Australian Government
Department of Health and Ageing
NICNAS

INVENTORY MULTI-TIERED ASSESSMENT AND PRIORITISATION (IMAP)

HUMAN HEALTH TIER II ASSESSMENT FOR

Xylenes

Chemical name in AICS	CAS Number
Benzene, 1,2-dimethyl-	95-47-6
Benzene, 1,4-dimethyl-	106-42-3
Benzene, 1,3-dimethyl-	108-38-3
Benzene, dimethyl-	1330-20-7

PREFACE

As part of the reform regarding assessment of Existing Chemicals, the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is implementing a new framework to address the human health and environmental impacts of industrial chemicals, not yet assessed, on the Australian Inventory of Chemical Substances (AICS).

The framework provides a more rapid, flexible and transparent approach for the assessment of existing chemicals.

The Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework was developed, with significant input from stakeholders, and will be applied in stages.

Stage One of this program, which will take three years, started 1 July 2012 and is examining 3000 chemicals meeting characteristics identified by stakeholders as needing priority assessment. This includes chemicals for which NICNAS already holds exposure information, chemicals identified as a concern or for which regulatory action has been taken overseas, and chemicals detected in international studies analysing chemicals present in babies' umbilical cord blood.

The IMAP framework is a science and risk-based model designed to align the assessment effort with the human health and environmental impacts of chemicals. It has three tiers of assessment, with the assessment effort increasing with each tier. The Tier I assessment is a high throughput approach using tabulated electronic data. The Tier II assessment is an evaluation of risk on a substance-by-substance or chemical category-by-category basis. Tier III assessments are conducted to address specific concerns that could not be resolved during the Tier II assessment.

This chemical/group of chemicals is/are being assessed at Tier II because the Tier I assessment indicated that it needed further investigation.

For more detail on the new program please visit: www.nicnas.gov.au

ACRONYMS & ABBREVIATIONS

ACToR	Aggregated Computational Toxicology Resource (US)
AICS	Australian Inventory of Chemical Substances
ASTDR	Agency for Toxic Substances and Disease Registry (US)
bw	bodyweight
CAS	Chemical Abstracts Service
CFR	Code of Federal Regulations (US)
CHO	Chinese hamster ovary
CosIng	Cosmetic Ingredients and Substances database (EU)
d	day
DNA	Deoxyribonucleic acid
EC	European Commission
EC3	Estimated concentration three
ECHA	European Chemicals Agency
ESIS	European Chemical Substances Information System
EU	European Union
EU RAR	European Union Risk Assessment Report
FDA	Food and Drug Administration (US)
FSANZ	Food Standards Australia and New Zealand
g	gram
g/mol	grams per mole
GHS	Globally Harmonized System of Classification and Labelling of Chemicals*
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GPMT	Guinea Pig Maximisation Test
h	hour
HGPRT	hypoxanthine guanine phosphoribosyltransferase
HPV	high production volume
HSDB	Hazardous Substances Data Bank
HSIS	Hazardous Substances Information System
HVICL	High Volume Industrial Chemicals List
IARC	International Agency for Research on Cancer
INCHEM	International Programme on Chemical Safety (also known as IPCS)
INCI	International Nomenclature of Cosmetic Ingredients
ip	intraperitoneal
IRIS	Integrated Risk Information System (US)
IUCLID	International Uniform Chemical Information Database
iv	intravenous
kg	kilogram
L	litre
LC50	median lethal concentration
LD50	median lethal dose
LCLo	lowest published lethal concentration
LLNA	local lymph node assay
LOAEL	lowest observed adverse effect level
LOEL	lowest observed effect level
m^3	cubic metre
mg	milligram
mg/cm^3	milligrams per cubic centimetre
mg/kg bw/d	milligrams per kilogram bodyweight per day
min	minute
mL	millilitre
µg	microgram
µL	microlitre
(m)SDS	(material) Safety Data Sheet

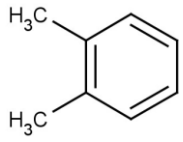
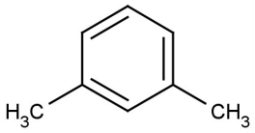
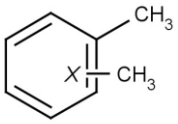
NIOSH	National Institute for Occupational Safety and Health (US)
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
NOHSC	National Occupational Health and Safety Commission
NTP	National Toxicology Program (US)
OECD	Organisation for Economic Cooperation and Development
OEL	occupational exposure limit
PCBU	person conducting a business or undertaking
PEL	permissible exposure limit
PND	postnatal day
ppb	parts per billion
PPE	personal protective equipment
ppm	parts per million
REACH	Registration Evaluation Authorisation of Chemicals (ECHA)
SD	Sprague Dawley
SIAP	SIDS Initial Assessment Profile (OECD)
SIAR	SIDS Initial Assessment Report (OECD)
SIDS	Screening Information Data Set (OECD)
SMILES	simplified molecular-input line-entry system
SPIN	Substances in Preparations In the Nordic countries
STEL	short-term exposure limits
STV	short-term value
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons (The Poisons Standard**)
TCLo	lowest published toxic concentration
TEEL	temporary emergency exposure limits
TSCA	Toxic Substances Control Act (US EPA)
TG	test guideline
TGA	Therapeutic Goods Administration
TLV	threshold limit values
TWA	time weighted average
UN	United Nations
US	United States of America
US EPA	United States Environmental Protection Agency
WHS	Work, Health and Safety
wt	weight
w/w	weight per weight

Glossary

NICNAS uses the IPCS Risk Assessment Terminology (IPCS, 2004) glossary, which includes:
Part 1: IPCS/OECD Key Generic Terms used in Chemical Hazard/Risk Assessment; and
Part 2: IPCS Glossary of Key Exposure Assessment Terminology.
The IPCS Risk Assessment Terminology can be accessed at:
http://www.who.int/ipcs/methods/harmonization/areas/ipcsterminologyparts1and2.pdf

*****Globally Harmonised System of Classification and Labelling of Chemicals (GHS) United Nations, 2009. Third edition. Can be accessed at: http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html

******The Poisons Standard (the SUSMP) can be accessed at: http://www.tga.gov.au/industry/scheduling-poisons-standard.htm

Chemical Name in AICS (Including Synonyms)	CAS Number	Structural Formula	Molecular Formula	Molecular Weight (g/mol)
Benzene, 1,2-dimethyl- o-xylene ortho-xylene o-xylol o-dimethylbenzene	**95-47-6**		C8H10	106.17
Benzene, 1,3-dimethyl- m-dimethylbenzene m-xylene meta-xylene m-xylol	**108-38-3**		C8H10	106.17
Benzene, 1,4-dimethyl- p-dimethylbenzene p-xylene para-xylene p-xylol	**106-42-3**		C8H10	106.17
Benzene, dimethyl- xylol Mixed xylenes	**1330-20-7**		C8H10	106.17

Grouping Rationale

Three members of the group xylenes: o-xylene (95-47-6), m-xylene (108-38-3) and p-xylene (106-42-3) are chemical isomers differing only in the position of the methyl groups on the benzene ring. The fourth member, mixed xylenes (1330-20-7) is a mixture of these three isomers. In addition, mixed xylenes typically contains 15-20% of ethylbenzene (100-41-4). Ethylbenzene is not being assessed as part of this group.

Mixed xylenes is the dominant form of xylene used in Australia. Assessment of mixed xylenes has to take account of the properties of each of the individual isomers. The members of the group mostly have similar physicochemical properties and demonstrate similar local and systemic toxic effects where data are available for all members.

The members of the group have similar reported uses.

Import, Manufacture and Use

Australian

Australian use and/or volume information is available for o-xylene, p-xylene and mixed xylenes from previous mandatory and/or voluntary calls for information.

o-xylene has reported commercial use including:
- industrial coatings
- automotive performance additive.

Mixed xylenes has reported site-limited use including:
- manufacture of other chemicals.

Mixed xylenes has reported commercial use including:
- component of fuel
- industrial and automotive surface coatings
- inks and cleaners in screen and lithographic printing
- lacquers and solvents

The total volume introduced into Australia reported for o-xylene under previous mandatory and/or voluntary calls for information was >0.09 tonnes.

Mixed xylenes is listed on the 2006 High Volume Industrial Chemicals List (HVICL) with a total reported volume between 10,000 tonnes and 99,999 tonnes.
Although no use data is available for p-xylene, the total volume introduced into Australia reported under previous mandatory and/or voluntary calls for information was 15 kg.

The National Pollutant Inventory (NPI) holds data for all sources of xylenes (individual or mixed isomers) in Australia.

International

The following international uses have been identified through the European Union Registration, Evaluation and Authorisation of Chemicals (EU REACH) dossiers, the Organisation for Economic Cooperation and Development Screening information data set International Assessment Report (OECD SIAR), Galleria Chemica, Substances and Preparations in the Nordic countries (SPIN) database, the European Commission Cosmetic Substances and Ingredients (CosIng) database and United States (US) Personal Care Products Council International Nomenclature of Cosmetic Ingredients (INCI) directory.

The chemicals have reported site-limited use including:
- manufacture of other chemicals (this is considered the predominant use for o-xylene, m-xylene and p-xylene)
- manufacture of textiles
- manufacture of plastics

The chemicals have reported commercial use including:
- fuel (this is considered the predominant use for mixed xylenes)
- in lubricants
- photographic chemicals
- drilling mud additives

The chemicals have reported domestic use. The individual isomers, o-xylene, m-xylene and p-xylene are reported to be present in a range of home maintenance and auto products (liquid) up to a concentration of 5%. p-Xylene also is reported to be present in printer cartridges. Mixed xylenes is reported to be present in a large number of home maintenance and auto products (liquid, aerosol and paste) up to a concentration of 95% (Household Products Database, HHPD).

The chemicals are included in CosIng database and US Personal Care Products Council INCI directory with the identified functions of masking, solvent and perfuming. However, there is currently no documented use of xylenes in cosmetic products in the United States (Personal Care Products Council 2011) and historical use in nail polishes in Europe appears to be being phased out (Sainio et al 1997).

Restrictions

Australian

Xylenes are listed in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) in schedule 5 and 6. Schedule 6 applies **except** in preparations containing 50% or less of xylene, or xylene and toluene. Schedule 5 applies except where Schedule 6 is applicable (Therapeutic Goods Administration).

Schedule 6 chemicals are labelled with 'Poison'. These are substances with a moderate potential for causing harm, the extent of which can be reduced by using distinctive packaging with strong warnings and safety

directions on the label.

Schedule 5 chemicals are labelled with 'Caution'. These are substances with a low potential for causing harm, the extent of which can be reduced through the use of appropriate packaging with simple warnings and safety directions on the label.

International

No international restrictions have been identified.

Existing Hazard Classification for Worker Health and Safety

The chemicals are all classified as hazardous with the following risk phrases for human health in the Hazardous Substances Information System (HSIS) (SWA HSIS 2013):

Xn; R20/21 (acute toxicity)
Xi; R38 (irritation)

Exposure Standards

Australian

Xylene (o-, m-, p- isomers) have an exposure standard of 350 mg/m³ (80 ppm) time weighted average (TWA) and 655 mg/m³ (150 ppm) short-term exposure limit (STEL) (SWA HSIS 2013). The exposure standards are not clearly linked to the CAS registry numbers for the chemicals and therefore there is uncertainty in the exposure standard for mixed xylenes.

International

The following exposure standards are identified for mixed xylenes and the individual isomers (Galleria Chemica):
An exposure limit (TWA) of 108–435 mg/m³ (25–100 ppm) in different countries such as USA, Canada, Denmark, Norway and Switzerland.

Health Hazard Information

Toxicokinetics

The individual isomers have similar absorption, distribution, and excretion patterns.

Xylenes are readily absorbed, particularly through inhalation and ingestion. Following absorption, xylenes are rapidly distributed throughout the body by systemic circulation. The majority of absorbed xylenes (72-95%) are excreted in the urine as the methylhippuric acid. Approximately 5% of absorbed xylenes are excreted unchanged in exhaled air. Elimination from most tissue compartments is rapid, with slower elimination from muscle and adipose tissue (ASTDR 2007; OECD 2003).

Acute Toxicity

Oral

The chemicals all exhibit low acute toxicity in animal tests as evidenced by reported oral median lethal dose (LD50) in rats of greater than 2000 mg/kg bw (OECD 2003; ASTDR 2007). Observed sub-lethal effects included those consistent with central nervous system depression.

Dermal

Mixed xylenes and the individual isomers are classified as hazardous with the risk phrase ‘Harmful in contact with skin’ (Xn; R21) in HSIS (SWA HSIS 2013). While the available data do not support this classification (LD50s reported between 3328–12180 mg/kg bw) (OECD 2003; ASTDR 2007), in the absence of more comprehensive information, the available data are not sufficient to recommend removal of the current HSIS classification.

Inhalation

Mixed xylenes and the individual isomers are currently classified as hazardous with the risk phrase ‘Harmful by inhalation’ (Xn; R20) in HSIS (SWA HSIS 2013). The reported 4-hour LC50 for p-xylene (LC50 of 20 mg/L in rats) support the classification. Reported available 6-hour LC50 for mixed xylenes and the individual isomers

(18.8–25.9 mg/L (4330–5984 ppm) in rats and 16.9–22.8 mg/L (3907–5267) in mice) are also generally supportive of the classification (OECD 2003; ASTDR 2007). Sublethal effects observed include adverse respiratory effects (laboured breathing, irritation of the respiratory tract, pulmonary oedema, pulmonary haemorrhage, and pulmonary inflammation) and those consistent with central nervous system depression. Ototoxic effects (hearing) have also been observed following acute exposure to approximately 1500 ppm.

Observation in humans

Deaths in humans have been reported following acute exposure to high concentrations of xylenes (ingestion of large, but undetermined quantity and inhalation exposure for several hours of 10,000 ppm) (ASTDR 2007). At lower concentrations, neurotoxic effects have been reported (see **neurotoxicity** below).

Irritation / Corrosivity

Skin Irritation

Mixed xylenes and the individual isomers are classified as hazardous with the risk phrase 'Irritating to skin' (Xi; R38) in HSIS (SWA HSIS 2013). Although sufficient information was not available to allow direct comparison with the classification criteria, the available data are generally supportive of this classification, with mild to moderate irritation observed in several species for mixed xylenes and the isomers m-xylene and o-xylene (ASTDR 2007).

Eye Irritation

Whilst irritation of the conjunctiva has been observed following instillation of mixed xylenes or m-xylene into the eyes of rabbits, sufficient information is not available to classify xylenes as eye irritants. No effects were observed in the corneas. In addition, although eye irritation has been observed in humans (see below), significant ocular lesions have not been observed in the absence of external factors (ASTDR 2007; REACH 2011).

Observation in humans

Cases of skin, eye and respiratory irritation following human exposure to xylenes have been reported.

Acute dermal exposure to xylenes has been associated with transient skin erythema (irritation) and dry and scaly skin (ASTDR, 2007).

Several studies in humans have reported eye irritation following exposure to xylene vapour at concentrations as low as 100 ppm. Loss of the corneal epithelium has been reported following direct contact of the eye with heated xylene from a pressurised hose. However the severity of the damage might have been influenced by thermal and physical effects (ASTDR 2007).

Nose and throat irritation have been reported following exposure to xylenes at 50–200 ppm or following chronic exposure to vapours of mixed xylenes at a geometric mean TWA concentration of 14 ppm. Limited effects on pulmonary function were observed at these doses (ASTDR 2007).

Sensitisation

Skin sensitisation

Mixed xylenes is reported to give a weak positive result in a mouse local lymph node assay with a stimulation index (SI) of 3.1 (REACH 2011). This response was only observed with 100% xylene. No other animal test data are available. Equivocal evidence of skin sensitisation in humans is available (see below).

Observation in humans

Skin sensitisation was not produced in any of 24 volunteers in a human maximisation test with xylene tested at 100% and subjects challenged at 25%. There is one case report of a person developing an allergic skin reaction (contact urticaria) following exposure for several months (predominantly <100 ppm xylene vapour). The person subsequently tested positive in a patch test suggesting that the reaction was immunologically mediated (ASTDR 2007; REACH 2011).

Although a weak positive (SI of 3.1) was observed in a single animal study, xylenes are not predicted (using the OECD QSAR Toolbox) to be protein binders. Given the widespread use of xylenes and absence of demonstrated sensitisation potential, xylenes are not considered to be sensitisers.

Repeat dose toxicity

Oral

Mild effects in the liver, including increased liver enzyme activities and increased liver weights, have been observed in animal tests with both mixed xylenes and the individual isomers. In the majority of cases histopathological changes were not observed. Reduced body weight gain was also observed in these studies, with minimal chronic nephropathy observed in one study. The NOAEL from the longest (two year) oral toxicity study is 250 mg/kg bw/day (ASTDR 2007; OECD 2003)

Clinical signs consistent with central nervous system toxicity have been observed in rats and mice following oral exposure to mixed xylenes typically at doses $\geq$ 800 mg/kg bw/day (ASTDR 2007).

Dermal

No chronic repeat-dose dermal toxicity data were available. A reduction in motor activity was observed in pregnant rats dermally exposed to xylene (form not specified) at 2000 mg/kg/day throughout gestation with reduced brain cholinesterase and inhibited foetal brain cholinesterase reported at doses of 200 and 2000 mg/kg bw/day (ASTDR 2007).

Inhalation

The critical effects observed in animals following inhalation exposure of xylenes are neurobehavioural effects. These are further described in **developmental toxicity and neurotoxicity** below.

Mild effects in the liver, including increased liver enzyme activities and increased liver weights, have been observed in animal tests with both mixed xylenes and the individual isomers. Minor histopathological changes suggest mild hepatic toxicity.

No effect on absolute or relative lung weights, or histopathological changes in the lungs, were reported in any studies.

Observation in humans

Reported adverse effects in humans following repeated exposure to xylenes relate to irritation (see above) and neurotoxicity (see below).

Genotoxicity

The genotoxicity of xylenes has been extensively investigated with consistently negative results reported in a variety of *in vitro* and *in vivo* assays and test systems (bacteria, yeast, insects, cultured mammalian cells, mice, rats, and humans). Based on the weight of evidence, xylenes are not considered genotoxic (OECD 2003; ASTDR 2007).

Carcinogenicity

Mixed xylenes was not carcinogenic in rats and mice treated orally up to and including the highest dose levels (500 and 1000 mg/kg bw/d) for rats and mice. Dermal exposure of mixed xylenes to the skin for 25 weeks resulted in no increase in skin tumours.

The International Agency for Research on Cancer (IARC) determined that there is 'inadequate evidence' in humans and in experimental animals for the carcinogenicity of xylenes (IARC, 1999).

Reproductive and developmental toxicity

Reproductive toxicity

A number of developmental studies (in rats, rabbits and mice) for the individual isomers and mixed xylenes are available for exposure by the inhalation route. The lowest reported NOAEL for developmental effects was 100 ppm. At this dose a reduction in foetal bodyweight was observed in the absence of maternal toxicity. At higher concentrations, developmental effects included skeletal variations, weight retardation and spontaneous abortions. Given limitations in the documentation of a number of the studies, it is difficult to determine whether these effects are secondary to maternal toxicity. These effects occurred at concentrations above those at which neurobehavioral effects have been observed (see **neurotoxicity** below) (ASTDR 2007; OECD 2003).

Neurobehavioural effects in offspring resulting from exposure during gestation have been reported in a number of studies, although evidence is not strong or consistent. A LOAEL of 500 ppm has been established based on

impaired performance in behavioural tests for neuromotor abilities (Rotarod) and for learning and memory (Morris water maze) in female rats exposed gestationally (days 7-20) to mixed xylenes (ASTDR 2007; US EPA 2003).

Other Health Effects

Neurotoxicity

Minor neurotoxic effects, including dizziness and impairment in reaction time, have been observed in humans following exposure to concentrations of 50-400 ppm (ASTDR, 2007).

A number of animal studies, which investigated the neurotoxic effects of xylenes, were available. Generally, a LOAEL of 100 ppm was established based on the lowest dose tested. Effects observed included decreased neuromotor abilities, increased sensitivity to pain, and impaired learning. Sensory deficits resulting from xylene exposure have been observed following repeated exposure at concentration levels around 800 ppm (ASTDR 2007).

Risk Characterisation

Critical Health Effects

The predominant route of exposure to xylenes is inhalation, therefore the critical health effects for risk characterisation are neurobehavioural effects. These have been observed in humans following exposure to concentrations of 50-400 ppm. Respiratory and ocular irritation effects have been observed at similar concentrations.

At higher concentrations, xylenes have the potential to cause systemic long-term effects including developmental toxicity and ototoxicity. Death may occur following exposure to very high concentrations. Skin and eye irritation have also been observed in occupational settings.

Public Risk Characterisation

The public are most likely to be exposed to xylene from petrol, automotive exhaust or when using consumer products containing xylene, especially if there is poor ventilation.

A number of studies investigating concentrations of xylenes in indoor and outdoor air are available. The levels found in air, even in homes after redecoration, painting, and varnishing (< 82 ppb) were several orders of magnitude below the levels at which the critical health effects have been observed. Whilst levels detected at self-serve petrol stations were higher (median concentration of 0.15 ppm), exposure to these levels would be for very short periods of time (ASTDR 2007). Therefore the risk to public health is not considered to be unreasonable.

Xylenes are listed in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) in schedules 5 and 6. Schedule 6 applies **except** in preparations containing 50% or less of xylene, or xylene and toluene. Schedule 5 applies except where Schedule 6 is applicable. A number of warning statements, first aid instructions and safety directions relating to skin and eye contact and inhalation of vapours apply. The current controls are considered adequate to minimise the risk to public health posed by domestic products containing the chemical.

Based on information on xylenes use in cosmetics internationally (see **International uses** above) significant use of xylenes in cosmetics is not anticipated in Australia and therefore the risk to public health is not considered to be unreasonable. If information becomes available indicating significant use of xylenes in cosmetics in Australia, the outcomes of this report may require amendment.

Occupational Risk Characterisation

During product formulation, dermal, ocular and inhalation exposure of workers to the chemical may occur, particularly where manual or open processes are used. These may include transfer and blending activities,

quality control analysis, and cleaning and maintenance of equipment. Worker exposure to the chemical at lower concentrations may also occur during use of formulated products containing the chemical. The level and route of exposure will vary depending on the method of application and work practices employed.

Given the critical health effects of the chemical, the chemical may pose an unreasonable risk to workers if adequate control measures to minimise dermal, ocular and inhalation exposure to the chemical are not implemented. The chemical should be appropriately classified and labelled to ensure that a person conducting a business or undertaking (PCBU), e.g. employer, at a workplace has adequate information to determine appropriate controls.

The data available support an amendment to the hazard classification in HSIS (refer to **Recommendation** section).

The current exposure standard in Australia for xylene (o-, m-, p- isomers) is considered adequately protective, although irritation and mild neurological effects, e.g. dizziness, may occur in some individuals. Based on the available data, the risk from exposure to mixed xylenes is similar to that of the individual isomers and, as such, the exposure standard for mixed xylenes should be the same as for the individual isomers.

NICNAS Recommendation

Assessment of the chemicals is considered to be sufficient provided that the recommendation is adopted for the amendment of the classification and labelling of the chemicals, and all requirements are met under workplace health and safety and poisons legislation as adopted by the relevant state or territory.

In addition, the inclusion of CAS registry information in the exposure standard information on HSIS would provide greater certainty in the exposure standard for mixed xylenes (1330-20-7). The current exposure standard listed on HSIS for Xylene (o-, m-, p- isomers) is considered applicable for all chemicals assessed in this report.

Regulatory Control

Public Health

Products containing the chemical should be labelled in accordance with state and territory legislation (SUSMP).

Occupational Health and Safety

The chemical is recommended for classification and labelling under the current approved criteria and adopted GHS as below. This does not consider classification of physical hazards and environmental hazards.

	Approved Criteria (HSIS)[a]	*GHS Classification*
Acute Toxicity	* Harmful in contact with skin (Xn; R21) Harmful by inhalation (Xn; R20)*	Harmful in contact with skin - Cat. 4 (H312) Harmful if inhaled - Cat. 4 (H332)
Irritation / Corrosivity	Irritating to respiratory system (Xi; R37) Irritating to skin (Xi; R38)*	May cause respiratory irritation - Specific target organ tox, single exp Cat. 3 (H335) Causes skin irritation - Cat. 2 (H315)

[a] Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(2004)].

* Existing Hazard Classification. No change recommended to this classification.

Advice for consumers

Products containing the chemical should be used according to label instructions.

Advice for industry

Control measures

Control measures to minimise the risk from dermal, ocular and inhalation exposure to the chemicals should be implemented in accordance with the hierarchy of controls. Approaches to minimise risk include substitution, isolation and engineering controls. Measures required to eliminate or minimise risk arising from storage, handling and use of a hazardous chemical are dependent on the physical form and the manner in which the chemical is used. Examples of control measures which may minimise the risk include, but are not limited to:

- use of local exhaust ventilation to prevent the chemical from entering the breathing zone of any worker;
- air monitoring to ensure control measures in place are working effectively and continue to do so;

- minimisation of manual processes and work tasks through automation of processes;
- work procedures that minimise splashes and spills;
- regular cleaning of equipment and work areas; and
- use of protective equipment that is designed, constructed, and operated to ensure that the worker does not come into contact with the chemical.

Guidance on managing risks from hazardous chemicals are provided in the *Managing Risks of Hazardous Chemicals in the Workplace—Code of Practice* available on the Safe Work Australia website.

Personal protective equipment should not be relied upon on its own to control risk and should only be used when all other reasonably practicable control measures do not eliminate or sufficiently minimise risk. Guidance in selection of personal protective equipment can be obtained from Australia, Australian/New Zealand or other approved standards.

Obligations under workplace health and safety legislation

Information in this report should be taken into account to assist with meeting obligations under workplace health and safety legislation as adopted by the relevant state or territory. This includes, but is not limited to:

- ensuring that hazardous chemicals are correctly classified and labelled;
- ensuring that (material) safety data sheets ((m)SDS) containing accurate information about the hazards (relating to both health hazards and physicochemical (physical) hazards) of hazardous chemical are prepared; and
- management of risks arising from storage, handling and use of a hazardous chemical.

Your work health and safety regulator should be contacted for information on the work health and safety laws in your jurisdiction.

Information on how to prepare an (m)SDS and how to label containers of hazardous chemicals are provided in relevant codes of practice such as the *Preparation of Safety Data Sheets for Hazardous Chemicals— Code of Practice* and *Labelling of Workplace Hazardous Chemicals—Code of Practice*, respectively. These codes of practice are available from the Safe Work Australia website

A review of physical hazards of the chemical has not been undertaken as part of this assessment.

References

OECD (2003). SIDS Initial Assessment Profile (SIAP) on Xylenes. Accessed at http://webnet.oecd.org/hpv/ui/handler.axd?id=a62e7888-04d7-4a47-b7fb-72a47e89e3a9

Galleria Chemica. Accessed January 2013. http://jr.chemwatch.net/galleria/

International Agency for Research on Cancer (IARC) 1999. Xylenes. IARC Monographs Volume 71. Accessed February 2013 at http://monographs.iarc.fr/ENG/Monographs/vol71/mono71-58.pdf

National Pollutant Inventory (NPI). Accessed February 2013 at http://www.npi.gov.au/index.html

OECD QSAR Toolbox version 3.0
http://www.oecd.org/chemicalsafety/assessmentofchemicals/theoecdqsartoolbox.htm

Personal Care Product Council, 2011. Compilation of Ingredients Used in Cosmetics in the United States,1st Edition.

REACH Dossier 2011. Formic acid (64-18-6). Accessed February 2013 at
http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances

REACH Dossier 2011. xylene (1330-20-7). Accessed January 2013 at
http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances

Safe Work Australia (SWA). Hazardous Substances Information system (HSIS). Accessed January 2013 at http://hsis.safeworkaustralia.gov.au/HazardousSubstance.

Sainio, E.-L., Engström, K., Henriks-Eckerman, M.-L. and Kanerva, L. (1997), Allergenic ingredients in nail polishes. Contact Dermatitis, 37: 155–162.

Substances in Preparations in Nordic Countries (SPIN). Accessed January 2013.
http://188.183.47.4/dotnetnuke/Home/tabid/58/Default.aspx

Therapeutic Goods Administration–Department of Health and Ageing 2012. Standard for the Uniform Scheduling of Medicines and Poisons No. 3 (the SUSMP 3). http://www.comlaw.gov.au/Details/F2012L01200, downloaded 7 February 2012.

U.S Environmental Protection Agency (EPA) (2005). Toxicological Review of xylenes (CAS No. 1330-20-7) In Support of Summary Information on the Integrated Risk Information System (IRIS). Accessed January 2013 at http://www.epa.gov/iris/toxreviews/0270tr.pdf

US Department of Health and Human Services, Household Products Database (HHPD), Health and safety information on household products. Accessed February 2013 at http://householdproducts.nlm.nih.gov/.