FURTHER PUBLIC SUBMISSIONS ON THE PROPOSED AMENDMENTS TO THE POISONS STANDARD

Regulation 42ZCZL, 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 interim decisions regarding 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 chemicals scheduling and medicines scheduling delegates.

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 for Medicines and Chemicals (SPF), issued by the National Coordinating Committee on Therapeutic Goods. The SPF is accessible atwww.tga.gov.au/industry/scheduling-spf.htm.

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

LIST OF SUBMISSIONS

Substance	Total number of public submissions
1-Butanol	One submission under 'submissions on multiple substances'
1-Propanol	One submission under 'submissions on multiple substances'
2,4-Diaminophenoxy ethanol sulfate	One submission under 'submissions on multiple substances'
Hexanoic acid, 2-ethyl-, 2-ethylhexyl ester	One submission under 'submissions on multiple substances'
Methylated spirits	Two submissions (one under 'submissions on multiple substances')
Oxalic acid	One submission under 'submissions on multiple substances'
Lauryl sulfate	Two submissions under 'submissions on multiple substances'

SUBMISSION ON MULTIPLE SUBSTANCES

One submission was on 1-butanol, 1-propanol, 2,4-diaminophenoxy ethanol sulfate, hexanoic acid, 2-ethyl-, 2-ethylhexyl ester, methylated spirits and lauryl sulfate; and

One submission was on oxalic acid and sodium and lauryl sulfate.

The Secretary
Scheduling Secretariat
GPO Box 9848
CANBERRA ACT 2601

Email: SMP@health.gov.au

Dear Sir/Madam

Public Comment Submission to the Delegate's Interim Decision under subsection 42ZCZP of the Therapeutic Goods Regulations 1990

We refer to the notice published on 30 June 2014 of the Delegate's interim decision under subsection 42ZCZP of the *Therapeutic Goods Regulations 1990*, inviting public submissions, with respect to certain substances, addressing a matter raised in section 52E of the *Therapeutic Goods Act 1989*.

Accord provided comments on the following ACCS agenda items for the March 2014 meeting:

- 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.

Accord also provided comments for consideration of sodium, ammonium and potassium lauryl sulfate at the joint meeting of the ACMS and ACCS held in March 2014.

Accord has reviewed the Interim Decisions & Reasons for Decisions by the Delegate of the Secretary to the Department of Health and Ageing and provides further comments on the Interim Decisions on the agenda items where we believe additional information may be useful for further consideration. These are:

- **1.3 – methylated spirits;**
- **1.5 – 1-butanol;**
- **1.6 – 1-propanol;**
- **1.10 – 2-ethylhexyl 2-ethylhexanoate;**
- **1.12 – 2,4-diaminophenoxyethanol sulfate; and**
- **2.1 – lauryl sulfates.**

Please see attached submission for details.

We look forward to further advice from the Delegate. Should the Delegate require any additional information from Accord at this stage please do not hesitate to contact me on (02) 9281 2322.

[redacted]

[redacted]

[redacted]

11 July 2014

ACCS meeting: March 2014

(1.3) Methylated spirits

Accord supports the Delegate's Interim Decision to maintain the current scheduling entry for methylated spirits and notes the discussion on the misalignment between the *Excise Act 1901* (Cth) and the Poisons Standard.

We have attempted to provide some information on denaturants and a potential solution for consideration by the ACCS at a future meeting.

It is our understanding that the *Excise (Denatured spirits) Determination 2006 (No. 2)* (**Determination**) was issued in 2006 which resulted in uncoupling of methyl isobutyl ketone (MIBK), denatonium benzoate and fluoroscein as denaturing agents. From taxation perspective this makes sense – both the MIBK and denatonium benzoate will "denature" ethanol. We understand that MIBK will cause central nervous system effects like nausea/vomiting at fairly low doses while denatonium benzoate is an embittering agent.

We understand that fluorescein was initially added for "spot test" when chemical analysis was not readily available – presumably, alcohol containing fluorescein was assumed to also contain other denaturing compounds. Given that spot chemical analysis is now easily achieved, we do not believe that fluorescein is a necessary denaturant.

It is worth noting that there are 20 ethanol denaturants allowed by the Determination. The list of denaturants including the minimum concentrations required is in the Schedule of the Determination[1]. Once again, these denaturants make sense from taxation perspective as they all make ethanol unfit for consumption.

From a public health perspective, it is perhaps not wise to allow ready access to ethanol denatured purely with chemicals that are toxic but do not have unpleasant odour or flavour e.g. methanol, isopropanol and MIBK. MIBK may be of particular concern for childhood poisoning as it is reported to have a pleasant odour and a sweet taste[2].

However, we must continue to allow products that are formulated with ethanol denatured with any of the 20 denaturants listed in the Determination. For example, ethanol used in many perfumes is denatured with methanol. We do not believe there have been any concerns raised with these types of products in the household – we understand the concern is with "methylated spirits", denatured ethanol, entering the household in its neat form.

To resolve the issue, we believe that the current methylated spirits entry in Schedule 5 can be amended so that denatonium benzoate is the only denaturant specified. Further, a new methylated spirits entry can be added in schedule 7, for ethanol denatured with substances other than denatonium benzoate, where it is not in preparations or admixtures, and in quantities less than 5L.

The proposed amendments to the Poisons Standard are as follows:

Schedule 5 (Amended):

METHYLATED SPIRIT(S) (being ethanol denatured with denatonium benzoate) except:

[1] http://law.ato.gov.au/atolaw/view.htm?Docid=ELD/ED200618/00001&PiT=99991231235958.
[2] http://www.epa.gov/iris/toxreviews/0173tr.pdf.

(a) When included in preparations or admixtures; or
(b) When packed in containers having a capacity of more than 5 litres.

Schedule 7 (New):

METHYLATED SPIRIT(S) (being ethanol denatured with a denaturing agent other than denatonium benzoate) except:

(a) When included in preparations or admixtures; or
(b) When packed in containers having a capacity of more than 5 litres.

ACCS meeting: March 2014

(1.5) 1-butanol

While Accord understands the potential logic of the Delegate for extending the ACCS recommendation for scheduling recommendation for 1-butanol to therapeutic goods and cosmetics, we do not agree with the ACCS advice that scheduling is required for 1-butanol and respectfully request that the ACCS reconsider its advice.

Accord notes that the health effects detailed in the NICNAS IMAP report for 1-butanol, skin and eye irritation and central nervous system effects from inhalation are common to most solvents. We note that one of the questions the Delegate asked that the ACCS consider specifically pointed to the fact that all short chain alkanols are expected to have skin and eye irritancy, including ethanol, included in Appendix B.

As the ACCS consideration for the reasons for their advice was not detailed, we are unsure why the recommendation for proposed scheduling was put forward given this consideration. As far as we are aware, there has been no identification of the difference in the risk profile of ethanol and 1-butanol.

When the ACCS considered tetrahydrofuran, a solvent, in the November 2013 meeting, Accord noted that the toxicity detailed in the NICNAS IMAP report was attributable to all solvents. The ACCS advised the Delegate that no scheduling was required, and the Delegate accepted the advice.

For consistency of scheduling consideration, we request that the Delegate defer the final decision and seek reconsideration from the ACCS.

ACCS meeting: March 2014

(1.6) 1-propanol

While Accord understands the potential logic of the Delegate for extending the ACCS recommendation for scheduling recommendation for 1-propanol to therapeutic goods and cosmetics, we do not agree with the ACCS advice that scheduling is required for 1-propanol and respectfully request that the ACCS reconsider its advice.

In the Delegate's Interim decision, it is noted that there appear to be no therapeutic goods or cosmetics where the concentration of 1-propanol would be likely to exceed 5 per cent cut-off. We are unsure of the basis for this conclusion – we note that a submission to the March 2014 ACCS meeting has flagged the use of 1-propanol at up to 18% in therapeutic goods.

Further, the NICNAS IMAP report itself reported up to 60% use of 1-propanol in arts, crafts and hobby materials. NICNAS has not demonstrated nor suggested that the current control (i.e. no specific regulatory control for 1-propanol in these products) of these products containing 1-propanol have failed either here in Australia or overseas.

1-propanol is used in cosmetics and therapeutic goods internationally at >60%. According to the World Health Organization Guidelines on Hand Hygiene in Health Care[3], 1-propanol can be used in alcohol-based handrubs in concentrations between 60% and 70%. We do not believe that the "POISON" signal heading would be appropriate for products like alcohol-based handrubs.

Alcohol-based handrubs contain as an active agent, ethanol, isopropanol and/or 1-propanol. While we note that 1-propanol is not necessarily a popular choice, this is a current financial consideration (1-propanol is more expensive than isopropanol or ethanol) rather than toxicity or other health concerns.

1-propanol is also used as solvent, fragrance and flavour ingredient, antifoaming agent, and viscosity decreasing agent in cosmetics.

Accord notes that the health effects detailed in the NICNAS IMAP report for 1-propanol, skin and eye irritation and central nervous system effects from inhalation, are common to most solvents. We note that one of the questions the Delegate asked that the ACCS consider specifically pointed to the fact that all short chain alkanols are expected to have skin and eye irritancy, including ethanol, included in Appendix B.

As the ACCS consideration for the reasons for their advice was not detailed, we are unsure why the recommendation for proposed scheduling was put forward given this consideration. As far as we are aware, there has been no identification of the difference in the risk profile of ethanol and 1-propanol.

When the ACCS considered tetrahydrofuran, a solvent, in the November 2013 meeting, Accord noted that the toxicity detailed in the NICNAS IMAP report was attributable to all solvents. The ACCS advised the Delegate that no scheduling was required, and the Delegate accepted the advice.

For consistency of scheduling consideration, we request that the Delegate defer the final decision and seek reconsideration from the ACCS.

[3] http://whqlibdoc.who.int/publications/2009/9789241597906_eng.pdf.

ACCS meeting: March 2014

(1.10) 2-ethylhexyl 2-ethylhexanoate

Having reviewed the discussion on 2-ethylhexyl 2-ethylhexanoate and the Interim Decision for the Poisons Standard entry, we understand that salts and derivatives of 2-ethylhexyl 2-ethylhexanoate are also captured by scheduling.

Noting that the concerns over the use of 2-ethylhexyl 2-ethylhexanoate relate to the metabolites 2-ethylhexanol and 2-ethylhexanoic acid, we are unsure whether capturing the salts and derivatives of 2-ethylhexyl 2-ethylhexanoate adequately mitigates these concerns.

All esters are reaction products of alcohol and acid. In the case of 2-ethylhexyl 2-ethylhexanoate, the alcohol is 2-ethylhexanol and the acid is 2-ethylhexanoic acid. Esterification is also a reversible reaction, which explains the metabolites of the ester being the two starting materials.

In order to capture chemicals with potential to generate 2-ethylhexanol and 2-ethylhexanoic acid, two separate schedule entries, one for alkyl 2-ethylhexanoates and the other for 2-ethylhexyl alkanoates may be prudent. Both entries should be excluding derivatives.

Given this consideration, we respectfully request that the Delegate defer the final decision and re-consult on a proposal for the two separate schedule entries.

In our initial submission, Accord noted that the Cosmetics Ingredient Review (CIR) reviewed the use of alkyl ethylhexanoates and concluded that current uses of these ingredients in cosmetics are safe when formulated to be non-irritating. We note that while the CIR recommendation mentions irritation, this was not their primary concern. The CIR also considered the metabolites of alkyl ethylhexanoates, and believed that the levels of metabolites produced in normal use of cosmetics did not raise concerns.

If the two proposed scheduled entries were to be consulted, with the proposed 10% cut-off from scheduling, Accord can consult with our Members and also our international colleagues to ensure that this limitation is in line with what is considered current normal use in cosmetics.

ACCS meeting: March 2014

(1.12) 2,4-diaminophenoxyethanol sulfate

In our initial submission, Accord provided comments that while 2,4-diaminophenoxyethanol sulfate is not specifically scheduled, it is captured by scheduling of phenylenediamines. Our Members have confirmed that the phenylenediamine schedule entry is currently being used for 2,4-diaminophenoxyethanol sulfate.

We note that the current phenylenediamine schedule entry specifically allows the use of the substance in eyelash and eyebrow tinting products – the Appendix F statement is only applied to hair dye preparations, not eyelash and eyebrow tinting products. For eyelash and eyebrow tinting products, a separate warning statement is detailed in the schedule 6 entry for phenylenediamines.

As there appear to have been no discussions at the ACCS meeting, nor in the Delegate's Interim Decision reasons on whether 2,4-diaminophenoxyethanol sulfate poses a higher risk than other phenylenediamines, we have assumed that the intent was to duplicate the phenylenediamine conditions, rather than to ban the use of the substance in eyelash and eyebrow tinting products.

Accord respectfully requests that the wording of the new schedule 6 entry be revised to better mirror the existing phenylenediamine schedule entry.

ACCS/ACMS joint-meeting: November 2013

(2.1) Lauryl sulfates

Accord notes the reasons, the Interim Decision of the Delegate and the amendments to the Schedule entry, and requests clarification on the intent of the amendment to the sodium lauryl sulfate schedule entry.

While the discussion for the amendments to the schedule entry and the wording of the Interim Decision focused on the salts of lauryl sulfate, we note that the words "excluding… derivatives" were also removed from the schedule entry. This results in a significant widening of the schedule entry, which from reading of the reasons, does not appear to have been intended.

Sodium lauryl sulfate is an anionic surfactant. The chemical make-up of sodium lauryl sulfate can be viewed as three basic sections:

1. The sulfate anionic "head",
2. 12-carbon (lauryl) aliphatic chain, and
3. Sodium counter-ion.

This basic structure is common to many anionic surfactants, with variations to:

1. the anionic "head" (e.g. glycinate, phosphate, carboxylate, etc.),
2. the length of the carbon chain, generally from C6–C22 (often a mix, going by the name of the source e.g. cocoyl, palmoyl, tallow, etc. but can also be mostly single length and go by the common name for the chain length e.g. stearyl (C18), cetyl (C16), lauryl (C12), etc.) and varying levels of ethoxylation and/or propoxylation of the carbon chain, and
3. the cationic counterion (e.g. sodium, potassium, ammonium, etc.).

Sodium lauryl sulfate is well known to be a harsh surfactant – it is for this reason that it is used in surfactant irritancy test as a comparison standard. We understand that variation to any of the three sections of sodium lauryl sulfate generally lessens the irritancy of the surfactant.

The consideration of hazard classification by the European Committee of Organic Surfactants and their Intermediates (CESIO) for different types of surfactants in *Classification and Labelling of Surfactants for human health hazards according to the Dangerous Substances Directive* (Document)[4] demonstrates this point. Table 4 of the Document is a good comparison of different types of anionic surfactant ("chemical ingredient" 2 is lauryl sulfate (different salts), and "chemical ingredient" 3 are "laureth" sulfates (mostly different levels of ethoxylation)).

Given that the derivatives of lauryl sulfates are generally less irritating that sodium lauryl sulfate, we do not believe that derivatives of lauryl sulfates should be included in the current sodium lauryl sulfate entry. We respectfully request that the words "excluding derivatives" be re-inserted into the schedule entry.

Noting that there are no regulatory restrictions placed on any of these surfactants anywhere else in the world, including sodium lauryl sulfate, a well-known and widely used surfactant based on human health concerns, and noting that mild to moderate skin and eye irritancy of surfactants is well known by the general public, it is our preferred position that these surfactants, including sodium lauryl sulfate be unscheduled. This would remove the current need for some imported rinse-off cosmetic products to be over-labelled with the Appendix E statement, E1.

[4] http://www.cefic.org/Documents/Other/Cesio-060501-Classification_labelling-human_health.pdf.

Johnson & Johnson Pacific

[redacted]

The Secretary
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11 July 2014

Dear sir/Madam

RE: Response to the Invitation to Comment on Reasons for Scheduling and Delegates Interim Decision from the ACCS-ACMS #9 meeting and from the ACCS #10 meeting

Johnson & Johnson Pacific Pty Ltd provides the following comments on item 2.1 from the ACCS-ACMS #9 meeting and item 1.2 from the ACCS #10 meeting under section 52E of the Therapeutic Goods Act 1989.

2.1 Lauryl sulfates

JJP supports the Delegates interim decision that the current listing of sodium lauryl sulfate (SLS) be amended to include all lauryl sulfate salts. By making the listing specific to lauryl sulfate salts, we understand that lauryl sulfate derivatives are still exempt from scheduling, which we support considering ingredients such as sodium laureth sulfate are commonly used as a safer alternative to SLS in cosmetic products. JJP reserves the right to provide further comment if the Delegates decision is changed in any way from the interim decision.

1.2 Oxalic acid

In our response 20 February 2014 to the committee's invitation to comment on the proposed amendment to the entry for oxalic acid referred by the Delegate for scheduling advice for consideration by the Advisory Committee on Chemicals Scheduling (ACCS) we provided an overview of the therapeutic purpose, pharmacology, toxicity/safety, dosage and misuse/abuse potential of potassium oxalate when incorporated in a mouthwash for tooth sensitivity.

We understand from the delegates post meeting comments that the Committee is willing to further consider the matter and that further information is needed regarding the supply of therapeutic products including potassium oxalate as an active ingredient for use in dentinal sensitivity without the currently required label signal heading "POISON" and with appropriate warning statements.

Based on the comments provided concerning the information needed and to enable the supply of therapeutic products including potassium oxalate as an active ingredient which has an established use in the literature and in Europe of providing effective relief to persons that suffer from dentinal sensitivity we provide the following further information.

Please note that the information provided previously was generally publically available. Some of the information provided in this submission is in respect of a specific formulation and as such these specific informations will be indicated as confidential as they are commercially sensitive.

Johnson & Johnson Pacific

[redacted]

1. **Therapeutic Purpose for which a potassium oxalate is used**

The major therapeutic use for potassium oxalate is the treatment of dentinal sensitivity. 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 and the insignificant clinical relevance.

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 to inhibit the movement of fluid which stimulates nerves causing the sensation of pain.

Calcium oxalate being an insoluble oxalic acid salt is currently exempt from scheduling whereas soluble oxalic acid salts are captured.

Mouthwash containing potassium oxalate is currently marketed in the UK and several other European countries as a Class IIa medical device for dental sensitivity (a product label example is shown below).

We are proposing that the committee further consider a specific exemption to the current oxalic acid schedule entry for mouthwash and if deemed necessary with an appropriate concentration cut-off as supported by the data provided to enable this product to be supplied in Australia.

[redacted]

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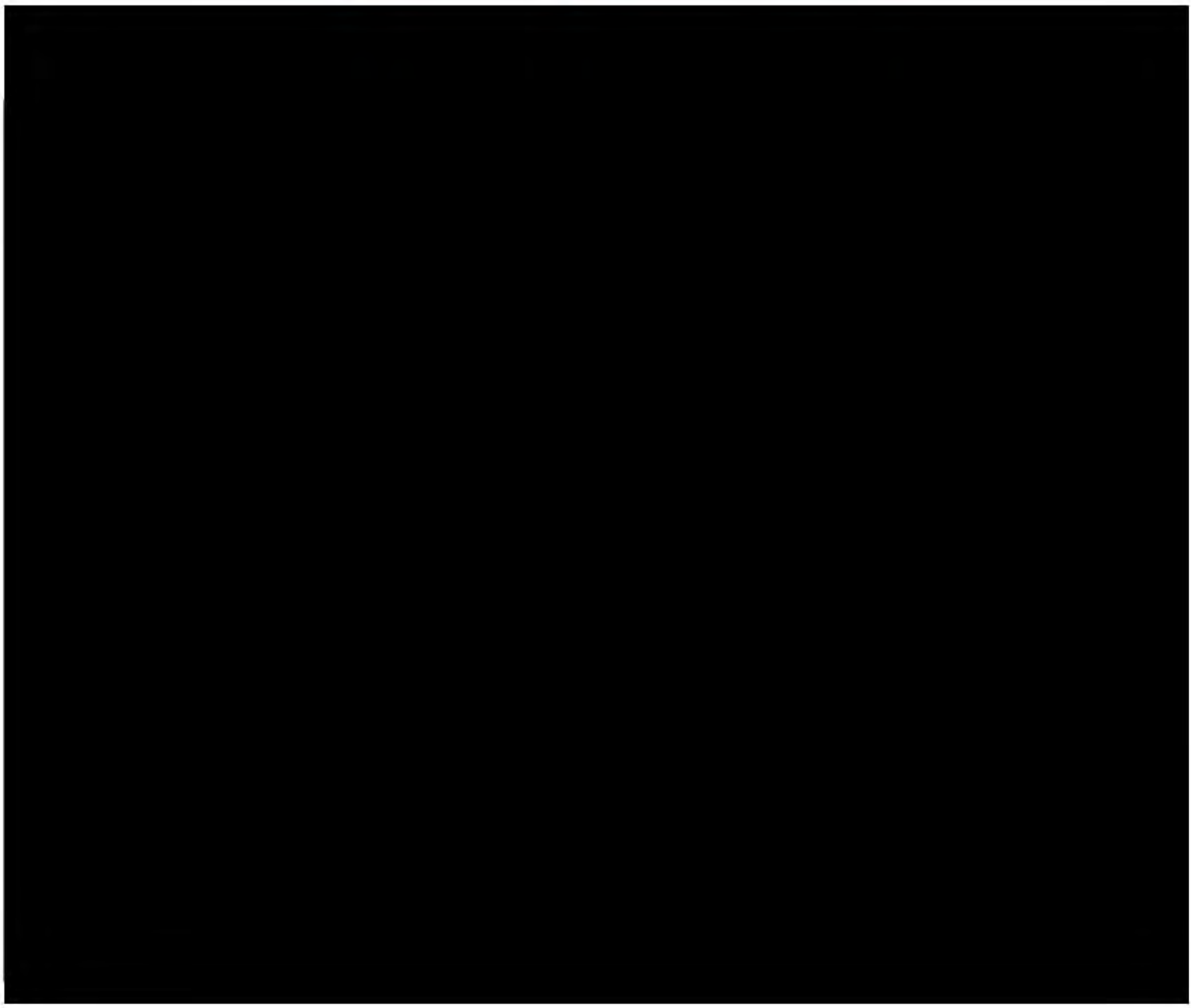
Johnson & Johnson Pacific



On the basis of a systematic safety review of the available data on oxalic acid (see Attachments 2, 3) we propose that labels for mouthwash containing potassium oxalate include the following warnings (or words to this effect) on the pack label are appropriate:

- KEEP OUT OF REACH OF CHILDREN
- Do not use this product if you are sensitive or allergic to oxalates
- Do not use this product if you have a history of kidney disease, hyperoxaluria, kidney stones or have a condition that affects your absorption of foods/nutrients, or take high doses of vitamin C (1,000 mg or more per day).
- If you experience discomfort or irritation, stop using the product.
- If a significant amount (more than 10 mL) is swallowed, drink a cup of milk or water and contact your doctor or an Accident and Emergency department.

These warnings are aligned with those already used on the European market. Similarly although no special handling precautions are required for the formulated product, a child resistant cap is considered prudent.

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2. Extent of use of potassium oxalate

Regulatory Restrictions:
Potassium Oxalate is restricted for use in Cosmetics in Europe
Cosmetic Directive Annex III: List of Substances which Cosmetics Products Must Not Contain Except Subject to the Restrictions Laid Down

Restrictions

Product type, body parts: Hair Care Products

Maximum concentration in ready for use preparation: 5%

Other: Professional use

Wording of conditions of use and warnings: For professional use only

There are no restrictions on the use of potassium oxalate in therapeutic goods in Europe. There are no formal restrictions in the US however a potassium oxalate mouthwash would be regulated as a medical device.

Literature
To ascertain the general extent of use of potassium oxalate a search of PubMed using the search terms "potassium oxalate, tooth sensitivity" yielded 53 hits and abstracts were collected. Other more generic searches such as "potassium oxalate, therapeutic use" yielded significant less number of hits. Overall the literature produced only limited descriptive information in the extent of use of potassium oxalate. Results of the search are provided in attachment A. Abstracts will be provided on request.

The literature indicates that the therapeutic use of potassium oxalate is mainly confined to tooth sensitivity. Of the 53 hits 12 hits provided information on the concentrations of potassium oxalate used in dentinal sensitivity or dentinal sensitivity models (Attachment A) which ranged from 1.4%, 3.0% to 30% and included in vivo and in vitro studies. Uses included relief of dentinal sensitivity (n=4), relief of dentinal sensitivity looking at selected teeth (n=4), single use in tooth restoration procedures (n=3), pre-clinical study (n=1) and use in demonstrating mode of action in pharmacology models (n=23). In addition 7 reviews on dentinal hypersensitivity referred to oxalate preparations.

Dosage forms used included mouthwash, gels and pastes which were used as either single applications or for daily use from twice a day for 5 days to 4 weeks (daily regimen unspecified).

No comments on adverse reactions were included in the abstracts.

Johnson & Johnson Pacific

[redacted]

[redacted]

In-market distribution

J&J first launched 1.4% potassium oxalate mouthwash formulation in the UK in September 2012. It is sold in 250mL and 500mL bottles. The product is now marketed in several European countries as shown in the table below:

Country	*Launch Date*	[redacted]
UK	September 2012	
Ireland	February 2013	
Italy	June 2013	
Sweden	October 2013	
Finland	October 2013	
Norway	October 2013	
Czech Republic	October 2013	
Slovakia	October 2013	
Hungary	October 2013	
Poland	October 2013	
Belgium/Luxembourg	January 2014	
Austria	February 2014	
Germany	February 2014	
Nederlands	February 2014	
TOTAL		

In-market safety

Johnson & Johnson maintains comprehensive databases on the in-market safety of their products. A report on the post marketing adverse events in Europe from 01 January 2012 to 30 June 2014 is provided in Attachment B.

In total 71 adverse events were reported. Of these 70 reports raised no safety concerns or unexpected safety findings and consisted mainly of non-serious oral reactions including burning sensation, peeling/sloughing in the mouth, dryness in the mouth and taste complaints. One event was considered life-threatening however its causality was confounded by a pre-existing condition.

This report found that the frequency of adverse events was very rare [redacted]

Clinical trial safety

The safety assessment of 2 clinical studies is provided in Attachment 1 together with their published reports. The formulation used in these studies is the same as is marketed in the EU.

Study 1: 4-week comparative clinical study

Subjects were actively questioned for the occurrence of adverse events. Of the 74 subjects included in the potassium oxalate mouthwash arm, no serious adverse events were reported and all adverse events were resolved without treatment or a change in study dosage. A total of 6 adverse events were reported. Three subjects experienced mild generalised sloughing of the gingival tissue which was considered probably related to the treatment while the remaining 3 reported adverse events were assessed as doubtful (mild blister/gingival irritation) or possible relationship (moderate worsening of tooth sensitivity) to the treatment.

Study 2: 5-day comparative clinical study

Of the 28 subjects included in the potassium oxalate mouthwash arm, no adverse events were observed or reported.

It is concluded that the potassium oxalate mouthwash is safe for use in dentinal sensitivity.**]**

3. Toxicity of potassium oxalate

To support the safety of the proposed mouthwash Johnson & Johnson commissioned:

- Systematic literature reviews on Acute and Chronic toxicity of oxalic acid
- Preclinical studies on delayed type hypersensitivity, mucosal irritation, and cytotoxicity

Reviews on Acute and Chronic toxicity

Acute Toxicity Review: "Risk Assessment: Acute Toxicity from potassium oxalate rinse ingestion" *is included in attachment 2 is provided for schedule committee review only and is to be regarded as confidential as it contains commercially sensitive information and is the subject of other health authority review.*

This report addresses the questions of:

- What are the minor, moderate and severe adverse events related to acute excessive oxalate exposure?
- What are the threshold levels for acute ingestion before an adverse event is seen in the normal population (adults and children)?
- Are there populations at increased risk of adverse events with acute excessive oxalate exposure?

This report found that:

Ingestion of up to 4g of oxalic acid (8.1g potassium oxalate) is unlikely to produce significant adverse events in the normal population (adults and children). Thus if consumed in its' entirety, a bottle of mouth rinse (1.4% dipotassium oxalate; 500mL) containing 3.4g

of oxalic acid is unlikely to cause adverse events in the adult healthy population. It was considered that for children and populations at risk of oxalate toxicity i.e. a subset of stone formers who hyperabsorb oxalate from the gut, and those with renal insufficiency, that mitigation strategies such as child resistant packaging and appropriate label warning statements could be employed to reduce this possible risk.

Chronic Toxicity Review: "Risk Assessment: Chronic Toxicity from potassium oxalate rinse following long term use and potential drug interactions" is included in attachment 3 *is provided for schedule committee review only and is to be regarded as confidential as it contains commercially sensitive information and is the subject of other health authority review.*

This report addresses the questions of:

- Are there safety considerations for the potential addition of potassium oxalate from retention of the rinse on a chronic basis in the general population and in populations where oxalate intake could be of issue (assuming average western diet)?
- What are the possible drug interactions?
- What are the expected chronic effects if a consumer were to potentially ingest the daily dose after each rinsing?

This report found that:

Addition of potassium oxalate from retention of the rinse
The calculated oxalate retention from mouthwash (1.4% dipotassium oxalate) is 6.85mg oxalic acid per rinse or 13.7mg per day with twice daily use. Given the contribution of oxalic acid from the average western diet is 70-150 mg/day, the addition of oxalate from this daily mouthwash use is unlikely to be clinically significant.
Elimination studies of oxalate have shown that peak urinary levels of oxalate occur in the first few hours after ingestion, therefore it is unlikely that oxalate from mouthwash use would accumulate significantly in the body to cause long term adverse effects in persons with normal renal function.

Chronic oxalate ingestions from long term use of a 1.4% dipotassium oxalate mouth wash as per label instructions is unlikely to present significant clinical risks to normal individuals.

Overseas experience with the use of the drug naftidrofuryl oxalate (which provides 4-9 times the amount of oxalate than is retained by the proposed mouthwash) in a compromised population (peripheral vascular disease with/without concomitant deficient renal function) has yielded few reports of kidney stones despite its widespread use. The label for this product does contain contraindications for persons with hyperoxaluria and kidney stones similar to those proposed for potassium oxalate mouthwash.

Various populations where oxalate intake could be an issue were considered and it was concluded that appropriate label warnings would be sufficient to reduce possible risk in population subgroups susceptible to adverse events from oxalate exposure.

Possible drug interactions

Cases of increased drug absorption in the presence of reduced calcium ions (due to binding with oxalate) were not located in the literature suggesting that use of oxalate containing mouthwash is unlikely to result in clinically significant drug interactions.

Concomitant use of vitamin C was considered due to its association with increasing oxalate levels in urine. No risk however was identified in the normal healthy population. However, general recommendations support the limiting of high dose vitamin C (>1g/day) in people with kidney stones or those with compromised renal function.

Potassium containing mouthwash misuse
The amount of oxalate ingested from a 2 x 10 mL dose of the proposed mouthwash is within the range of oxalate consumed in the average western diet (70-150 mg/day). Given the experience of naftidrofuryl oxalate in a patient population where the daily intake of oxalate is 114mg in addition to that provided by the diet it is reasonable to conclude that unintentional ingestion of a 10 mL dose (68.5mg) is unlikely to results in adverse effect in the healthy population. However should the dose be consumed regularly an increased risk of contributing to kidney stone formation is theoretically possible. The risk of unintentionally consuming a whole dose is mitigated by the product label clearly calling the product out as a mouthwash and the directions clearly directing the user to rinse and expel the mouthwash.

Preclinical studies
Three preclinical studies using 1.4% potassium oxalate mouthwash F#12027-027 as test material are summarised below. In each case the test material was used undiluted. The full study reports are provided in Attachment 4.

<u>Maximisation test for delayed–type hypersensitivity (ISO 10993-10:2010)</u>
Summary
30 male young adult Hartley Albino guinea pigs were allocated to 1 of 4 groups: Test group (n=12); negative control group (n=6); positive control group (n=6); and naive positive control group (n=6).
The study consisted of 2 phases: the induction phase and the challenge phase.

During the induction phase the test animals were exposed to the test material intradermally and examined 6 days later for irritation. On day 7 the test material was applied topically with an occlusive bandage. The animals' skin was examined 48 hours later for irritation.

In the challenge phase (14 days after the induction phase topical application) both the test and the negative control animals were exposed to the test material using a similar topical exposure method as used in the induction phase. The application sites were assessed after 24 hours.

The skin reactions of the animals exposed to the test material in both the induction and the challenge phase were compared to skin reactions of the animals not exposed to the test material in the induction phase (negative controls). Skin reaction scores in animals of the

test group greater than skin reaction scores of the negative control group were considered to represent significant sensitization.

The test group animals did not exhibit scores higher than those of the negative controls and no sensitisation potential of the test material was detected in this study.

It was concluded that the test article is non-sensitising.

Oral Mucosa Irritation test (ISO 10993-10:2010)

Summary

3 female young adult Syrian Harlan Sprague Dawley hamsters were included in this study. Cotton pellets saturated with the test material and saline were inserted into the left and right cheek pouches of the hamsters for 5 minutes respectively. After removal of the pellets the cheek pouches were examined for any abnormality. This was repeated four times hourly.

Twenty four hours after the final treatment the cheek pouches were macroscopically evaluated and the animals euthanized for tissue removal and histological examination.

Macroscopically the level of erythema was noticeably greater for test cheek pouches than for the control cheek pouches however no evidence of irritation was noted microscopically in either the test or control cheek pouches.

It was concluded that the test article is non-irritating to mucosal tissue.

Cytotoxicity – ISO Agar Diffusion Test (ANSI/AAMI/ISO 10993- 5:2009)

Summary

Multiple cultures of L-929 mammalian fibroblast cells were prepared in accordance with a standard. The cell cultures were plated 24-48 hours before applying the test article to allow for the growth of a cell monolayer. All test, positive and negative control plates were prepared in triplicate and incubated for at least 24 hours at 37°C.
The test article was not considered to be cytotoxic in this test.

4. Proposal

Potassium oxalate is currently captured under the schedule entry for oxalic acid which requires a product label to carry the signal heading “POISON”. This requirement prevents the supply of potassium oxalate, a metallic oxalic acid salt that is efficacious in the relief of tooth sensitivity. Potassium oxalate formulations are available in Europe for this use.

In the preparation of a mouth wash the formulation reacts with calcium salts (calcium oxalate is exempted under the current schedule entry) to form salts that block dentinal tubules. This is a mechanical action and it is expected that this product be regulated as a medical device as it is in Europe.

We propose that potassium oxalate be exempted from the entry:
Schedule 6: OXALIC ACID except its derivatives and insoluble salts

This could be done by altering the current schedule as follows:

Johnson & Johnson Pacific

[redacted]

Schedule 6: OXALIC ACID except:

(a) its derivatives and insoluble salts; or
(b) potassium oxalate when used in mouthwash preparations

OR by creating a specific entry for potassium oxalate when use in mouthwash preparations.

If considered necessary an appropriate concentration cut-off could be included.

Given the nature of the intended use of a mouthwash (rinse mouth and expel liquid) and the mode of action/interaction of the ingredient in the mouth, the toxicological cut-offs of the Scheduling Policy Framework for Schedule 6 poisons do not seem relevant.

Safety assessments and European in-market safety data provided in this submission have shown that when included in a mouthwash (particularly at the concentration of 1.4%) potassium oxalate does not present as a health hazard in the normal healthy population. It is however considered prudent to include warning statements for specific populations as addressed section 1 of this submission and as included in the UK label presented in section 1 (Therapeutic Purpose for which a potassium oxalate is used) of this response.

[redacted]

Attachments to 1.2 Oxalic acid Response

Attachment A – Pubmed search - extent of use of potassium oxalate

[redacted]

1.2 Oxalic acid

ATTACHMENT A – PUBMED SEARCH - EXTENT OF USE OF POTASSIUM OXALATE

A literature search was conducted 3 July 2014 using PubMed database to collate published clinical usage information on potassium oxalate in dentinal sensitivity. A summary of the hits to the search term "potassium oxalate, tooth sensitivity" are tabled below. The abstract for each hit was collected and used to ascertain the relevance of the hit. Full reports sought for those studies that reflected daily use of a potassium oxalate formulation.

Hit #	Concentration	Dosage form	Duration	n	Comments
1	1.4%	Mouth wash	5 days (used 2X a day)	28	Study provided in Attachment 1
2	various	Various	Not stated		Review, insufficient detail.
3	1.4%	Mouth wash	Not stated		In vitro study.
4	Not stated	Not stated	7 days (regimen unclear)		Total n=19; 2 trial groups. Oxalate preparation not specified.
5	Not stated	Not stated	3 single applications 1 week apart	36	n in this study refers to individual sensitive teeth. Does not reflect daily use.
6	3%	gel	Not stated		In vitro study.
7	Not stated	Not stated	4 months (single use)	36	Does not reflect proposed use. Used under resin-based composite restoration.
8	Not stated	Not stated	18 months (single use)	10	Does not reflect proposed use. Used under resin-based composite restoration.
9	Not stated	various	Not stated		General review; in Hebrew.
10	Not stated	Not stated	4 weekly applications	11	Does not reflect proposed use. Split mouth comparative study, actives not identified.131 teeth selected.
11	Not stated	Not stated	Not stated		In-vitro - Oxalic acid liner used as a control.
12	3%	gel	4 weekly applications	34	Does not reflect proposed use. Total of 34 patients with 164 sensitive teeth allocated to 1 of 3 groups.
13	Not stated	Not stated	Not stated		In vitro study.
14	Not stated	Not stated	Not stated		Does not reflect proposed use. Concerned effect on resin cements.
15	Not stated	Not stated	Not stated		In-vitro study using bovine teeth.
16	Not stated	Not stated	4 weeks (regimen unclear)	65	Subjects allocated to one of 4 treatment groups. Efficacy reported.
17	Not stated	Not stated	Not stated		Review of dentin hypersensitivity.
18	Not stated	Not stated	Not stated		In vitro study.
19	5%	paste	Not stated		In vitro study.
20	Not stated	Not stated	4 weeks (regimen unclear)	48	Subjects allocated to 1 of 2 treatment groups
21	Not stated	Not stated	Not stated		In vitro study.
22	Not stated	Not stated	Not stated		In vitro study.
23	30%	Not stated	Not stated		In vitro study.
24	3%	gel	Not stated		In vitro study.

25	3%	gel	3 weeks (single application)	25	Subjects allocated to 1 of 2 treatment groups
26	Not stated	Not stated	Not stated	87	Oxalate used not specified. Insufficient information.
27	Not stated	Not stated	Not stated		In vitro study.
28	Not stated	Not stated	Not stated		In vitro study.
29	Not stated	Not stated	Not stated		In vitro study.
30	3%	gel	Not stated		In vitro study.
31	?	Mouth wash	Not stated		Review.
32	Not stated	Not stated	Not stated		In vitro study.
33	Not stated	Not stated	Not stated		Pre-clinical pharmacology study.
34	Not stated	Not stated	Not stated		In vitro study.
35	30%	gel	Single use	30	Does not reflect proposed use. Chinese article.
36	Not stated	Not stated	Not stated		Does not concern potassium oxalate.
37	Not stated	Not stated	Not stated		In vitro study.
38	Not stated	Not stated	Not stated		In vitro study.
39	Not stated	Not stated	Not stated		Review of dentin hypersensitivity.
40	Not stated	Not stated	Not stated		Pre-clinical pharmacology study.
41	Not stated	Not stated	Not stated		In vitro study.
42	3%	solution	Single use	13	Tooth extracted after application for microscopic examination
43	Not stated	Not stated	Not stated		Review of dentin hypersensitivity.
44	Not stated	Not stated	Not stated		In vitro study.
45			Not stated		Does not concern potassium oxalate.
46	Not stated	Not stated	Not stated		In vitro study.
47	Not stated	Not stated	Not stated		Review; in French.
48	Not stated	Not stated	Not stated		Review; in Croatian.
49	Not stated	Not stated	Not stated		Review of dentin hypersensitivity.
50	Not stated	Not stated	Not stated		In vitro study.
51	Not stated	Not stated	Not stated		Does not concern potassium oxalate.
52	Not stated	Not stated	Not stated		Efficacy study. No information in extract.
53	30%	Not stated	4 single treatments over 4 weeks	17	Does not reflect proposed use.

Australian Competition & Consumer Commission

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[redacted]

14 July 2014

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

Sent electronically to SMP@health.gov.au

Dear Secretary Medicines & Poisons Scheduling

Australian Competition and Consumer Commission submission

I wish to thank you for the opportunity to offer comment on the Delegate's interim decision in relation to the ACCC's proposal to amend the Poison's Standard references to methylated spirits. I am writing to urge you to reconsider the decision not to amend the scheduling of methylated spirits in the light of the seriousness with which the ACCC views the hazard posed to the community.

The ACCC considers the amendment to the scheduling to be a critical element of the range of measures that might be taken to address the increasing instances of serious burns associated with the growing popularity of decorative burners powered predominantly by ethanol fuel.

The most serious of the burns arising from these products involve the face and upper body which may be permanently disfiguring to the victim. The incidents are typically characterised by the injured party refuelling the burner while the burner is still lit and the flame invisible, or while the burner is still warm. The volatile nature of methylated spirits results in the fuel exploding on impact with the heat, and spreading uncontrolled flames in various directions.

The ACCC views the provision of appropriate warnings on methylated spirits containers to be an integral measure to assist in promulgating and reinforcing the safety warnings to consumers in terms they are more likely to heed than is currently

the case. Namely the proposed warning outlines the consequences to the person which may arise from actions taken, which the current warning does not.

I would also like to draw your attention to a spate of such burns occurring in Queensland in recent days which have led to the publication of a Safety Warning Notice and a Product Safety Investigation for ethanol burners. As we note in our submission, the Queensland Health Department has indicated that 4 serious burns related to ethanol burners came to one hospital in as many days.

Given the limitations associated with the collection of injury data in select Australian hospitals, the ACCC is of the view that the numbers of injuries formally attributed to the use of burners and methylated spirits is underrepresented in the data. The cost to the community in social and economic terms is difficult to quantify.

Please find attached the ACCC's submission in relation to the Delegate's interim decision. [redacted]

[redacted]

Australian Competition and Consumer Commission (ACCC)

- Response to Delegate's Interim Decision on Methylated Spirits

BACKGROUND

On 15 November 2013, the Australian Competition and Consumer Commission (ACCC) requested that the warning statement applied to methylated spirits be amended to alert consumers to the serious burn hazard that methylated spirits may pose when refuelling ethanol burners. A delegate of the Secretary to the Department of Health provided notice of the interim decision not to amend the Poisons Standard as proposed and has provided an opportunity for the ACCC to make further submissions, until 15 July 2014.

ACCC POSITION

Addressing the Delegate's reasons in order, the ACCC contends:

1. ***Difficulties in achieving, through a schedule entry amendment, the requested outcome of warning consumers of the fire risks associated with using methylated spirits to refill burners while alight or hot.***

The efficacy of warning labels is a key factor for the ACCC in the development of effective and efficient responses to product hazards. We have commissioned meta-analysis and literature reviews, participated in and commissioned research on specific labels and been part of the development (and mandating) of information and warning labels.

The request for an addition to the warning on methylated spirits is based on the understanding that, to be effective, there are three required parts of a warning, namely (a) the hazard, (b) the consequences, and (c) the required compliance behaviour.[1]

This conclusion is based on well-established work, especially in relation to the efficacy of warnings in workplaces, where good warnings are thought to require an alert word (e.g. danger); statements of the hazard, its seriousness and probable consequences; and information on how to avoid the hazard.

[1] Austin, "The efficacy of warning labels: a review of the research", commissioned research for the Australian Competition and Consumer Commission, 2012.

See for example, Adams, Bochner, Bilik "The effectiveness of warning signs in hazardous work places: cognitive and social determinants' Applied Ergonomics, (29, 247-254) 1998.

Analysis of the identified cases of injury and of some incidents without injury indicates that a key contributing component is the general absence of understanding that re-filling a hot receptacle is likely to ignite the fluid. Re-filling is identified in the data as associated with injury and would qualify as 'reasonably foreseeable use'.

Providing an estimate of the likely effect of such a change in warnings is problematic. In scientific research terms the only way to do this would be to have two similar populations with different warnings and measuring the rate of injury in both. The argument for the requested change rests on first principles and is directed at overcoming clear deficiencies in the existing warnings. The ACCC view is that without a specific warning or alert on the risk these incidents will continue. The absence of this specific alert means the current warning is likely to be ineffective.

2. There are already appropriate flammability warnings on product labels.

As noted above the view of the ACCC is that the current warnings do not address a specific hazard, and that individuals are being injured though lack of understanding of the nature of the risk. The ACCC's concern about the current SUSMP warning is noted above,

In terms of the adequacy of other warnings, the ACCC is aware of the Material Safety Data Sheet (MSDS) system. However neither the Risk Phrases (R) nor Safety Phrases (S) well describe the risk or safety points associated with the ignition process where fuel is added to a physically hot stove that has just been extinguished. It is this risk that is the focus of this application from the ACCC.

Risk phrases are normally a general description of the hazards. Safety phrases provide information on safe storage and handling, and personal protection.

The closest phrases of some utility that appear on the MSDS for fuel generally marketed as suitable for fuel stoves include:

- R 11 - Highly flammable
- S15 - Keep away from heat
- S16 - Keep away from sources of ignition - No smoking

We are aware of the progressive adoption and implementation of the Globally Harmonised System of Classification and Labelling of Chemicals (the GHS) within Australia. On our reading of the Code of Practice - Preparation of Safety Data Sheets for Hazardous Chemicals the new Hazard and Precautionary statements in the GHS do not appear to resolve this gap in the new Safety Data Sheets (SDS)

Therefore our view remains that this risk needs to be covered in another way, such as the SUSMP.

3. ***There are a range of other uses for methylated spirit where the applicant's proposed warning statements would not be applicable.***

The proposed warning is consistent in meaning and purpose to the existing flammability warning, which is provided in recognition that methylated spirits is widely used as fuel for a variety of burners, including lamplights, camp stoves and heating equipment. The use of methylated spirits as a cleaner and multiple applications does not preclude or interfere with existing warnings provided. The proposed warning has broader application than decorative spirit burners and the reference to the term 'methylated spirit burners' is deliberately generic so as to eliminate confusion and encourage users to consider the consequences of refuelling any such burner.

4. ***The ACCC should consider attaching the suggested warning statement to the burners, rather than to the fuel.***

The ACCC is currently collaborating with State and Territory regulators to develop a broad strategy to address this hazard through a range of tactics. One of these is to consider regulation of decorative burners, in line with the harmonised approach that is in development by the European Commission and European Union member states.

The ACCC notes from market surveillance and industry consultation that warning statements and comprehensive safety instructions are currently often voluntarily provided with these products and notwithstanding these, injuries persist. Warnings on the fuel itself would serve to augment those provided with burners.

The ACCC aims to address this issue both through warnings on the fuel and a remedy in relation to the burner as the most effective solutions. There would appear to be no reason to wait for one in order to introduce the other.

The ACCC further contends:

Public response

The proposal to amend the schedule attracted 6 submissions from the public during the latest consultation period. The ACCC notes 3 of the submissions are positively in favour of the proposal (one stating such a warning would be 'good for the category') and 2 submissions provide qualified support subject to the need being demonstrated and sufficient lead time being provided. Only one submission did not offer support for the amendment.

Cost of injury

Assessment of the costs associated with burn injury is very difficult. It depends on a number of factors of which the most important is the percentage of the body burned. We reviewed these issues with the University of Queensland, Centre for Children's Burns and Trauma Research, which had helped the ACCC identify injury cases. They pointed us to two recent studies in Australia and in the US. The Australian study gave the average cost of an adult burn as $71,056 AUD (US $73,000) and for a child burn as $83,535 AUD.

The ACCC notes the recent alert from the Queensland Department of Health in relation to this product. This warning was issued after a single Queensland hospital admitted 4 patients with serious burns associated with ethanol burners in as many days. A number of documents related to recent injuries are listed in the attachments.

Cost of compliance to Industry

The assessment of the costs to industry arising from a label change, as applicable to bean bags, is regarded as modest by industry. Industry advises that costs associated with a print label change only would be minimal subject to suppliers being given a sufficient lead time to implement changes to specifications and sell through existing stock.

Printing a label on a bottle is considered to be an expedient, cost effective and simple solution for industry.

While the proposed remedy in relation to ethanol burners themselves is not yet determined it should be noted that the relative cost of incorporating a warning for the wide variety of burners has a far higher impost on industry. Burners comprise a variety of component materials and features, and there is a greater level of complexity required to make the warning permanent, heat resistant, contrasting and properly positioned. This is technically more burdensome and costly for suppliers than production of a standard printed label for a bottle.

Immediacy of warning

The presence of the warning on the bottle is more immediate than those on a burner and would complement any warnings provided on or with a burner. It may also be the case that once the burner has been lit, a user may not note the warning on the burner or not be looking for it when refuelling. This is in contrast to having the warning provided on the bottle, potentially always seen and visible when refuelling. The proposed warning is likely to produce more consistent results for the user in terms of visibility, legibility and its ability to attract attention.

Bio and other methylated spirits based fuels

The ACCC would like to see a warning on all ethanol burner fuels. The ACCC considers that even though some ethanol fuels may not fit the current definition of 'methylated spirits' contained in the Poisons Standard, this is no reason to not introduce a warning on the predominant kind of fuel that does fit the current definition. A proposal to review the definition could capture bio-fuel in due course.

Efficacy of warning and balance of costs/benefits

The ACCC acknowledges that there is no practical way to demonstrate the degree to which the proposed warning label will reduce the degree of risk or the incidence of burns vis-à-vis the existing warning.

The case for change rests on the clear absence in the existing warning of a known hazard and the need to repair this deficiency because it is associated with both injuries and incidents. The ACCC argues that a modest, minimally disruptive change to the warning label is outweighed by the need to redress this deficiency, the actual and potentially severe nature of injury and the knowledge of the costs associated with burns.

CONCLUSION

The ACCC recommends the Poisons Standard to be amended to provide a prominent new warning statement for methylated spirits as follows:

1. '**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',** (or similar)

2. 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.

Attachments

Appendix 1 *Girl burnt in campsite mood flame accident,* Sydney Morning Herald, December 27, 2011 (http://www.smh.com.au/nsw/girl-burnt-in-campsite-mood-flame-accident-20111227-... 25/05/2012)

Appendix 2 Media statement. *Ethanol burners spark health warning*. QLD Health, 2 July 2014.

Appendix 3 Safety Warning Notice, Attorney-General and Minister for Justice QLD, 10 July 2014.

Appendix 4 Media release. *Queensland Health: The dangers of open-flame, decorative lamps*. Royal Brisbane and Women's Hospital, 17 April 2012.

References

The following references are relevant to the hazard presented by ethanol burners and / or support the introduction of labelling requirements.

(1) Jansbeken JRH, et al. *Methylated spirit burns: An ongoing problem*. Burns (2012), doi:10.1016/j.burns.2011.10.006

(2) Ahn, Chris S, Maitz, Peter KM, *The true cost of a burn*. Burns 38 (2012) 967-974, doi:10.1016/j.burns.2012.05.016

(3) Patil, Vikram, et al. *Do Burn Patients Cost More? The Intensive Care Unit Costs of Burn Patients Compared With Controls Matched for Length of Stay and Acuity*. (2010), DOI:10.1097/BCR.0b013e3181e4d6a4

(4) Carey, Kathleen PHD, et al. *Measuring the cost of care for children with acute burn injury*. (2010), DOI:10.1097/TA.0b013e318265c88a

(5) Niedermeyer, Hans-Georg, et al. *Study of Safety Requirements for Open Stoves or Fireplaces Using Alcohol Fuels*. Revision 5.3, May 2010

smh.com.au
The Sydney Morning Herald

Girl burnt in campsite mood flame accident

Published: December 27, 2011 - 9:40AM

A 12-year-old girl has been flown to a Sydney hospital with serious burns after a camping accident on the NSW south coast.

The girl and her family were sitting at a table at Crookhaven Heads Tourist Park, Culburra Beach, where there was a mood flame burning from a stainless steel canister, police said.

The flame was almost out so one of the adults began to refill the container with ethanol fuel.

As she did this a gust of wind made the flame flare, igniting the girl's hair and clothing.

The flames were quickly smothered by family members and the girl was placed in a shower until paramedics arrived.

She was taken by ambulance to Shoalhaven Memorial District Hospital on Monday evening before being airlifted to Westmead Hospital suffering burns to 35 per cent of her body.

She remains in a serious but stable condition.

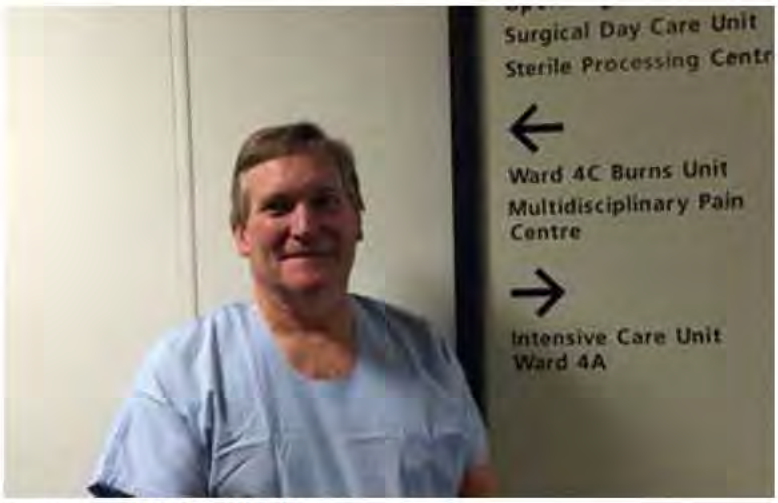
AAP with Stephanie Gardiner

Ethanol burners spark health warning

Wednesday 2 July 2014

A spike in serious burn cases has prompted Queensland Health to issue a statewide warning.

Royal Brisbane and Women's Hospital burns surgeon Professor Michael Muller said he wanted to warn people about the safe use of ethanol burners this winter after recent incidents.



Professor Michael Muller

"I've seen four patients in as many days with severe burns caused by an explosion of ethanol when re-lighting the flame," Professor Muller said.

"Three out of these four patients are currently in Intensive Care.

"It's very concerning because as a result, these patients will require surgery, a lengthy hospital stay, possible scarring, months of pain and years of rehab.

"As little as one second of body contact with material heated to a temperature of 70 degrees can inflict a full third-degree burn."

Ethanol-burning fireplaces are generally open-flamed devices that are fuelled by bioethanol, so burning is considered 'clean' and delivers heat with no smoke, spitting or ash.

Burns appear to occur when people think the flame is almost out so they refill the container with ethanol fuel. This has, in these serious instances, caused the flames to erupt and burn people.

Last updated: 2 July 2014

SAFETY WARNING NOTICE

Australian Consumer Law (Qld) section 129 (1)(a) and (b)

I, Jarrod Bleijie, Attorney-General and Minister for Justice publish this safety warning notice pursuant to section 129 (1) (a) and (b) of the Australian Consumer Law (Qld).
This safety warning notice relates to unvented ethanol fuelled fireplaces for domestic use that do not require professional installation. They can be moveable or fixed installations.
These goods are under investigation to determine whether they will or may cause injury to any person; or by a reasonably foreseeable use (including a misuse) will or may cause injury to any person.

Potential Hazard:

These products often operate with an open flame with a tempered glass shield and are free standing. Exposure to open flames may increase the risk of fire and injury, particularly in an environment where children are present or combustible materials such as clothes or curtains are close by.

Due to the type of fuel used by these devices the flame may be difficult to see particularly in daylight which may increase the injury risk when being refilled. There is also a risk of combustible gas build up in unventilated areas.

What consumers should do:

Consumers are urged to strictly follow manufacturer's instructions carefully:

- never leave a product unattended,
- never store fuel in the same room,
- have an appropriate fire extinguisher close by,
- do not use for cooking or throw anything combustible into the fireplace,
- never leave children unsupervised around these devices,
- never use a different fuel than that recommended by the manufacturer; and
- take added precautions when refilling the product to ensure the flame is totally extinguished and surface has cooled.

Consumers and suppliers of these products are advised to contact the Office of Fair Trading via safety@justice.qld.gov.au or on 07 30085983 if they have experienced a safety incident.

Dated this: 10th day of July 2014.

JARROD BLEIJIE MP
Attorney-General and Minister for Justice

Royal Brisbane and Women's Hospital
media release
Queensland Government
Metro North Health Service District

17 April 2012

Queensland Health: The dangers of open-flame, decorative lamps

Queensland Health is warning of the dangers of open-flame, decorative lamps.

Associate Professor Michael Muller, a burns surgeon at Royal Brisbane and Women's Hospital (RBWH), knows first-hand the potentially devastating effects of burning open-flamed, ethanol-fuelled lamps.

"Currently, four out of 16 patients on the ward have been admitted for burns caused by one of these devices," Assoc. Prof. Muller said.

"The patients have between 10 per cent and 20 per cent burns to their bodies, require surgery for skin grafting, are in considerable pain and will be with us for up to three weeks," he said.

The lamps run on ethanol and, when combined with poor design, can be very dangerous as the ethanol can ignite very easily.

The lamps are popular and several different varieties are available on the market.

Assoc. Prof. Muller said the danger comes when filling and lighting them.

"If the person is in a hurry or distracted there can be disastrous consequences," he said.

There is the potential for severe burns resulting from explosions, clothing and household objects catching fire, as well as flammable fuel being spilled and fire spreading quickly, he said.

-ENDS-

Interview opportunities are available with patients. Please contact RBWH Marketing and Communications on 3646 7863.