Final decisions and reasons for decisions by delegates of the Secretary to the Department of Health – Part 2

December 2014

Notice under subsections 42ZCZS and 42ZCZX of the Therapeutic Goods Regulations 1990 (the Regulations)

A delegate of the Secretary to the Department of Health hereby gives notice of the delegates' final decisions for amending the Poisons Standard (commonly referred to as the *Standard for the Uniform Scheduling of Medicines and Poisons* – SUSMP) under subsections 42ZCZS and 42ZCZX of the Therapeutic Goods Regulations 1990 (the Regulations). This notice also provides the reasons for each decision and the date of effect (implementation date) of the decision.

The delegate's final decisions and reasons relate to scheduling proposals referred to the July 2014 meeting of the Advisory Committee on Chemicals Scheduling (ACCS#11).

Scheduling proposals referred to the expert advisory committees

Pre-meeting public notice

A 'pre-meeting' public notice inviting submissions on the scheduling proposals referred to the expert advisory committees was published on 29 May 2014 at: http://www.tga.gov.au/consultation-invitation/consultation-invitation-public-comment-accs-acms-and-joint-accsacms-meetings-july-2014.

Edited versions of public submissions received in response to this invitation were published on 14 November 2014 at http://www.tga.gov.au/scheduling-submission/public-submissions-scheduling-matters-referred-accs11-and-joint-accs-acms9.

Interim decisions

The delegate's interim decisions on recommendations by the ACCS#11 were published on 14 November 2014 at http://www.tga.gov.au/scheduling-decision-interim/reasons-scheduling-delegates-interim-decision-and-invitation-further-comment-accs-november-2014-chemicals. This public notice also invited further comment from the applicant and from those parties who made a valid submission in response to the original invitation for submissions.

Further submissions from parties other than those who made a valid submission in response to the original invitation or the applicant, or those received after the closing date, may not be considered by the delegate.

Edited versions of valid public submissions received in response to the interim decisions are published at http://www.tga.gov.au/public-submissions-scheduling-matters.

Final decisions

In accordance with subsection 42ZCZR of the Regulations, if a delegate makes an interim decision on an application, the delegate may make a final decision either confirming, varying or setting aside

the interim decision, but only after considering any valid submissions received in response to the interim decisions.

Matters not referred to an advisory committee

A delegate may decide not to refer a scheduling proposal to an expert advisory committee for advice and instead may make a delegate-only decision. When deciding not to refer a matter to a committee, the delegate considers the scheduling guidelines as set out in the *Scheduling Policy Framework for Chemicals and Medicines* (SPF, 2010), available at http://www.tga.gov.au/publication/ncctg-scheduling-policy-framework.

Publishing of the amendments to the Poisons Standard

The amendments to the Schedules, Appendices or other parts of the Poisons Standard are published electronically on ComLaw as amendments to the *Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP) prior to the date of effect (implementation date) of the final decisions. Further information, including links to the Poisons Standard on ComLaw, is available at http://www.tga.gov.au/publication/poisons-standard-susmp.

Glossary

Abbreviation	Name
AAN	Australian Approved Name
AC	Active constituent
ACCC	Australian Competition and Consumer Commission
ADI	Acceptable daily intake
APVMA	Australian Pesticides and Veterinary Medicines Authority
ARfD	Acute reference dose
CAS	Chemical Abstract Service
EPA	Environmental Protection Authority
FAISD	First Aid Instructions and Safety Directions
FDA	Food and Drug Administration (United States)
FSANZ	Food Standards Australia New Zealand
GHS	Globally Harmonised System for Classification and Labelling of Chemicals
IMAP	Inventory Multi-tiered Assessment Prioritisation
ISO	International Standards Organization
LC_{50}	The concentration of a substance that produces death in 50 per cent of a population of experimental organisms. Usually expressed as mg per litre (mg/L) as a concentration in air.
LD_{50}	The concentration of a substance that produces death in 50 per cent of a population of experimental organisms. Usually expressed as milligrams per kilogram (mg/kg) of body weight.
LOAEL	Lowest observed adverse effect level
LOEL	Lowest observed effect level

Abbreviation	Name
NCCTG	National Coordinating Committee on Therapeutic Goods
NHMRC	National Health and Medical Research Council
NICNAS	National Industrial Chemicals Notification & Assessment Scheme
NOAEL	No observed adverse effect level
NOEL	No observable effect level
NOHSC	National Occupational Health & Safety Commission
OCS	Office of Chemical Safety
PEC	Priority existing chemical
PIC	Poisons Information Centre
SUSDP	Standard for the Uniform Scheduling of Drugs and Poisons
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons
WHO	World Health Organization
WP	Working party
WS	Warning statement

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Final decisions on matters referred to an expert advisory committee

1. Scheduling proposals referred to the July 2014 meeting of the Advisory Committee on Chemicals Scheduling – Part 2 (ACCS#11)

SUMMARY OF FINAL DECISIONS

Substance	Final Decision
Phenylenediamines	Amend current Schedule 6 entry to specify arylated derivatives are included. Amend current Appendix C, E and F entries to specify arylated derivatives are included and new warning statement. Create new Appendix C entries: 1,2-BENZENEDIAMINE in preparations for cosmetic use and skin colouration (including tattooing). 1,3-BENZENEDIAMINE in preparations for cosmetic use and skin colouration (including tattooing). Implementation date – 1 February 2015 for the new and amended to the Appendix C, 1 July 2015 for the amendments to the Schedule 6, Appendix E and Appendix F entries.
Rosin	New Schedule 5 entry: ROSIN when packaged for use as a soldering flux or in flux-cored solder. Delete current Appendix B entry for Colophony Create new Appendix F entries to allow appropriate warning statements relating to the risks of breathing these fumes Implementation date – 1 July 2015
Toluenediamine	Amend current Schedule 6 entry to include: (c) in nail polish preparations containing 2,5-toluenediamine **except** when labelled 'avoid contact with skin' Create a new Appendix C entry: 2,4-TOLUENEDIAMINE in preparations for skin colouration (including tattooing) and dyeing of hair, eyelashes or eyebrows. Implementation date – 1 February 2015 for the new Appendix C entry, 1 February 2016 for the amendment to the Schedule 6 entry.

1.10 PHENYLENEDIAMINES

Scheduling decision

- To amend the current Schedule 6 entry to specify arylated derivatives are included.

†PHENYLENEDIAMINES including alkylated and arylated derivatives not elsewhere specified in these Schedules:

(a) in preparations packed and labelled for photographic purposes;
(b)

- To amend the current Appendix C, E and F entries to specify arylated derivatives are included and to add a new warning statement.

- To create new Appendix C entries:

  1,2-BENZENEDIAMINE in preparations for cosmetic use and skin colouration (including tattooing).

  1,3-BENZENEDIAMINE in preparations for cosmetic use and skin colouration (including tattooing).

- Implementation date, 1 February 2015 for the amendments to the Appendix C, E and F entries and 1 July 2015 for the amendment to the current Schedule 6 entry.

Scheduling proposal

The ACCS considered the following proposal referred by the delegate for advice:

- To review the generic listings for phenylenediamines in Schedule 6 and Appendices C, E and F, taking into consideration recommendations contained in NICNAS IMAP reports relating to the isomers 1,2-benzenediamine, 1,3-benzenediamine and 1,4-benzenediamine-N-phenyl. This will include consideration of broadening the scope of the generic phenylenediamine listing to include aryl as well as alkyl derivatives.

The committee considered and discussed the resolutions with an implementation date of 1 February/1 July/1 October 2015.

On 24 April 2014, NICNAS, under its IMAP programme, requested that the delegate consider a proposal to amend the phenylenediamine Schedule 6 group entry to exclude 1,2-benzenediamine, 1,3-benzenediamine and 1,4-benzenediamine-N-phenyl from this entry and create a new Appendix C entry for hair dye and/or eyelash and eyebrow tinting preparations containing these substances.

The delegate's reason for referring this scheduling proposal to the ACCS was that there are existing generic SUSMP entries for phenylenediamines *and their alkyl derivatives not elsewhere specified in the schedules* in Schedule 6 and Appendices C, E and F. The Schedule 6 entry exempts preparations for dyeing hair and eyelash/eyebrow when labelled with warning statements for skin irritation and eye damage, while the Appendix C entry precludes use in preparations for skin colouration and dyeing eyelash/eyebrow (except when in Schedule 6).

The delegate asked the ACCS the following questions:

- Does the ACCS consider that the NICNAS IMAP reports have raised issues that require amendment to the existing entries for PHENYLENEDIAMINES in Schedule 6, or Appendices C, E and F? Specifically, is there a requirement to list any of the three referred compounds as separate entries from the generic one or separately list the 1,2- and 1,3- isomers in Appendix C?

- Is the existing generic entry in Schedule 6 and Appendices E & F sufficiently clear, given that it exempts any hair dye and eyelash/eyebrow dyeing preparations containing a phenylenediamine when labelled with the prescribed warning statements? The scheduling history of this generic entry is quite complex.

- Is the existing generic entry in Appendix C sufficiently clear, given that it prevents use of any phenylenediamine in skin colouration preparations, but also prevents use in eyelash/eyebrow dyeing preparations, *except when covered by the Schedule 6 entry (which provides an exemption for appropriately labelled preparations)*?

- Noting an issue raised that the current wording of the Appendix C entry that precludes use in skin colouration preparations may not be interpreted in some jurisdictions to cover tattooing preparations used by intradermal injection, is there a need to amend the Appendix C entry to specifically include preparations for skin tattooing?

- Is the mutagenicity potential for the 1,2- and 1,3- isomers (but not the N-phenyl derivative) sufficient reason to prevent their use in all hair dye and eyelash/eyebrow dyeing preparations, by creating a separate entry in Appendix C banning these uses?

- Does the ACCS support the proposed broadening of the generic entries to include N-aryl derivatives, to capture the referred N-phenyl in the generic entry? The wording would then become: PHENYLENEDIAMINES, *including alkylated and arylated derivatives not elsewhere specified in these schedules*.

- Given the sensitising potential of the three compounds, are additional warning statements needed to specifically address this toxic endpoint, or are the existing warning statements (intended to cover sensitisation potential) adequate?

- Considering the mutagenicity potential for the 1,2- and 1,3- isomers, are there any other types of preparations available to the public that would require inclusion in a Schedule 6 (or 7?) entry?

Substance summary

- Please refer to the NICNAS IMAP human health Tier II assessment reports for 1,2-benzenediamine; 1,2-benzenediamine, dihydrochloride; 1,3-benzenediamine; 1,3-benzenediamine, dihydrochloride; and 1,4-benzenediamine, N-phenyl and a salt. These reports are publicly available on the NICNAS website:

  http://www.nicnas.gov.au/chemical-information/imap-assessments/imap-assessment-details?assessment_id=848,

  http://www.nicnas.gov.au/chemical-information/imap-assessments/imap-assessment-details?assessment_id=909,

  http://www.nicnas.gov.au/chemical-information/imap-assessments/imap-assessment-details?assessment_id=832,

  http://www.nicnas.gov.au/chemical-information/imap-assessments/imap-assessment-details?assessment_id=910 and

  http://www.nicnas.gov.au/chemical-information/imap-assessments/imap-group-assessment-report?assessment_id=893.

Scheduling status

These substances are not specifically scheduled. As these substances belong to phenylenediamine chemical group, the phenylenediamine Schedule 6 and Appendix C, E and F entries are applicable.

Schedule 6

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 diethyl-para-phenylenediamine or dimethyl-para-phenylenediamine in opaque strip packaging provided the directions for use include the statement, "Do not discard testing solutions into the pool";
(c) in hair dye preparations except when the immediate container and primary pack are labelled with the following statements:

KEEP OUT OF REACH OF CHILDREN, and

WARNING - This product contains ingredients which may cause skin irritation to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye.

written in letters not less than 1.5 mm in height; or

(d) in eyelash and eyebrow tinting products when the immediate container and primary pack are labelled with the following statement:

WARNING - This product contains ingredients which may cause skin irritation to certain individuals, and when used for eyelash and eyebrow tinting may cause injury to the eye. A preliminary test according to the accompanying directions should be made before use.

written in letters not less than 1.5 mm in height.

Appendix C

†PHENYLENEDIAMINES in preparations for skin colouration and dyeing of eyelashes or eyebrows **except** when included in Schedule 6.

Appendix E

Poisons	**Standard statements**
Phenylenediamines and alkylated phenylenediamines • in hair dyes.	A - For advice, contact a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor (at once). E1 - If in eyes wash out immediately with water.
• in other preparations.	A - For advice, contact a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor (at once). G1 - Urgent hospital treatment is likely to be needed. (Note – the words 'at once' to be added to instruction A). G3 - If swallowed, do NOT induce vomiting. E1 - If in eyes wash out immediately with water. S1 - If skin or hair contact occurs, remove contaminated clothing and flush skin and hair with running water.

Appendix F

Poisons	Warning statements	Safety direction
Phenylenediamines and alkylated phenylenediamines • in hair dyes.	21. WARNING – This product contains ingredients which may cause skin irritation to certain individuals. A preliminary test according to accompanying directions should be made before use. This product must not be used for dying eyelashes or eye brows; to do so may be injurious to the eye.	
• in preparations other than hair dyes.		1. Avoid contact with eyes. 4. Avoid contact with skin. 8. Avoid breathing dust (or) vapour (or) spray mist.

Scheduling history

In January 1955, the Committee on Poisons Schedules (CPS) decided to list phenylene toluene and other alkylated benzene diamines in Schedule 2. At that time Schedule 2 substances were considered to be poisons, the sale of which was restricted to certain specified categories of vendors and which were subject to identical packing and labelling requirements to those of Schedule 1 but which were not required to be entered in a poisons register.

In March 1980, the PSC decided to delete the Schedule 6 aromatic amines entry and amend the Schedule 6 phenylene diamines entry to include alkylated phenylene diamines.

In May 1985, the PSC noted that a number of phenylene diamines in Schedule 6 listing were individually listed as well as being included in the general entry for phenylene diamines. The PSC agreed that the individual entries were not required in addition to the general entry for phenylene diamines and decided to delete the individual entries. The PSC agreed that no change was required to the Schedule 2 phenylene diamines entry.

In August 2000, the NDPSC agreed to exempt hair dye products containing phenylenediamines or toluenediamines from scheduling, conditional upon specified labelling.

In February and June 2004, the NDPSC considered the outcomes of investigations into incorrectly packed and labelled eyelash/brow tints containing phenylenediamines/toluenediamine and in October 2004, the NDPSC agreed to foreshadow amendments to prohibit use for eyelash/brow tinting. This proposal was varied by the February 2005 NDPSC meeting which instead agreed to foreshadow two options: to allow either salon use only, or all domestic use, of these eyelash/brow tints as Schedule 6 products (when compliant with the specified labelling).

In June 2005, the NDPSC concluded that the potential risk of causing a strong allergic response in a small number of individuals could be minimised through appropriate labelling. The NDPSC therefore agreed to that eyelash/brow tints were Schedule 6 poisons when appropriately labelled.

In June 2006, the NDPSC considered a request for flexibility in applying the mandatory labelling for eyelash/brow tints containing phenylenediamine and toluenediamine. The NDPSC indicated that, as the main risk was sensitisation, which in this case did not demonstrate a clear dose response, strong label warnings were required before such products could be available as Schedule 6. As there was a risk of separation of an outer pack from the immediate container, it was appropriate that all mandatory labelling continued to be applied to the immediate container, regardless of pack size. That the Schedule 6 warning statement would need to be applied, whether the use was domestic or industrial, or the product would default to Appendix C. The NDPSC further confirmed that the introduction to both Appendix E and F provided sufficient flexibility to allow for variation of product use and formulation.

In February 2007, the NDPSC considered the labelling requirements for single use composite pack hair preparations, including those containing phenylenediamines or toluenediamine, in view of amending various references to 'hair dyes' to 'hair preparations'. The NDPSC decided not to amend these references as there was potential for inadvertent capture of products for non-dying use patterns.

In February 2008, the NDPSC considered the scheduling of phenylenediamine and toluenediamine in eyelash/brow tints including restricting non-professional supply to ≤ 5 mL and limiting non-professional supply to 'complete kit' forms (i.e. all reagents). The NDPSC agreed that it was not appropriate to address separate supply of a developer for eyelash/brow tinting through the scheduling process as there was little evidence of an actual public health risk from products not being sold in 'complete kit' form. The NDPSC also agreed that there was little evidence to support a pack size restriction on the availability of eyelash/brow tints containing phenylenediamine / toluenediamine.

Pre-meeting public submissions

No submissions have been received.

Summary of ACCS advice to the delegate

The ACCS recommended that:

- the current Schedule 6 phenylenediamine group entry be amended to include arylated derivatives;
- a new Appendix C entry be created for skin colouration (including tattooing), hair dye, eyelash and eyebrow tinting preparations containing 1,2-benzenediamine and 1,3- benzenediamine; and
- appropriate Appendix E and F statements for phenylenediamines are required.

The ACCS recommended an implementation date of 1 February 2015 for the Appendix C new entry and the amendment. The ACCS recommended an implementation date of 1 July 2015 for the Schedule 6 amendment.

The matters under subsection 52E (1) of the *Therapeutic Goods Act 1989* considered relevant by the Committee included: c) the toxicity of a substance; and d) the dosage, formulation, labelling, packaging and presentation of a substance.

The reasons for the recommendation comprised the following:

- 1,2 and 1,3- phenylated diamines genotoxicity and carcinogenicity.
- Arylated phenylenediamines risk of sensitisation can be mitigated by appropriate labelling.

Delegate's interim decision

The scheduling of the phenylenediamines is complex. It uses a combination of listing in Appendix C, to restrict their use in certain types of dye products where the risks of skin/eye irritancy are unacceptable (skin colouration and dyeing of eyebrows and eyelashes), and listing in Schedule 6 for hair dyes and other permitted products where label warning statements can provide appropriate protection to product users. In considering the current recommendations in the five NICNAS IMAP reports, the delegate accepts the advice of the ACCS that further restrictions need to be placed on the use of two of the phenylenediamines with highest mutagenic potential, and that the Appendix C entries be broadened to ensure that the prohibition of their use for skin colouration includes use in tattooing. It is also proposed to broaden the Schedule 6 generic entry so that it capture both alkyl and aryl derivatives of phenylenediamine.

Accordingly, the delegate's interim decision is to make relevant amendments to both the Schedule 6 generic entry for phenylenediamines, to broaden the scope of the current Appendix C entry to include skin tattooing preparations, and to make new listings in Appendix C to restrict all uses of the 1,2- and 1,3- isomers in products used for cosmetic purposes (mainly hair dyes) and skin colouration, where the potential for direct application to human skin exists.

The delegate has determined NOT to adopt ACCS recommendations for inclusion of Schedule 6 sub-clauses that provide an exemption for products listed in Appendix C. The current practice of using a 'dagger symbol' in the stem entry designating substances in the schedules that also have a listing in Appendix C seems to be a more appropriate mechanism for identifying such additionally restrictive conditions.

The delegate indicated that implementation of the Appendix C restrictions should be as early as possible, to reinforce the public health implications of allowing any further sale of products with the highest mutagenic potential. **An implementation date of 1 February 2015 for the Appendix C entry** is therefore applicable. For the **Schedule 6 amendment, the delegate has proposed an implementation date of 1 July 2015,** this is to allow for an orderly process of product re-labelling where necessary.

The delegate considered the relevant matters under section 52E (1) of the *Therapeutic Goods Act 1989*: (a) the risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; (d) the dosage, formulation, labelling, packaging and presentation of a substance; and (e) the potential for abuse of a substance.

Delegate's considerations

The delegate considered the following in regards to this proposal:

- Scheduling proposal;
- Public submissions received;
- ACCS advice;
- Section 52E of the *Therapeutic Goods Act 1989*;
- Scheduling factors;
- Other relevant information.

Public submissions on the interim decision

No public submissions were received.

Delegate's final decision

The delegate has confirmed the interim decision as no evidence has been received to alter the interim decision. The delegate has confirmed that the reasons for the final decision are in keeping with those for the interim decision.

Schedule 6 – Amendment

†PHENYLENEDIAMINES including alkylated and arylated derivatives 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 diethyl-para-phenylenediamine or dimethyl-para-phenylenediamine in opaque strip packaging provided the directions for use include the statement, "Do not discard testing solutions into the pool";
(c) in hair dye preparations **except** when the immediate container and primary pack are labelled with the following statements:

KEEP OUT OF REACH OF CHILDREN, and

WARNING – This product contains ingredients which may cause skin irritation to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye.

written in letters not less than 1.5 mm in height; or

(d) in eyelash and eyebrow tinting products when the immediate container and primary pack are labelled with the following statement:

WARNING – This product contains ingredients which may cause skin irritation to certain individuals, and when used for eyelash and eyebrow tinting may cause injury to the eye. A preliminary test according to the accompanying directions should be made before use. written in letters not less than 1.5 mm in height.

Appendix C – Amended Entry

PHENYLENEDIAMINES, including alkylated and arylated derivatives, in preparations for skin colouration, tattooing and dyeing of eyelashes or eyebrows **except** when included in Schedule 6.

Appendix C – New Entry

1,2-BENZENEDIAMINE in preparations for cosmetic use and skin colouration (including tattooing).

1,3-BENZENEDIAMINE in preparations for cosmetic use and skin colouration (including tattooing).

Appendix E, Part 2 –Amended Entry

Poisons	Standard statements
Phenylenediamines ~~and~~ including both alkylated and arylated phenylenediamines • in hair dyes.	A - For advice, contact a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor (at once). E1 - If in eyes wash out immediately with water.
• in preparations other than hair dyes.	A - For advice, contact a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor (at once). G1 -Urgent hospital treatment is likely to be needed. (Note – the words 'at once' to be added to instruction A). G3 - If swallowed, do NOT induce vomiting. E1 - If in eyes wash out immediately with water. S1 - If skin or hair contact occurs, remove contaminated clothing and flush skin and hair with running water.

Appendix F, Part 3 – Amended Entry

Poisons	Warning statements	Safety direction
Phenylenediamines ~~and~~ including both alkylated and arylated phenylenediamines • in hair dyes.	21. WARNING – This product contains ingredients which may cause skin irritation to certain individuals. A preliminary test according to accompanying directions should be made before use. This product must not be used for dying eyelashes or eye brows; to do so may be injurious to the eye.	
• in preparations other than hair dyes.	28. (Over) (Repeated) exposure may cause sensitisation.	1. Avoid contact with eyes. 4. Avoid contact with skin. 8. Avoid breathing dust (or) vapour (or) spray mist.

1.11 ROSIN

Scheduling decision

- To create a new Schedule 5 entry:

ROSIN when packaged for use as a soldering flux or in flux-cored solder.

- To delete the current Appendix B entry for COLOPHONY
- To create new Appendix F entries:

Part 1 – New Entry

108. Breathing of solder fumes is harmful and may cause asthma or sensitisation.

Part 2 – New Entry

37. Avoid breathing solder fumes

Part 3 – New Entry

Poison	Warning statements	Safety direction
Rosin	Breathing of solder fumes is harmful and may cause asthma or sensitisation.	Avoid breathing solder fumes.

- To create a new index entry:

COLOPHONY

See also ROSIN

- Implementation date, 1 July 2015

Scheduling proposal

The ACCS considered the following proposal referred by the delegate for advice:

- To place rosin in Schedule 5 with exemptions at low concentrations.

The committee considered and discussed the resolutions with an implementation date of 1 February/1 June/1 October 2015.

On 23 April 2014, NICNAS, under its IMAP programme, requested that the delegate consider a proposal to include rosin in Schedule 5.

The delegate's reason for referring this scheduling proposal to the ACCS was that while the scheduling of rosins has been previously considered by the NDPSC in 1997 and 1998, with no scheduling action taken, other than to list 'colophony' in Appendix B, NICNAS has again raised the issue of respiratory and skin sensitisation as a reason for developing a new schedule entry. Accordingly, this requires advice from the ACCS.

The delegate asked the ACCS the following questions:

- Does the ACCS support the rejection of previous NDPSC consideration of the health risks associated with rosins and their management by worker health and safety (WHS) authorities?
- If so, is listing in Schedule 5, with appropriate prescribed warning statements in Appendix F, the best way of managing non-occupational exposures to products (specifically solder flux) available to the general public?
- Can the ACCS recommend any cut-off concentration to exempt for a Schedule 5 entry?
- Under what name should the listing be made? Is the term 'ROSIN' sufficient, or should the listing include all the terms used in the NICNAS IMAP report? Should there be a cross-

reference to '*colophony*' in the SUSMP index and should the '*colophony*' entry in Appendix B be withdrawn?

- What types of consumer products are likely to be captured by Schedule 5 listing, and what advice does ACCS offer in relation to management of the regulatory impact?

Substance summary

Please refer to the NICNAS IMAP human health Tier II assessment report for *rosin, hydrogenated rosin and salts*. This report is publicly available on the NICNAS website: http://www.nicnas.gov.au/chemical-information/imap-assessments/imap-group-assessment-report?assessment_id=872.

Scheduling status

Rosin is listed as colophony in Appendix B.

Substance	Date of entry	Reason for listing	Area of use
Colophony	February 1997	b. Use pattern restricts hazard.	7. General 7.4 Flux

Scheduling history

Colophony was considered by the NDPSC in February 1997 and February 1998.

In February 1997, the NDPSC indicated that colophony was well recognised as a skin and respiratory system sensitiser, and at higher concentrations an irritant to skin, the respiratory tract and mucosal surfaces. The allergenicity and irritant properties depend, to some extent, on the composition of the products, and both acid and neutral components have been shown to play a role in sensitisation. The NDPSC noted that the main risk of adverse health effects from colophony exposure would be associated with exposure to fume while using "rosin" cored solders. There appears to be minimal risk of skin contact with "rosin" in the core of these solders because of their physical form. The risk attached to hobby use of these solders is probably much lower but asthmatics and very frequent users could experience adverse health effects. Safety Data Sheets and labels of local products did not adequately warn of health effects. The NDPSC agreed that health warning statements should appear on the product labels and noted that this could be done by reverse scheduling so that colophony could be exempt from scheduling on the condition that the product was labelled with the health warnings. It was also agreed that, because the main concern was with the thermal degradation products in solder, any health warnings should be confined to that type of colophony product.

Pre-meeting public submissions

One submission was received. The submission indicated that there are no restrictions in the EU or the USA for the use of these substances in cosmetics. The submissions requested that the substances be unscheduled.

Summary of ACCS advice to the delegate

The ACCS recommended that a new Schedule 5 entry be created for rosin when packaged for use as a soldering flux or in flux-cored solder. The committee, in addition, recommended appropriate Appendix E and F statements for rosin and a cross-index for colophony be created.

The ACCS recommended an implementation date of 1 July 2015.

The matters under subsection 52E (1) of the *Therapeutic Goods Act 1989* considered relevant by the Committee included: b) the purposes for which a substance is to be used and the extent of use of a substance.

The reason for the recommendation is:

- Respiratory sensitisation.

Delegate's interim decision

The delegate notes, and accepts, ACCS advice that the sensitising potential for rosins warrants inclusion in Schedule 5. The respiratory and skin sensitising potential has been well characterised for uses mainly associated with fumes generated when soldering using rosin-based solder flux and flux-cored solder. The delegate therefore agrees to create a new Schedule 5 entry for rosins, with appropriate warning statements in Appendix F relating to the risks of breathing these fumes. A consequent amendment is the need to delete the current Appendix E entry for colophony, an alternative name for rosins, and to make relevant cross-references in the SUSMP index.

The delegate indicated that a long implementation time is necessary to allow for orderly relabelling of any affected products therefore an **implementation date of 1 July 2015** is applicable for the scheduling decision.

The delegate considered the relevant matters under section 52E (1) of the *Therapeutic Goods Act 1989*: (a) the risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; and (c) the toxicity of a substance.

Delegate's considerations

The delegate considered the following in regards to this proposal:

- Scheduling proposal;
- Public submission received;
- ACCS advice;
- Section 52E of the *Therapeutic Goods Act 1989*;
- Scheduling factors;
- Other relevant information.

Public submissions on the interim decision

One submission was received which supported the delegate's interim decision to restrict the scheduling of rosin to when it is used as a soldering flux or in flux-cored solder.

Delegate's final decision

The delegate notes the submissions received in response to publication of the interim decision and confirms the interim decision as no evidence has been received to alter the interim decision.

Please note there was a typographical error in the interim decision. It should state "A consequent amendment is the need to delete the current Appendix B entry for colophony."

The delegate has confirmed that the reasons for the final decision are in keeping with those for the interim decision.

Schedule 5 – New Entry

ROSIN when packaged for use as a soldering flux or in flux-cored solder.

Appendix B – Delete Entry

COLOPHONY

Appendix F, Part 1 – New Entry

108. Breathing of solder fumes is harmful and may cause asthma or sensitisation.

Appendix F, Part 2 – New Entry

37. Avoid breathing solder fumes

Appendix F, Part 3 – New Entry

Poison	Warning statements	Safety direction
Rosin	Breathing of solder fumes is harmful and may cause asthma or sensitisation.	Avoid breathing solder fumes.

Index – New Entry

COLOPHONY

See also ROSIN

1.12 TOLUENEDIAMINE

Scheduling decision

- To amend the current Schedule 6 entry to include:

(c) in nail polish preparations containing 2,5-toluenediamine **except** when labelled 'avoid contact with skin'.

- To create a new Appendix C entry:

2,4-TOLUENEDIAMINE in preparations for skin colouration (including tattooing) and dyeing of hair, eyelashes or eyebrows.

- Implementation date, 1 February 2015 for the new Appendix C entry and 1 February 2016 for the amendment to the current Schedule 6 entry.

Scheduling proposal

The ACCS considered the following proposal referred by the delegate for advice:

- To amend the Schedule 6 toluenediamine group entry to exempt 1,3-benzenediamine, 2-methyl- from the Schedule 6 entry and create a new Appendix C entry for 1,3-benzenediamine, 2-methyl-.

- To amend the Schedule 6 toluenediamine group entry to exempt 1,3-benzenediamine, 4-methyl- and its salts and derivative from this entry and create a new Appendix C entry for hair dye and eyebrow/eyelash tinting preparations containing 1,3-benzenediamine, 4-methyl- and its salts and derivative.

- To amend the Schedule 6 toluenediamine group entry to include nail polish preparations containing toluenediamine.

The committee considered and discussed the resolutions with an implementation date of 1 February/1 June/1 October 2015.

On 23 April 2014, NICNAS, under its IMAP programme, requested the delegate consider a proposal to amend the Schedule 6 toluenediamine group entry to exempt 1,3-benzenediamine, 2-methyl- from the Schedule 6 entry and create a new Appendix C entry for 1,3-benzenediamine, 2-methyl-.

The reasons for the request were:

- systemic acute effects (acute toxicity from oral and dermal exposure). Safe Work Australia's HSIS indicates that this substance is 'Harmful if swallowed' and 'Harmful in contact with skin';
- local effects (skin sensitisation). Safe Work Australia's HSIS notes that this substance 'May cause sensitisation by skin contact'; and
- systemic long-term effects (mutagenicity). Safe Work Australia's HSIS notes that this substance has 'Possible risk of irreversible effects'.

Secondly, NICNAS proposed to amend the current Schedule 6 toluenediamine group entry to exempt 1,3-benzenediamine, 4-methyl from this entry and create a new Appendix C entry for hair dye and eyebrow/eyelash tinting preparations containing 1,3-benzenediamine, 4-methyl-.

The reasons for the request were:

- systemic acute effects - acute toxicity from oral and dermal exposure;
- local effects (skin sensitisation and eye irritation);
- systemic long-term effects - carcinogenicity, genotoxicity and reproductive toxicity; and
- the substance may also cause harmful effects following repeated oral exposure.

Thirdly, NICNAS proposed that the current Schedule 6 toluenediamine group entry be amended to include nail polish preparations containing toluenediamine.

The reasons for this request were:

- systemic acute effects (by the oral, dermal and inhalation route);
- local effects (skin sensitisation and eye irritation); and
- the chemical may also cause harmful health effects following repeated oral exposure.

The NICNAS IMAP programme referred three toluenediamine isomers for scheduling consideration. These isomers are the 2,4 -diamine, 2,5 -diamine and 2,6 -diamine. There are existing generic SUSMP entries for toluenediamine in Schedule 6 and Appendices C, E and F. The Schedule 6 entry exempts preparations for dyeing hair and eyelash/eyebrow when labelled with warning statements for skin irritation and eye damage, while the Appendix C entry precludes use in preparations for skin colouration and dyeing eyelash/eyebrow (except when in Schedule 6).

The NICNAS scheduling proposals for the three isomers are comparable and the delegate has determined that they be considered as a group, addressing possible revision of the current SUSMP entries for toluenediamine.

The delegate asked the ACCS the following questions:

- Does the ACCS consider that the NICNAS IMAP reports have raised issues that require amendment to the existing entries for TOLUENEDIAMINE in Schedule 6, or Appendices C, E and F? Specifically, is there a requirement to list any of the three isomers as separate entries from the generic one?
- Is the existing generic entry in Schedule 6 and Appendices E & F sufficiently clear, given that it exempts any hair dye and eyelash/eyebrow dyeing preparations containing a toluenediamine when labelled with the prescribed warning statements? The scheduling history of this generic entry is quite complex. Are there likely to be any toluenediamines left in the generic entry if it is amended to exclude the 2,4-, 2,5- and 2,6 -isomers?
- Is the existing generic entry in Appendix C sufficiently clear, given that it prevents use of any toluenediamine in skin colouration preparations, but also prevent use in eyelash/eyebrow dyeing preparations, except when covered by the Schedule 6 entry (which provides an exemption for appropriately labelled preparations)?
- Is the mutagenicity potential for the 2,4- and 2,6 -isomers (but not the 2,5 -isomer) sufficient reason to prevent their use in all hair dye and eyelash/eyebrow dyeing preparations, by creating a separate entry in Appendix C banning these uses?
- Is there a need to create a specific amendment to the generic entry to cover the use of the 2,5 -isomer in nail polish preparations, or is a separate entry required for this use?
- Given the sensitising potential of the three isomers, are additional warning statements needed to specifically address this toxic endpoint, or are the existing warning statements (intended to cover sensitisation potential) adequate?
- Considering the mutagenicity potential for the 2,4- and 2,6- isomers, are there any other types of preparations available to the public that would require inclusion in a Schedule 6 (or 7?) entry?
- Are there any other toluenediamines in the current schedules, or is the current wording of the Schedule 6 entry (… not elsewhere specified in these schedules) redundant?

Substance summary

Please refer to the NICNAS IMAP human health Tier II assessment reports for: *1,3-benzenediamine, 2-methyl-; 1,3-benzenediamine, 4-methyl-; 1,3-benzenediamine, 4-methyl-, sulfate;* and *1,4-benzenediamine, 2-methyl-*. These reports are publicly available on the NICNAS website:

http://www.nicnas.gov.au/chemical-information/imap-assessments/imap-assessment-details?assessment_id=851;

http://www.nicnas.gov.au/chemical-information/imap-assessments/imap-assessment-details?assessment_id=831;

http://www.nicnas.gov.au/chemical-information/imap-assessments/imap-assessment-details?assessment_id=936; and

http://www.nicnas.gov.au/chemical-information/imap-assessments/imap-assessment-details?assessment_id=869.

Scheduling status

1,3-benzenediamine, 4-methyl-; 1,3-benzenediamine, 2-methyl-; 1,3-benzenediamine, 4-methyl-, sulfate; and 1,4-benzenediamine, 2-methyl- are not specifically scheduled. As 1,3-benzenediamine, 4-methyl-; 1,3-benzenediamine, 2-methyl-; 1,3-benzenediamine, 4-methyl-, sulfate; and 1,4-

benzenediamine, 2-methyl- belong to the chemical group toluenediamine, which is in Schedule 6 and Appendices C, E and F.

Schedule 6

†TOLUENEDIAMINE not elsewhere specified in these Schedules:

(a) in hair dye preparations **except** when the immediate container and primary pack are labelled with the following statements:

KEEP OUT OF REACH OF CHILDREN, and

WARNING – This product contains ingredients which may cause skin irritation to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye.

written in letters not less than 1.5 mm in height; or

(b) in eyelash and eyebrow tinting products when the immediate container and primary pack are labelled with the following statement:

WARNING – This product contains ingredients which may cause skin irritation to certain individuals, and when used for eyelash and eyebrow tinting may cause injury to the eye. A preliminary test according to the accompanying directions should be made before use.

written in letters not less than 1.5 mm in height.

Appendix C

TOLUENEDIAMINE in preparations for skin colouration and dyeing of eyelashes or eyebrows **except** when included in Schedule 6.

Appendix E

Poisons	**Standard statements**
Toluenediamine • in hair dyes.	A - For advice, contact a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor (at once). E1 - If in eyes wash out immediately with water.
• in other preparations.	A - For advice, contact a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor (at once). G1 - Urgent hospital treatment is likely to be needed. (Note – the words 'at once' to be added to instruction A). G3 - If swallowed, do NOT induce vomiting. E1 - If in eyes wash out immediately with water. S1 - If skin or hair contact occurs, remove contaminated clothing and flush skin and hair with running water.

Appendix F

Poisons	Warning statements	Safety direction
Toluenediamine • in hair dyes.	21. WARNING – This product contains ingredients which may cause skin irritation to certain individuals. A preliminary test according to accompanying directions should be made before use. This product must not be used for dying eyelashes or eye brows; to do so may be injurious to the eye.	
• in other preparations.		1. Avoid contact with eyes. 4. Avoid contact with skin. 8. Avoid breathing dust (or) vapour (or) spray mist.

Scheduling history

In January 1955, the CPS decided to list phenylene toluene and other alkylated benzene diamines in Schedule 2. At that time Schedule 2 substances were considered to be poisons, the sale of which was restricted to certain specified categories of vendors and which were subject to identical packing and labelling requirements to those of Schedule 1 but which were not required to be entered in a poisons register.

In March 1980, the PSC decided to delete the Schedule 6 aromatic amines entry and amend the Schedule 6 phenylene diamines entry to include alkylated phenylene diamines.

In May 1985, the PSC noted that a number of phenylene diamines in Schedule 6 listing were individually listed as well as being included in the general entry for phenylene diamines. The PSC agreed that the individual entries were not required in addition to the general entry for phenylene diamines and decided to delete the individual entries. The PSC agreed that no change was required to the Schedule 2 phenylene diamines entry.

In August 2000, the NDPSC agreed to exempt hair dye products containing phenylenediamines or toluenediamines from scheduling, conditional upon specified labelling.

In February and June 2004, the NDPSC considered the outcomes of investigations into incorrectly packed and labelled eyelash/brow tints containing phenylenediamines/toluenediamine and in October 2004, the NDPSC agreed to foreshadow amendments to prohibit use for eyelash/brow tinting. This proposal was varied by the February 2005 NDPSC meeting which instead agreed to foreshadow two options: to allow either salon use only, or all domestic use, of these eyelash/brow tints as Schedule 6 products (when compliant with the specified labelling).

In June 2005, the NDPSC concluded that the potential risk of causing a strong allergic response in a small number of individuals could be minimised through appropriate labelling. The NDPSC therefore agreed to that eyelash/brow tints were Schedule 6 poisons when appropriately labelled.

In June 2006, the NDPSC considered a request for flexibility in applying the mandatory labelling for eyelash/brow tints containing phenylenediamine and toluenediamine. The NDPSC indicated

that, as the main risk was sensitisation, which in this case did not demonstrate a clear dose response, strong label warnings were required before such products could be available as Schedule 6. As there was a risk of separation of an outer pack from the immediate container, it was appropriate that all mandatory labelling continued to be applied to the immediate container, regardless of pack size. That the Schedule 6 warning statement would need to be applied, whether the use was domestic or industrial, or the product would default to Appendix C. The NDPSC further confirmed that the introduction to both Appendix E and F provided sufficient flexibility to allow for variation of product use and formulation.

In February 2007, the NDPSC considered the labelling requirements for single use composite pack hair preparations, including those containing phenylenediamines or toluenediamine, in view of amending various references to 'hair dyes' to 'hair preparations'. The NDPSC decided not to amend these references as there was potential for inadvertent capture of products for non-dying use patterns.

In February 2008, the NDPSC considered the scheduling of phenylenediamine and toluenediamine in eyelash/brow tints including restricting non-professional supply to ≤ 5 mL and limiting non-professional supply to 'complete kit' forms (i.e. all reagents). The NDPSC agreed that it was not appropriate to address separate supply of a developer for eyelash/brow tinting through the scheduling process as there was little evidence of an actual public health risk from products not being sold in 'complete kit' form. The NDPSC also agreed that there was little evidence to support a pack size restriction on the availability of eyelash/brow tints containing phenylenediamine / toluenediamine.

Pre-meeting public submissions

One submission was received. The submission indicated that any scheduling change should be aligned with the EU. An extended implementation period of 24 months should be given if the substance is currently in use.

Summary of ACCS advice to the delegate

The ACCS recommended that a new clause be added to the Schedule 6 entry to allow exemption of nail polishes containing the 2,5 isomer when labelled 'avoid contact with skin'. The committee also recommended that the current Appendix C entry be amended, so that all cosmetic products containing the 2,4-toluenediamine isomers (including hair dyes and eyelash/eyebrow tinters) are prohibited and no longer qualify for inclusion in Schedule 6 or for the exemption clauses.

The ACCS recommended an implementation date of 1 February 2015 for the Appendix C entry. For the amended Schedule 6 entry, the committee recommended an implementation date of 1 July 2015.

The matters under subsection 52E (1) of the *Therapeutic Goods Act 1989* considered relevant by the Committee included: c) the toxicity of a substance.

The reasons for the recommendation comprised the following:

- Genotoxicity and carcinogenicity of 2,4-toluenediamine.
- 2,5-Toluenediamine's risk of skin sensitisation that can be mitigated with appropriate labelling.

Delegate's interim decision

The scheduling of the toluenediamines is complex. It uses a combination of listing in Appendix C, to restrict their use in certain types of dye products where the risks of skin/eye irritancy are unacceptable (skin colouration and dyeing of eyebrows and eyelashes), and listing in Schedule 6 for hair dyes and other permitted products where label warning statements can provide appropriate protection to product users. In considering the current recommendations in the four NICNAS IMAP

reports, the delegate accepts the advice of the ACCS relating to the need for further restrictions on the use of 2,4-toluenediamine and 2,6-toluenediamine (isomers designated in the NICNAS reports with highest mutagenic potential), and that the Appendix C entries be broadened to ensure that the prohibition of their use for skin colouration includes use in tattooing.

Accordingly, the delegate's interim decision is to make relevant amendments to both the Schedule 6 generic entry for toluenediamines, to broaden the scope of the current Appendix C entry to include skin tattooing preparations, and to make new listings in Appendix C to restrict all uses of the 2,4-isomer in products used for cosmetic purposes (mainly hair dyes) and skin colouration, where the potential for direct application to human skin exists. The delegate notes that the ACCS considered the mutagenic potential of the 2,6-isomer to be equivocal and that there was no recommendation to include this isomer in the Appendix C listing.

The delegate has determined NOT to adopt the ACCS recommendations for inclusion of a Schedule 6 sub-clause that references products listed in Appendix C. The current practice of using a 'dagger symbol' in the stem entry designating substances in the schedules that also have a listing in Appendix C seems to be a more appropriate mechanism for identifying such additionally restrictive conditions. Furthermore, the delegate does NOT accept ACCS recommendations to delete the Schedule 6 sub-clauses that relate to labelling and use in hair dye and eyelash/eyebrow tinting products. Such a recommendation would remove controls over all toluenediamines other than the 2,4-isomer in such products.

The delegate does accept ACCS advice that a new sub-clause be added to the Schedule 6 entry to allow for an appropriate warning statement for nail polish preparations containing the 2,5-isomer.

The delegate indicated that implementation of the Appendix C restrictions should be as early as possible, to reinforce the public health implications of allowing any further sale of products with the highest mutagenic potential. **An implementation date of 1 February 2015 for the Appendix C entry** is therefore applicable. For the **Schedule 6 amendment, the delegate has proposed an implementation date of 1 July 2015**, this is to allow for an orderly process of product re-labelling where necessary.

The delegate considered the relevant matters under section 52E (1) of the *Therapeutic Goods Act 1989*: (a) the risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; (d) the dosage, formulation, labelling, packaging and presentation of a substance; and (e) the potential for abuse of a substance.

Delegate's considerations

The delegate considered the following in regards to this proposal:

- Scheduling proposal;
- Public submissions received;
- ACCS advice;
- Section 52E of the *Therapeutic Goods Act 1989*;
- Scheduling factors;
- Other relevant information.

Public submissions on the interim decision

One submission was received which supported the delegate's interim decision but requested a six month extension of the implementation date for the Schedule 6 amendment only. This would allow for orderly labelling of any affected products.

Delegate's final decision

The delegate notes the submissions received in response to publication of the interim decision and, except for changing the proposed implementation date, confirms the interim decision as no evidence has been received to alter the interim decision. The delegate has confirmed that the reasons for the final decision are in keeping with those for the interim decision.

The delegate agrees to a revised implementation date of 1 February 2016 for the Schedule 6 entry. The delegate notes that delayed publication of the interim decision justifies the requested extension of the implementation date to enable orderly re-labelling of affected products.

Schedule 6 – Amendment

†TOLUENEDIAMINE not elsewhere specified in these schedules

(a) in hair dye preparations **except** when the immediate container and primary pack are labelled with the following statements:

KEEP OUT OF REACH OF CHILDREN, and

WARNING – This product contains ingredients which may cause skin irritation to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye.

written in letters not less than 1.5 mm in height; or

(b) in eyelash and eyebrow tinting products when the immediate container and primary pack are labelled with the following statement:

WARNING – This product contains ingredients which may cause skin irritation to certain individuals, and when used for eyelash and eyebrow tinting may cause injury to the eye. A preliminary test according to the accompanying directions should be made before use.

written in letters not less than 1.5 mm in height; or

(c) in nail polish preparations containing 2,5-toluenediamine **except** when labelled 'avoid contact with skin'.

Appendix C – New Entry

2,4-TOLUENEDIAMINE in preparations for skin colouration (including tattooing) and dyeing of hair, eyelashes or eyebrows.