



Polymers which may release nonylphenol: Human health tier II assessment

28 June 2019

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Chemicals in this assessment

Chemical Name in the Inventory	CAS Number
Ethanol, 2-amino-, compound with .alpha.-(nonylphenyl)-.omega.-hydroxypoly(oxy-1,2-ethanediyl) phosphate	59139-23-0
Oxiranemethanol, polymer with nonylphenol	68072-38-8
Phenol, 4-nonyl-, polymer with sulfur chloride (SCl₂)	68845-17-0
Fatty acids, tall oil, esters with polyethylene glycol mono(nonylphenyl) ether	68990-46-5
1,2,3-Propanetriol, polymer with 1,3-diisocyanatomethylbenzene, methyloxirane, oxirane and 1,2-propanediol, isononylphenyl ether	80146-18-5
Phenol, nonyl-, polymer with 1,3-diisocyanatomethylbenzene and methyloxirane polymer with oxirane ether with 1,2-propanediol (2:1)	103479-07-8

Chemical Name in the Inventory	CAS Number
1,2,3-Propanetriol, polymer with 1,3-diisocyanatomethylbenzene, methyloxirane and oxirane, nonylphenol blocked	119012-30-5
1,2,3-Propanetriol, polymer with 2,4-diisocyanato-1-methylbenzene, methyloxirane and oxirane, nonylphenol blocked	119012-31-6
1,2,3-Propanetriol, polymer with 2,4-diisocyanato-1-methylbenzene, methyloxirane, oxirane and 1,2-propanediol, nonylphenol blocked	119012-32-7
1,2,3-Propanetriol, polymer with 1,3-diisocyanatomethylbenzene, methyloxirane, oxirane and 1,3-propanediol, nonylphenol blocked	119012-33-8
2-Oxepanone, polymer with oxirane, 2-propenoate, nonylphenyl ether, block	120145-64-4
1,2-Ethanediol, polymer with .alpha.-hydro-.omega.-hydroxypoly(oxy-1,2-ethanediyl), 5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethylcyclohexane and [(4-nonylphenoxy)methyl]oxirane	131794-65-5

Preface

This assessment was carried out by staff of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) using the Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework.

The IMAP framework addresses the human health and environmental impacts of previously unassessed industrial chemicals listed on the Australian Inventory of Chemical Substances (the Inventory).

The framework was developed with significant input from stakeholders and provides a more rapid, flexible and transparent approach for the assessment of chemicals listed on the Inventory.

Stage One of the implementation of this framework, which lasted four years from 1 July 2012, examined 3000 chemicals meeting characteristics identified by stakeholders as needing priority assessment. This included chemicals for which NICNAS already held exposure information, chemicals identified as a concern or for which regulatory action had been taken overseas, and chemicals detected in international studies analysing chemicals present in babies' umbilical cord blood.

Stage Two of IMAP began in July 2016. We are continuing to assess chemicals on the Inventory, including chemicals identified as a concern for which action has been taken overseas and chemicals that can be rapidly identified and assessed by using Stage One information. We are also continuing to publish information for chemicals on the Inventory that pose a low risk to human health or the environment or both. This work provides efficiencies and enables us to identify higher risk chemicals requiring assessment.

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.

These assessments are carried out by staff employed by the Australian Government Department of Health and the Australian Government Department of the Environment and Energy. The human health and environment risk assessments are conducted and published separately, using information available at the time, and may be undertaken at different tiers.

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

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

Disclaimer

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ACRONYMS & ABBREVIATIONS

Grouping Rationale

The chemicals in this group are polymers that contain nonylphenol (NP) as a monomer. These polymers belong to 2 main groups. The first group includes NP incorporated by an ether bond and the cross-linked polymers (CAS Nos. 68072-38-8 and 68845-17-0). These are not likely to release NP, except following environmental degradation. The second group includes NP-blocked isocyanate polymers, which are not expected to contain unreacted isocyanate groups. These polymers are expected to release NPs at low levels on end use.

The polymers in this group are generally of low concern to human health. However, the products manufactured using these polymers may contain NP (from incomplete polymerisation) or may release NP (as a result of hydrolysis from the polymers) under certain conditions. The main health concern which applies to all the chemicals in the group is their environmental degradation to NPs; and therefore, there is the potential to increase the secondary human exposure to nonylphenols via the environment.

Import, Manufacture and Use

Australian

No specific Australian use, import, or manufacturing information has been identified for the polymers in this report.

International

The following international uses have been identified through Galleria Chemica; the Substances in Preparations in Nordic countries (SPIN) database; and the United States Environmental Protection Agency (US EPA) Chemical and Product Categories (CPCat):

The following chemicals have reported uses in 1 or several consumer products:

- CAS No.119012-32-7: in products such as adhesives, binding agents, caulking compounds, fillers, padding material, primer, paints, lacquers and varnishes;
- CAS No. 68072-38-8: as a photochemical at 1–5 %;

- CAS No. 131794-65-5: products not specified.

The chemical CAS No. 119012-32-7 has reported commercial uses in general and specialised construction, bricklaying, civil engineering, test drilling and boring, and painting.

The following chemicals have reported site-limited uses in formulation, packaging, and chemical manufacturing:

- CAS No. 68072-38-8: as a photochemical;
- CAS No. 68990-46-5: as a surfactant;
- CAS No. 103479-07-8: as a reprographic agent in construction; and
- CAS No. 119012-31-6.

The chemical CAS No. 59139-23-0 has reported non-industrial use as an inert ingredient approved for use in pesticide products (not exceeding 7 %), applied to food pre- and post-harvest and animals without the requirement of a tolerance or a residue restriction) (US EPA Inert Ingredients).

No specific use information has been identified for CAS Nos. 68845-17-0, 80146-18-5, 119012-30-5, 119012-33-8, and 120145-64-4.

Restrictions

Australian

No known restrictions have been identified for the polymers in this group.

International

Nonylphenol, branched and linear, ethoxylated (covering well-defined substances, UVCB, polymers and homologues, which include any of the individual isomers or combinations thereof) are listed in the REACH Regulation Annex XIV 'Authorisation List of substances of very high concern (SVHC)'. They are considered as 'having probable serious effects to the environment and endocrine disrupting properties' (ECHA, 2019).

Currently, NPs and nonylphenol ethoxylates (NPEs) cannot be placed on the market for sale to the general public as substances or in mixtures at individual concentrations ≥ 0.1 % for uses in cleaning, textile and leather processing, cosmetic and personal care products (REACH Regulation Annex XVII 'Restriction List'; ECHA, 2015).

An update to Annex XVII indicates that NPEs 'shall not be placed on the market after 3 February 2021 in textile articles which can be reasonably expected to be washed in water during their normal lifecycles, in concentrations equal or greater than 0.01 % by weight of that textile article or of each part of the textile article' (ECHA, 2016).

Several NPs and NPEs are also subject to export notification and prior informed consent (PIC) Regulation, which regulate the import and export of hazardous chemicals in international trade (ECHA).

The US EPA has proposed a significant new use rule (SNUR) for 15 NPs and NPEs that requires notification to the US EPA before manufacture (including import) or processing of any of these 15 chemicals for a significant new use. This provides the US EPA with 'the opportunity to evaluate the new uses and protect against unreasonable risks, if any, from potential new exposures to NPs and NPEs, before that activity occurs' (US EPA, 2014).

Recently, the US EPA has issued the final rule (effective 30 November 2018) in order to add NPEs category to the list of toxic chemicals subject to reporting under the Emergency Planning and Community Right-to-Know Act (EPCRA) and the Pollution Prevention Act (PPA). The US EPA determined that 'short-chain NPEs are highly toxic to aquatic organisms and longer chain NPEs, while not as toxic as short-chain NPEs, can break down in the environment to short-chain NPEs and nonylphenol, both of which are highly toxic to aquatic organisms' (US Federal Register, 2018).

The NPs and NPEs are listed in Schedule 1 'List of Toxic Substances' under the Canadian Environmental Protection Act 1999. Following a notice in 2004 requiring the preparation and implementation of pollution prevention plans, the use of NPs and NPEs in product manufacturing and imports has significantly reduced by 96 %, compared with the 1998 base level. It is also indicated that 'NP and NPEs releases to the environment will continue to be monitored, notably through the National Pollutant Release Inventory, to determine if further risk management is warranted (Environment Canada, 2016).

Existing Worker Health and Safety Controls

Hazard Classification

The polymers are not listed on the Hazardous Chemical Information System (HCIS) (Safe Work Australia).

Exposure Standards

Australian

No specific exposure standards are available.

International

No specific exposure standards are available.

Health Hazard Information

The polymers in this group are nonylphenol-based polymers. No data are available on the health hazards of the polymers in this group. The bioavailability of these polymers is likely to be negligible due to their large molecular size. It is considered that nonylphenols released from the decomposition of these polymers (whether from environmental degradation or during end use) will generally be the critical driver of toxicity.

The critical health hazards of nonylphenols and nonylphenol ethoxylates (which generally will degrade to nonylphenols) have been previously identified in the Tier II Human Health assessments under the Inventory Multi-tiered Assessment and Prioritisation (IMAP) Framework. These include local effects (corrosivity), acute effects from oral exposure, and systemic long-term effects (reproductive and developmental toxicity) (NICNASa; NICNASb).

Risk Characterisation

Critical Health Effects

The majority of these polymers are not expected to readily release nonylphenols. Therefore, no significant health effects are expected from the presence of nonylphenols in these polymers. Where these polymers do release NPs or NPEs (NPEs eventually degrade to NPs) due to environmental degradation there is a potential of increasing secondary human exposure to nonylphenols via the environment. Additionally, the blocked isocyanate polymers may be sources of nonylphenols in the workplace.

The critical health hazards of nonylphenols and nonylphenol ethoxylates (which generally will degrade to nonylphenols) include local effects (corrosivity), acute effects from oral exposure, and systemic long-term effects (reproductive and developmental toxicity).

Public Risk Characterisation

The use of NPs and NPEs has been restricted in consumer products overseas, mainly on the basis of environmental risks.

Considering the environmental breakdown of the polymers in this group, there may be a potential for human exposure to NPs indirectly through the environment, as part of the environmental pool of NPs. However, the risk to human health from exposure to NPs is considered acceptable given the concentration levels for NPs are maintained in accordance with the Australian Guidelines for Water Recycling on the 'planned use of recycled water (treated sewage and stormwater) to augment drinking water supplies'. A maximum concentration of 2.9 µg/L has been set for 4-nonylphenol in secondary treated sewage and a guideline value of 500 µg/L is derived for drinking water augmentation (EPHC-NHMRC-NRMMC, 2008). Overall, the polymers in this group and their breakdown products are not considered to pose an unreasonable risk to public health.

Occupational Risk Characterisation

Given the critical systemic long-term effects of NPs, the polymers in this group could pose an unreasonable risk to workers unless adequate control measures to minimise exposure are implemented. The polymers should be appropriately classified and labelled to ensure that a person conducting a business or undertaking (PCBU) at a workplace (such as an employer) has adequate information to determine the appropriate controls.

The NP-blocked isocyanates may be workplace sources of NP exposure and these chemicals should be treated accordingly.

NICNAS Recommendation

Assessment of these polymers is considered to be sufficient, provided that all requirements are met under workplace health and safety and poisons legislation as adopted by the relevant state or territory.

NICNAS recommends that formulators of products containing these polymers should take into account the concentration of the breakdown NPs in the products when determining label instructions.

Regulatory Control

Work Health and Safety

Based on available data, the amount of nonylphenol expected to be available from these polymers is very low and; therefore, the health risk to workers from these polymers is controlled when correct classification and labelling are considered, and adequate control measures to minimise occupational exposure and protective clothing are implemented. Should empirical data become available for the individual polymers indicating that a classification is appropriate, the data may be used to make recommendation(s) for classification.

Advice for industry

Control measures

Control measures to minimise the risk from 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 storing, handling and using a hazardous chemical depend on the physical form and the manner in which the chemicals are used. Examples of control measures that could minimise the risk include, but are not limited to:

- minimising manual processes and work tasks through automating processes;
- work procedures that minimise splashes and spills;

- regularly cleaning equipment and work areas; and
- using protective equipment that is designed, constructed, and operated to ensure that the worker does not come into contact with the chemicals.

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

Obligations under workplace health and safety legislation

Information in this report should be taken into account to help meet 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 the chemicals are prepared; and
- managing risks arising from storing, handling and using 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 the physical hazards of these chemicals has not been undertaken as part of this assessment.

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Last Update 28 June 2019

Chemical Identities

Chemical Name in the Inventory and Synonyms	Ethanol, 2-amino-, compound with .alpha.-(nonylphenyl)-.omega.-hydroxypoly(oxy-1,2-ethanediyl) phosphate nonylphenol, ethoxylated, phosphate, monoethanolamine salt polyethylene glycol nonylphenyl ether phosphate ethanolamine salt
CAS Number	59139-23-0
Structural Formula	

No Structural Diagram Available

Molecular Formula	C ₂ H ₇ NO.x(C ₂ H ₄ O) _n C ₁₅ H ₂₄ O.xH ₃ O ₄ P
Molecular Weight	424.49

Chemical Name in the Inventory and Synonyms	Oxiranemethanol, polymer with nonylphenol nonyl phenol, glycidyl polyether 2-nonylphenol;oxiran-2-ylmethanol
CAS Number	68072-38-8
Structural Formula	
Molecular Formula	(C ₁₅ H ₂₄ O.C ₃ H ₆ O ₂) _x
Molecular Weight	294.43

Chemical Name in the Inventory and Synonyms	Phenol, 4-nonyl-, polymer with sulfur chloride (SCl₂)
CAS Number	68845-17-0
Structural Formula	

	No Structural Diagram Available
Molecular Formula	(C15H24O.Cl2S)x
Molecular Weight	

Chemical Name in the Inventory and Synonyms	Fatty acids, tall oil, esters with polyethylene glycol mono(nonylphenyl) ether nonyl phenyl ethoxy, tallow fatty acid reaction mixture nonylphenoxypoly(ethyleneoxy)ethanol, tall oil fatty acid ester
CAS Number	68990-46-5
Structural Formula	No Structural Diagram Available
Molecular Formula	((C2H4O)nC15H24O.)x
Molecular Weight	

Chemical Name in the Inventory and Synonyms	1,2,3-Propanetriol, polymer with 1,3-diisocyanatomethylbenzene, methyloxirane, oxirane and 1,2-propanediol, isononylphenyl ether
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CAS Number	80146-18-5
Structural Formula	
Molecular Formula	(C ₉ H ₆ N ₂ O ₂ .C ₃ H ₈ O ₃ .C ₃ H ₈ O ₂ .C ₃ H ₆ O.C ₂ H ₄ O) _x
Molecular Weight	444.48

Chemical Name in the Inventory and Synonyms	Phenol, nonyl-, polymer with 1,3-diisocyanatomethylbenzene and methyloxirane polymer with oxirane ether with 1,2-propanediol (2:1) benzene, 1,3-diisocyanatomethyl-, polymer with methyloxirane polymer with oxirane ether with 1,2-propanediol (2:1), and nonylphenol oxirane, polymer with methyloxirane, ether with 1,2-propanediol (2:1), polymer with 1,3-diisocyanatomethylbenzene and nonylphenol oxirane, methyl-, polymer with 1,3-diisocyanatomethylbenzene and oxirane, nonylphenol-blocked
CAS Number	103479-07-8
Structural Formula	No Structural Diagram Available
Molecular Formula	(C ₁₅ H ₂₄ O.C ₉ H ₆ N ₂ O ₂ .C ₃ H ₆ O.C ₂ H ₄ O) _x
Molecular Weight	276.29

Chemical Name in the Inventory and Synonyms	1,2,3-Propanetriol, polymer with 1,3-diisocyanatomethylbenzene, methyloxirane and oxirane, nonylphenol blocked
CAS Number	119012-30-5

Structural Formula	No Structural Diagram Available
Molecular Formula	(C ₁₅ H ₂₄ O.C ₉ H ₆ N ₂ O ₂ .C ₃ H ₈ O ₃ .C ₃ H ₆ O.C ₂ H ₄ O) _x
Molecular Weight	

Chemical Name in the Inventory and Synonyms	1,2,3-Propanetriol, polymer with 2,4-diisocyanato-1-methylbenzene, methyloxirane and oxirane, nonylphenol blocked benzene, 1,3-diisocyanato-4-methyl, polymer with 1,2,3-propanetriol, methyloxirane, oxirane and nonyl phenol
CAS Number	119012-31-6
Structural Formula	No Structural Diagram Available
Molecular Formula	(C ₁₅ H ₂₄ O.C ₉ H ₆ N ₂ O ₂ .C ₃ H ₈ O ₃ .C ₃ H ₆ O.C ₂ H ₄ O) _x
Molecular Weight	

Chemical Name in the	1,2,3-Propanetriol, polymer with 2,4-diisocyanato-1-methylbenzene,
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Inventory and Synonyms	methyloxirane, oxirane and 1,2-propanediol, nonylphenol blocked benzene, 1,3-diisocyanato-4-methyl-, polymer with 1,2,3-propanetriol, 1,2-propanediol, methyloxirane, oxirane and nonyl phenol
CAS Number	119012-32-7
Structural Formula	No Structural Diagram Available
Molecular Formula	Unspecified
Molecular Weight	

Chemical Name in the Inventory and Synonyms	1,2,3-Propanetriol, polymer with 1,3-diisocyanatomethylbenzene, methyloxirane, oxirane and 1,3-propanediol, nonylphenol blocked
CAS Number	119012-33-8
Structural Formula	No Structural Diagram Available
Molecular Formula	(C15H24O.C9H6N2O2.C3H8O3.C3H8O2.C3H6O.C2H4O)x

Molecular Weight	
Chemical Name in the Inventory and Synonyms	2-Oxepanone, polymer with oxirane, 2-propenoate, nonylphenyl ether, block
CAS Number	120145-64-4
Structural Formula	No Structural Diagram Available
Molecular Formula	Unspecified
Molecular Weight	

Chemical Name in the Inventory and Synonyms	1,2-Ethanedione, polymer with .alpha.-hydro-.omega.-hydroxypoly(oxy-1,2-ethanediyl), 5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethylcyclohexane and [(4-nonylphenoxy)methyl]oxirane cyclohexane, 5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethyl-, polymer with 1,2-ethanediol, .alpha.-hydro-.omega.-hydroxypoly(oxy-1,2-ethanediyl) and [(4-nonylphenoxy)methyl]oxirane poly(oxy-1,2-ethanediyl), alpha.-hydro-omega.-hydroxy-, polymer with 1,2-ethanediol, 5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethylcyclohexane and [(4-nonylphenoxy)methyl]oxirane
CAS Number	131794-65-5
Structural Formula	

**No Structural
Diagram Available**

Molecular Formula	(C ₁₈ H ₂₈ O ₂ .C ₁₂ H ₁₈ N ₂ O ₂ .C ₂ H ₆ O ₂ .(C ₂ H ₄ O) _n H ₂ O) _x
Molecular Weight	

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