of 1-Butanol and 1-Propanol to be considered by both the ACCS and ACMS to ensure the potential impact to therapeutic products have been taken into consideration. Cosmetic and therapeutic products containing 1-Propanol should be exempt from the scheduling.

If a Schedule 6 entry is created for Diethylene Glycol Monoethyl Ether the conditions of ethylene glycol monoalkyl ethers should apply. If a restriction to the concentration is applied to use of the ingredient in cosmetic preparations, the cut off should be at a concentration of at least 2.6%.

As the committee is considering the current scheduling of oxalic acid we request specific attention to the oxalic acid salt potassium oxalate and propose that it be exempted form scheduling for concentrations in mouthwash up to 3% intended for use in the symptomatic relief treatment of sensitive teeth.

Additionally, should the Committee and Delegate decide to proceed with the proposals, current cosmetic and therapeutic products in the market should not be impacted. Appropriate transition times should be given to allow sponsors and manufacturers to implement the changes for new products.

Yours faithfully,

References:

[1] Noonan SC, Savage GP. Oxalate content of foods and its effect on humans Asia Pacific J Clin Nutr. 1999; 8(1): 64-74

[2] Scientific Committee on Consumer Safety (SCCS). The SCCS's notes of guidance for the testing of cosmetic ingredients and their safety evaluation, 7th revision SCCS/1416/11

[3] Hodgkinson A, Zarembski PM. Oxalic acid metabolism in man: a review. Calcif Tissue Res. 1968 Oct 21;2(2): 115-32

[4] Holmes RP, Assimos DG. The impact of dietary oxalate on kidney stone formation. Urol Res. 2004 Oct;32(5):311-6

[5] Zarembski PM, Hodgkinson A. The oxalic content of English diets. Br J Nutr. 1962;16:627-34

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[10] Coulter-Mackie MB et al. Primary hypoxoxaluria Type I. IN:GeneReviews [Internet] 1993. Seattle (WA): university of Washington, Seattle