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February 2019

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

1,3-Isobenzofurandione, hexahydromethyl-

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment and Energy.

This Public Report is available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

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Director
NICNAS

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SUMMARY

The following details will be published in the NICNAS *Chemical Gazette:*

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
STD/1671	Henkel Australia Pty Ltd	1,3-Isobenzofurandione, hexahydromethyl-	Yes	≤ 100 tonnes per annum	Curing agent for epoxy resins

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified chemical is recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the following table.

Hazard classification	*Hazard statement*
Sensitisation, Skin (Category 1)	H317 – May cause an allergic skin reaction
Serious Eye Damage/Eye Irritation (Category 1)	H318 – Causes serious eye damage
Sensitisation, Respiratory (Category 1)	H334 – May cause allergy or asthma symptoms or breathing difficulties if inhaled

Human health risk assessment
Provided that the recommended controls are being adhered to, under the conditions of the occupational settings described, the notified chemical is not considered to pose an unreasonable risk to the health of workers.

When used in the proposed manner, the notified chemical is not considered to pose an unreasonable risk to public health.

Environmental risk assessment
Based on the reported use pattern, the notified chemical is not considered to pose an unreasonable risk to the environment.

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- The notified chemical should be classified as follows:
  - Sensitisation, Skin (Category 1): H317 – May cause an allergic skin reaction
  - Serious Eye Damage/Eye Irritation (Category 1): H318 – Causes serious eye damage
  - Sensitisation, Respiratory (Category 1): H334 – May cause allergy or asthma symptoms or breathing difficulties if inhaled

  The above should be used for products/mixtures containing the notified chemical, if applicable, based on the concentration of the notified chemical present.

Health Surveillance

- As the notified chemical is a skin and respiratory sensitiser, employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of skin or respiratory sensitisation.

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified chemical:
  - Enclosed, automated processes, where possible

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure to the notified chemical:
  - Avoid contact with skin and eyes
  - Avoid inhalation of aerosols, mists and dusts

- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical:
  - Safety glasses
  - Imperative gloves
  - Protective clothing
  - Respirator if inhalation exposure is expected

  Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- A copy of the SDS should be easily accessible to employees.

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Disposal

- Where reuse or recycling is not appropriate, dispose of the notified chemical in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

Storage

- The handling and storage of the notified chemical should be in accordance with the Safe Work Australia Code of Practice for *Managing Risks of Hazardous Chemicals in the Workplace* (SWA, 2012) or relevant State or Territory Code of Practice.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by physical containment, collection and subsequent safe disposal.

Regulatory Obligations

Secondary Notification
This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from an industrial curing agent for epoxy resins, or is likely to change significantly;
- the amount of chemical being introduced has increased, or is likely to increase, significantly;
- the chemical has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

Safety Data Sheet
The SDS of a product containing the notified chemical provided by the notifier was reviewed by NICNAS. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Henkel Australia Pty Ltd (ABN: 82 001 302 996)
135-141 Canterbury Road
KILSYTH VIC 3137

NOTIFICATION CATEGORY
Standard: Chemical other than polymer (more than 1 tonne per year)

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: analytical data, impurities and additives/adjuvants.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed for all physico-chemical, toxicological and ecotoxicological endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
EU (2013) and USA

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
MHHPA

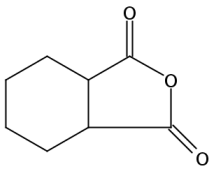
CAS NUMBER
25550-51-0

CHEMICAL NAME
1,3-Isobenzofurandione, hexahydromethyl-

OTHER NAME(S)
ECA 100NC (contains 75-95% notified chemical)

MOLECULAR FORMULA
$C_9H_{12}O_3$

STRUCTURAL FORMULA



D1—CH_3

MOLECULAR WEIGHT
168.19 g/mol

ANALYTICAL DATA
Reference NMR, IR, GC, GC-MS spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 99%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: colourless liquid (IPCS, 2006)

Property	Value	Data Source/Justification
Freezing Point	- 29 °C	IPCS, 2006
Boiling Point	290 °C	IPCS, 2006
Density	1,150 kg/m^3	IPCS, 2006
Vapour Pressure	1 × 10^{-3} kPa at 20 °C	IPCS, 2006
Water Solubility	8.4 g/L at 20 °C	Measured. Substance hydrolyses in water. ECHA
Hydrolysis as a Function of pH	$t_{1/2}$ pH7 < 1 day at 25 °C $t_{1/2}$ pH9 < 1 day at 25 °C $t_{1/2}$ pH4 < 1 day at 25 °C	Measured. US EPA HPVIS
Partition Coefficient (n-octanol/water)	log Pow = 2.59 at 25 °C	Calculated. US EPA EPI Suite
Adsorption/Desorption	log K_{oc} = 1.0 at 20 °C	Calculated. US EPA EPI Suite
Dissociation Constant	Not determined	Contains no dissociable functionality
Flash Point	154 °C* 145 °C	SDS IPCS, 2006
Flammability	Not determined	Not expected to be highly flammable based on flash point
Autoignition Temperature	Not determined	Not expected to autoignite during use based on flash point
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidising properties

* Properties for the imported product ECA 100NC (contains 75-95% notified chemical)

DISCUSSION OF PROPERTIES

Reactivity
The notified chemical is expected to be stable under normal conditions of use.

Physical hazard classification
Based on the submitted physico-chemical data depicted in the above table, the notified chemical is not recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will not be manufactured within Australia. It will be imported in formulations at 80-99% concentration for reformation into epoxy resin hardeners which will be used to react with various epoxy resins to produce plastic automotive parts.

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	5	18	30	100	100

PORT OF ENTRY
Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
Manufacturer: Dixie Chemical Company Inc (USA)
Recipient: Henkel Australia Pty Ltd

TRANSPORTATION AND PACKAGING
The notified chemical in formulations at 80-99% concentration will be imported into Australia by sea and transported by road in 220 kg steel drums or 1000 kg Schutz containers. The concentrates will be distributed to industrial users in the automotive manufacture sector.

USE
The notified chemical will be used as a component of epoxy resin hardeners which will be reacted with various epoxy resins to produce plastic automotive parts.

OPERATION DESCRIPTION
The imported formulations containing the notified chemical will be distributed to formulators for reformulation into epoxy resin hardeners.

At the reformulation sites, the imported formulations containing the notified chemical will be pumped from the drums into a mixing vessel under an inert atmosphere where they will be blended with other raw materials. Blending will be carried out in enclosed and automated systems. Once blending is complete, quality assurance (QA) workers will take aliquots of samples for laboratory analysis. An automated and metered process will be applied to dispense the finished products into individual end-use packaging.

End-users in the automotive manufacture sector will then mix the epoxy resin hardener containing the notified chemical with epoxy resins to produce plastic automotive parts. The notified chemical will make up ~50% of the reactants that are used to make the automotive plastic parts. Following the ring opening reaction, the notified chemical will be incorporated into a polymer which will be cured under heat and very little of the notified chemical will remain in the finished plastic parts. Enclosed and automated processes are expected during manufacture of the plastic parts.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transportation	1 – 2	6 – 12
Storage	1 – 2	50 – 100
Processing	4 – 6	150 – 240
Research	2	30
Disposal	1 – 2	10 – 20

EXPOSURE DETAILS

Transport and storage
Exposure of transport and storage workers to the notified chemical is not expected, except in the event of an accidental spill or breach of the container.

Reformulation and end-use
Dermal and ocular exposure of workers to the notified chemical at up to 50% concentration may occur during reformulation and end-use processes when mixing and transferring materials containing the notified chemical, during QA laboratory testing, and equipment cleaning and maintenance. Given that the notified chemical has low vapour pressure, significant inhalation exposure is not expected unless aerosols or mists are formed during the mixing processes. Exposure to the notified chemical is expected to be minimised through the use of enclosed and automated systems, local exhaust ventilation and suitable personal protective equipment (PPE) capable of protecting workers from exposure to the notified chemical, including impervious gloves, safety glasses, protective clothing and respirators if necessary.

Once the resin has cured, the notified chemical will be bound into the solid plastic parts and will not be available for exposure.

6.1.2. Public Exposure

The notified chemical will be for industrial use only and will not be made available to the public. The public may come into contact with plastic automotive parts containing the notified chemical. However, once the resin has cured the notified chemical is expected to be bound into the solid plastic parts and will not be available for exposure.

6.2. Human Health Effects Assessment

No toxicological data were provided for the notified chemical. Information on the expected health effects of the notified chemical is based on analogues of the notified chemical: 1,3-isobenzofurandione, hexahydro- (hexahydrophthalic anhydride, HHPA, CAS No. 85-42-7); and two isomers of the notified chemical: 1,3-isobenzofurandione, hexahydro-5-methyl- (CAS No. 19438-60-9) and 1,3-isobenzofurandione, hexahydro-4-methyl (CAS No. 57110-29-9). The suitability of the analogues is based on their similarity in chemical structure to the notified chemical. The notified chemical is a cyclic acid anhydride and other chemicals of the same class [including trimellitic anhydride (TMA) and hexahydro-4-methylphthalic anhydride (4-MHHPA)] were also used for read-across where hazard data are lacking for the notified chemical.

Absorption, distribution, metabolism and excretion (ADME)

No toxicokinetic data were submitted for the notified chemical. Based on studies in humans, the notified chemical is expected to be excreted in the urine following inhalation or dermal absorption. Five volunteers were exposed (via inhalation) to the analogue chemical 1,3-isobenzofurandione, hexahydro- (hexahydrophthalic anhydride, HHPA, CAS No. 85-42-7) at 80 µg/m^3 for 8 hours. Following the exposure period, > 85% of the inhaled dose was excreted in urine as hexahydrophthalic acid (WHO 2009).

In a separate study, analogue 1 (HHPA) in petrolatum was applied to the back skin of three volunteers for 48 hours and urine was collected for 72 hours. The excreted amounts of hexahydrophthalic acid were 1.4-4.5%, 0.2-1.3% and 0-0.4% respectively, indicating minimal dermal absorption (WHO 2009).

The distribution of HHPA following inhalation exposure to radioactively labelled HHPA [($^3H_2$)HHPA] was evaluated in guinea pigs and rats. The mucosa of the nasal region and trachea contained the highest levels of the chemical, while the lung tissue contained negligible amounts. Tissue-bound radioactivity was found in the gastrointestinal tract and conjunctiva (both species) and in the kidney cortex of rats (amounts present was not described). Radioactivity persisted for at least 7 days after exposure (WHO 2009).

The anhydride moiety of cyclic acid anhydrides has been found to readily react with amino acids, forming protein conjugates such as serum albumin conjugates (WHO 2009). Phthalic anhydride-exposed workers have also been found to possess measurable plasma protein and albumin adduct levels that correlate with exposure (WHO 2009).

The half-life of phthalic acid in the urine of phthalic anhydride-exposed workers was reported to be approximately 14 hours, and the half-life of hexahydrophthalic acid in the urine of HHPA-exposed workers was reported as 2–3 hours (WHO 2009). Plasma half-lives of 1.7–1.8 h for hexahydrophthalic acid in plasma was reported for two male volunteers exposed to HHPA at 80 µg/m^3 for 8 hours (WHO 2009).

The notified chemical is expected to have a similar absorption, distribution, metabolism and excretion (ADME) profile to that of HHPA, given the structural similarity between the two chemicals.

Acute toxicity

The notified chemical is expected to have low acute oral, dermal and inhalation toxicity based on information available for the analogue chemicals 1,3-isobenzofurandione, hexahydro-5-methyl-, 1,3-isobenzofurandione, hexahydro-4-methyl, 4-MHHPA, HHPA and TMA.

Irritation

The notified chemical is expected to be slightly irritating to the skin, and classification is not warranted based on information available for the analogue chemicals MHHPA, HHPA and TMA (NICNAS).

The notified chemical is expected to be a severe eye irritant based on information available for the analogue chemicals 1,3-isobenzofurandione, hexahydro-5-methyl-, 1,3-isobenzofurandione, hexahydro-4-methyl, HHPA and TMA.

Sensitisation
The notified chemical is expected to be a respiratory sensitiser based on information available for the analogue chemicals 1,3-isobenzofurandione, hexahydro-5-methyl-, 1,3-isobenzofurandione, hexahydro-4-methyl, HHPA and TMA. Using the OECD Quantitative Structure−Activity Relationship (QSAR) Toolbox v3.4, the analogues HHPA and TMA were found to present protein binding alerts for skin sensitisation (acylation: direct acylation involving a leaving group) and respiratory sensitisation (acylation: ring opening acylation at a carbonyl group) (NICNAS).

Repeated dose toxicity
Based on information available for the analogue chemicals HHPA and TMA, the notified chemical is not expected to cause adverse effects following repeated oral or inhalation exposure.

Mutagenicity/Genotoxicity
The notified chemical is not expected to be genotoxic based on available *in vitro* and *in vivo* data on cyclic acid anhydrides (WHO 2009). The OECD Quantitative Structure–Activity Relationship (QSAR) Toolbox v3.4 found the isomer analogues did not have DNA binding alerts for genotoxicity and OASIS–TIMES (version 2.27.19) predicted negative in vitro (bacterial reverse mutation and chromosomal aberration) and in vivo (micronucleus test and liver genotoxicity) results for genotoxicity (NICNAS).

Carcinogenicity
The notified chemical is not expected to be carcinogenic based on OECD Quantitative Structure–Activity Relationship (QSAR) Toolbox v3.4 analysis of the two isomer analogues of the notified chemical (NICNAS).

Reproduction and developmental toxicity
The notified chemical is not expected to cause specific reproductive or developmental toxicity effects based on the information available for the analogue chemicals HHPA and TMA (NICNAS) and other cyclic acid anhydrides (WHO 2009).

Observations on human exposure
Workers exposed to the notified chemical were found to have specific IgE or IgG antibodies which indicated the potential for the notified chemical to have sensitisation effects (WHO 2009). Case studies of workers exposed to MHHPA, HHPA and TMA summarised in the NICNAS IMAP report (NICNAS) provide further evidence on respiratory sensitisation and/or skin sensitisation potential of MHHPA and other cyclic acid anhydrides.

Health hazard classification
Based on the available information, the notified chemical is recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the following table.

Hazard classification	*Hazard statement*
Sensitisation, Skin (Category 1)	H317 – May cause an allergic skin reaction
Serious Eye Damage/Eye Irritation (Category 1)	H318 – Causes serious eye damage
Sensitisation, Respiratory (Category 1)	H334 – May cause allergy or asthma symptoms or breathing difficulties if inhaled

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
Based on the available information, the notified chemical is expected to present a concern for a number of health effects including skin and respiratory sensitisation, and severe eye irritation.

The notified chemical is included on the candidate list of substances of very high concern (SVHC) for inclusion in Annex XIV of REACH, based on the respiratory sensitising properties of the notified chemical.

Given the potential for severe eye irritation and skin and respiratory sensitisation, exposure to the notified chemical via any exposure route should be avoided.

During reformulation and end-use, exposure of workers to the notified chemical is expected to be limited given the use of engineering controls (such as enclosed and automated systems, and sufficient ventilation) and PPE (including protective clothing, impervious gloves, safety glasses and respirators). Once the final product (automotive plastic parts) is formed, the notified chemical will be bound within the solid matrix and will not be available for exposure.

Provided that the recommended controls are being adhered to, under the conditions of the occupational settings described, the notified chemical is not considered to pose an unreasonable risk to the health of workers.

6.3.2. Public Health

The notified chemical is intended for industrial use only and will not be made available to the public. Members of the public may come into contact with automotive plastic parts containing the notified chemical. However, the notified chemical is expected to be bound within the solid matrix and will not be available for exposure.

When used in the proposed manner, the notified chemical is not considered to pose an unreasonable risk to public health.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical will be imported as a liquid in steel drums or Schutz containers. The notified chemical is pumped directly from the containers to blending tanks where it is blended with other chemical agents to form a plastic hardener premix in an enclosed system. This premix is then moulded into plastic automotive parts. Releases are expected to be restricted to spillages from containers during handling and are likely to represent a worst-case loss of 1000 kg of the imported volume. The spillages are expected to be cleaned up with absorbents and disposed of as waste to a licensed disposal company in accordance with waste regulations.

RELEASE OF CHEMICAL FROM USE

The notified chemical in the hardener pre-mix is used to react with various epoxy resins to produce solid plastic automotive parts. The mixture reacts with the epoxy material, to form a polymer and is cured by heat. Therefore, only traces of unreacted notified chemical are expected to remain in the final product.

RELEASE OF CHEMICAL FROM DISPOSAL

The notified chemical will be cured within plastic articles, and is expected to share the fate of the plastic articles. These are expected to be disposed of to landfill at the end of their useful lives.

7.1.2. Environmental Fate

The majority of the notified chemical will be cured within an inert plastic matrix, and will share the fate of the plastic articles. Therefore, the notified chemical is not expected to be mobile or bioavailable. Based on the values of the logPow and the notified chemical's instability in water, it is not expected to be bioaccumulative. In landfill, the notified chemical is expected to degrade through biotic and abiotic processes to form water and oxides of carbon.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has not been calculated as release of the notified chemical to the aquatic environment will be limited based on its reported use pattern.

7.2. Environmental Effects Assessment

No ecotoxicological reports were provided for the notified chemical. Based on its structural similarity to the notified chemical, 1,3-isobenzofurandione, tetrahydro-5-methyl- (MTHPA, CAS No. 34090-76-1) was used as an analogue. The notified chemical is a cyclic acid anhydride and other chemicals grouped as cyclic anhydrides

by US EPA HPVIS, were used to support the findings on aquatic ecotoxicity for read-across where hazard data are lacking.

The results from acute ecotoxicological investigations conducted on the notified chemical and the analogue 1,3-Isobenzofurandione, tetrahydro-5-methyl- (MTHPA) are presented below:

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	LC50 500 mg/L[1]	Not harmful to fish
Daphnia Toxicity	EC50 130 mg/L[2]	Not harmful to aquatic invertebrates
Algal Toxicity	EC50 79 mg/L[3]	Harmful to algae

[1] notified chemical tested on Japanese rice fish (*Oryzias latipes)* conducted under, Semi-Static conditions, (US EPA HPVIS, citing JCIEIC, 1992).
[2] analogue chemical (MTHPA); test conducted under, Static conditions (US EPA HPVIS, citing OERA, 1997)
3 analogue chemical (MTHPA); tested on *Selanastrum capricornutum* under Static conditions, (US EPA HPVIS, citing OERA, 1997)

Based on the above ecotoxicological endpoint for the notified chemical, it is not expected to be harmful to aquatic organisms on an acute basis. Therefore, the notified chemical is not formally classified under the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* (United Nations, 2009) for acute toxicity.

7.2.1. Predicted No-Effect Concentration

A predicted no-effect concentration (PNEC) was calculated for the notified chemical using the 72-h EC50 algae endpoint of 79.0 mg/L, three acute studies and an assessment factor of 100. The PNEC for the notified chemical is calculated as 790 µg/L.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (Alga)	79.0	mg/L
Assessment Factor	100	
Mitigation Factor	1.00	
PNEC:	790.00	µg/L

7.3. Environmental Risk Assessment

The Risk Quotient (Q = PEC/PNEC) has not been calculated, since the PEC value is not available. The notified chemical readily degrades in water and is not bioaccumulative. On the basis of the low expected aquatic release from the assessed use pattern as part of an epoxy resin system for plastic automotive parts, the notified chemical is not expected to pose an unreasonable risk to the environment.

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