

Nonylphenol propoxylates and related compounds: Human health tier II assessment



02 March 2018

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Chemicals in this assessment

Chemical Name in the Inventory	CAS Number
Oxirane, methyl-, polymer with oxirane, mono(nonylphenyl) ether	37251-69-7
Oxirane, methyl-, polymer with oxirane, mono(2,4-dinonylphenyl) ether	66988-46-3
Oxirane, methyl-, polymer with oxirane, mono(nonylphenyl) ether, branched	68891-11-2
Poly[oxy(methyl-1,2-ethanediyl)], .alpha.-(1-oxo-2-propenyl)-.omega.-(nonylphenoxy)-	71926-19-7
Oxirane, methyl-, polymer with oxirane, mono(4-isooctylphenyl) ether	60572-08-9
Oxirane, [(4-nonylphenoxy)methyl]-, polymer with .alpha.-hydro-.omega.-hydroxypoly(oxy-1,2-ethanediyl)	185529-30-0

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

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ACRONYMS & ABBREVIATIONS

Grouping Rationale

The chemicals in this group are alkoxyate ether derivatives of nonylphenol or octylphenol with the alkoxyate chain containing either propylene oxide (PO) in combination with ethylene oxide (EO), or PO only. This group of chemicals are used primarily as non-ionic surfactants, but are not as widely produced compared with the nonylphenol ethoxylates (NPEs), which have been extensively studied (NICNASa).

There is a lack of information on these chemicals. In the absence of information to indicate lower toxicity for this group, they will be assumed to be represented by data on NPEs and octylphenol ethoxylates (OPEs). Whilst the local toxicity of the chemicals in this group may vary, the systemic toxicity of the chemicals are expected to be due to the breakdown into nonylphenols (NPs) or octylphenols (OPs).

There is a lack of information on dinonylphenol derivatives. In the absence of information to indicate lower toxicity for this group, they will be assumed to be represented by data on NPEs. Dinonylphenol alkoxyates have; therefore, been included in this

assessment.

Import, Manufacture and Use

Australian

No specific Australian use, import, or manufacturing information has been identified.

International

The chemicals have reported commercial uses including as (Zgola-Grzeskowiak A. et. al., 2014; Galleria Chemica; SciFinder):

- additives to fuel blends for automotive engines;
- dispersing agents in dyes in the textile industry; and
- co-surfactants in coatings, printing ink compositions and in low-foaming wetting agents or detergents.

Polypropylene glycol mono(nonylphenyl) ester acrylate (CAS No. 71926-19-7) has reported site-limited use as a starting material for acrylic polymers (Galleria Chemica).

The chemicals have reported non-industrial uses as dispersants in pharmaceutical and agrochemical formulations.

Whilst certain NPEs and OPEs have a range of cosmetic and domestic uses (NICNASa), these uses have not been identified for the chemicals in this group (Personal Care Products Council; US Household Products Database).

Restrictions

Australian

No known restrictions have been identified for the chemicals.

Some of the chemicals of this group are synthesised through processes which may result in 1,4-dioxane as an impurity. This impurity (listed under dioxane) is controlled through listing in the Poisons Standard (SUSMP) in Schedule 6, with schedule labelling requirements applying above 100 ppm (Appendix G) (SUSMP, 2018).

International

No known restrictions have been identified.

Existing Worker Health and Safety Controls

Hazard Classification

The chemicals 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

Limited hazard data are available for these chemicals. In the absence of information to indicate lower toxicity for this group, they will be assumed to be represented by data on NPEs and octylphenol ethoxylates (OPEs). Based on data for NPEs and other alcohol ethoxylates (NICNASa; NICNASb) the chemicals are expected to cross biological membranes, with absorption decreasing with increasing EO/PO units (or chain length). Following systemic absorption, the chemicals are expected to break down to NPs and OPs. Other metabolic pathways could include shortening of the EO/PO chain and oxidation of terminal alcohols (NICNASa; Pattys Toxicology, 2001).

The acute oral toxicity of NPEs and OPEs ranged from low to moderate. Acute toxicity was shown to reduce with increasing chain lengths for the ethoxylates. In the absence of available data, hazard classification for systemic acute effects following exposure is recommended. Dermal absorption is expected to be low; therefore, a systemic acute effect following dermal exposure is not expected.

Studies for NPEs and OPEs and another group of similar analogues (alcohol ethoxylates) showed moderate to severe skin and eye irritation, depending on the degree of ethoxylation (NICNASa; NICNASb). In the absence of available data for the chemicals, hazard classification for skin and eye irritation is recommended.

NPEs and OPEs are generally not considered to have skin sensitisation potential, and similar results are expected for the chemicals. However, polypropylene glycol mono(nonylphenyl) ester acrylate (CAS No. 71926-19-7) is a potential sensitiser based on the acrylate moiety (NICNASa).

NPEs and OPEs are not considered to cause serious damage to health following repeated oral exposure, or to be genotoxic or carcinogenic. While there is some evidence that NPEs are toxic to reproduction the effects appear to be specific to direct spermicidal use, which is not relevant to industrial uses of the chemicals. Reproductive and developmental effects were not observed with OPEs.

The Tier II assessment for NPEs and OPEs is available at https://www.nicnas.gov.au/chemical-information/imap-assessments/imap-group-assessment-report?assessment_id=1844. This report should be read in conjunction with this Tier II assessment.

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation are skin and eye irritation. The chemicals could also cause systemic acute effects from oral exposure. However, these health effects are applicable mainly for chemicals with a shorter chain length and the effects could reduce with increasing chain lengths.

Polypropylene glycol mono(nonylphenyl) ester acrylate (CAS No. 71926-19-7) may be a potential skin sensitiser.

The chemicals may biodegrade to NPs and OPs in the environment and some products containing the chemicals can also contain residual amounts of NPs and OPs. Therefore, critical health effects of NPs and OPs could also be applicable for risk characterisation under those situations, particularly following secondary exposure from environmental sources.

Public Risk Characterisation

Given the uses identified for these chemicals, it is unlikely that the public will be exposed. Hence, the public risk from this chemical is not considered to be unreasonable.

The chemicals are expected to biodegrade in the environment to eventually form NPs and OPs. However, the risk to humans from nonylphenol is considered acceptable if the concentration levels are maintained in accordance with the limitations for nonylphenol set out in 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 detected for 4-nonylphenol in secondary treated sewage and a guideline value of 500 µg/L is derived for drinking water augmentation (NRMCC-EPHC-NHMRC, 2008).

Detected levels of OPs in urine, overseas and Australian domestic waste water is significantly lower than NPs (OSPAR, 2006; CSIRO, 2010; CDC, 2012). Overall, the chemicals are not considered to pose an unreasonable risk to public health.

Occupational Risk Characterisation

During product formulation, exposure may occur, particularly where manual or open processes are used. These could include transfer and blending activities, quality control analysis, and cleaning and maintaining equipment. Worker exposure to the chemicals at lower concentrations could also occur while using formulated products containing the chemicals. The level and route of exposure will vary depending on the method of application and work practices employed.

The chemicals could pose an unreasonable risk to workers unless adequate control measures to minimise oral, dermal and ocular exposure are implemented. The chemicals 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.

Based on available read-across data, hazard classification is recommended.

NICNAS Recommendation

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

Further assessment of the chemicals may be necessary if new hazard data become available.

Regulatory Control

Work Health and Safety

The chemicals are recommended for classification and labelling aligned with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) as below. The CAS number represents chemicals with a range of alkoxy units. This hazard classification should be applicable for chemicals with alkoxy chains <30 and only when specific hazard data are not available for the specific lengths. This does not consider classification of physical hazards and environmental hazards.

From 1 January 2017, under the model Work Health and Safety Regulations, chemicals are no longer to be classified under the Approved Criteria for Classifying Hazardous Substances system.

Hazard	Approved Criteria (HSIS) ^a	GHS Classification (HCIS) ^b
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Hazard	Approved Criteria (HSIS) ^a	GHS Classification (HCIS) ^b
Acute Toxicity	Not Applicable	Harmful if swallowed - Cat. 4 (H302)
Irritation / Corrosivity	Not Applicable	Causes serious eye irritation - Cat. 2A (H319) Causes skin irritation - Cat. 2 (H315)

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

^b Globally Harmonized System of Classification and Labelling of Chemicals (GHS) United Nations, 2009. Third Edition.

* Existing Hazard Classification. No change recommended to this classification

Advice for industry

Control measures

Control measures to minimise the risk from oral, dermal and ocular 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:

- using closed systems or isolating operations;
- 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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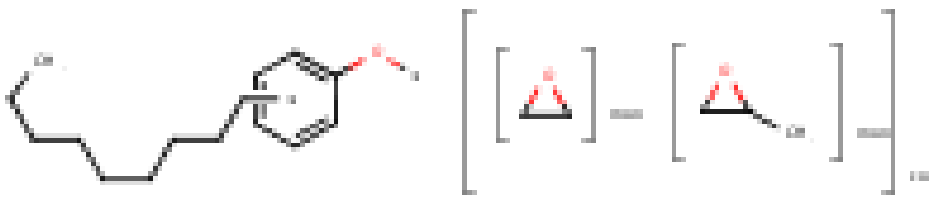
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Last Update 02 March 2018

Chemical Identities

Chemical Name in the Inventory and Synonyms	Oxirane, methyl-, polymer with oxirane, mono(nonylphenyl) ether polyethylene, polypropylene glycol, mono(nonylphenyl) ether ethylene oxide - propylene oxide copolymer mono(nonylphenyl) ether Soprophor
CAS Number	37251-69-7
Structural Formula	
Molecular Formula	$C_{15}H_{24}O \cdot (C_3H_6O \cdot C_2H_4O)_x$
Molecular Weight	322.49

Chemical Name in the Inventory and Synonyms	Oxirane, methyl-, polymer with oxirane, mono(2,4-dinonylphenyl) ether nonylphenol ethoxylate propoxylate
CAS Number	66988-46-3

Structural Formula	
Molecular Formula	C ₂₄ H ₄₂ O.(C ₃ H ₆ O.C ₂ H ₄ O) _x
Molecular Weight	448.73

Chemical Name in the Inventory and Synonyms	Oxirane, methyl-, polymer with oxirane, mono(nonylphenyl) ether, branched (C9) branched alkylphenol ethoxylate propoxylate
CAS Number	68891-11-2
Structural Formula	<p style="text-align: center;">No Structural Diagram Available</p>

Molecular Formula	Unspecified
Molecular Weight	Unspecified

Chemical Name in the Inventory and Synonyms	Poly[oxy(methyl-1,2-ethanediyl)], .alpha.-(1-oxo-2-propenyl)-.omega.-(nonylphenoxy)-polypropylene glycol, mono(nonylphenyl) ester acrylate
CAS Number	71926-19-7
Structural Formula	No Structural Diagram Available
Molecular Formula	(C3H6O) _n C18H26O2
Molecular Weight	Unspecified

Chemical Name in the Inventory and Synonyms	Oxirane, methyl-, polymer with oxirane, mono(4-isooctylphenyl) ether oxirane, polymer with 4-isooctylphenol and methyloxirane
CAS Number	60572-08-9
Structural Formula	

	No Structural Diagram Available
Molecular Formula	(C14H22O.C3H6O.C2H4O)x
Molecular Weight	Unspecified

Chemical Name in the Inventory and Synonyms	Oxirane, [(4-nonylphenoxy)methyl]-, polymer with .alpha.-hydro-.omega.-hydroxypoly(oxy-1,2-ethanediyl) 306-94-5A
CAS Number	185529-30-0
Structural Formula	No Structural Diagram Available
Molecular Formula	(C2H6O2)(C18H28O2)
Molecular Weight	Unspecified

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