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February 2019

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

1,3-Isobenzofurandione, tetrahydro-5-methyl-

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/1672	Henkel Australia Pty Ltd	1,3-Isobenzofurandione, tetrahydro-5-methyl-	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

The environmental hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS) is presented below. Environmental classification under the GHS is not mandated in Australia and carries no legal status but is presented for information purposes.

Hazard classification	*Hazard statement*
Acute (Category 3)	H402 - Harmful to aquatic life

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 and USA

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
MTHPA

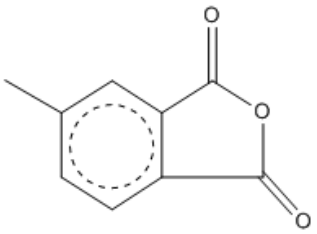
CAS NUMBER
34090-76-1

CHEMICAL NAME
1,3-Isobenzofurandione, tetrahydro-5-methyl-

OTHER NAME(S)
ECA 100NC (contains 5-15% notified chemical)

MOLECULAR FORMULA
$C_9H_{10}O_3$

STRUCTURAL FORMULA



MOLECULAR WEIGHT
166.18 g/mol

ANALYTICAL DATA
Reference IR, GC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
5-15% in the product ECA 100NC

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: oily liquid^

Property	Value	Data Source/Justification
Freezing Point	- 29 °C^	Estimated based on analogue data
Boiling Point	124 °C^	Estimated based on analogue data
Density	1,166 – 1,220 kg/m^3 at 25 °C*	SDS
Vapour Pressure	2 – 3 × 10^{-3} kPa at 25 °C	SDS
Water Solubility	9.5 g/L at 20 °C	Measured. Substance hydrolyses in water. ECHA
Hydrolysis as a Function of pH	t1/2 pH 7 < 1 day at 25 °C$^+$ t1/2 pH 9 < 1 day at 25 °C$^+$ t1/2 pH 4 < 1 day at 25 °C$^+$	Estimated based on analogue data
Partition Coefficient (n-octanol/water)	log Pow = 1.88 at 40 °C	Measured. ECHA
Adsorption/Desorption	log K_{oc} = 1.0 at 20 °C	Calculated. EPA EPI Suite
Dissociation Constant	Not determined	No dissociable functionality
Flash Point	350 °C^	Estimated based on analogue data
Flammability	Not determined	Not expected to be 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

^ Estimated based on an analogue chemical (1,3-isobenzofurandione, 3a,4,7,7a-tetrahydromethyl-, CAS No. 26590-20-5) (IPCS, 2008)
* Properties for the imported product ECA 100NC (contains 5-15% notified chemical)
$^+$ Estimated based on an analogue chemical (HMPA, 1,3-Isobenzofurandione, hexahydromethyl-, CAS No. 25550-51-0)

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 10-30% 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	26	50	50	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 10-30% concentration will be imported into Australia by sea and transported by road in 220 kg steel drums or 1000 kg Schutz containers. The formulations 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 ~5% of the reactants that are used to make the automotive plastic parts. Following the ring opening reaction, the notified chemical will be incorporated in to 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 30% 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 respiratory protection 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 studies were provided for the notified chemical. Information on the expected health effects of the notified chemical is primarily based on an acceptable analogue of the notified chemical, 1,3-isobenzofuranedione, tetrahydromethyl- (CAS No. 11070-44-3). The suitability of the analogue is based on its similarity in chemical structure to the notified chemical. The notified chemical is a cyclic acid anhydride and other chemicals of the same class were also used for read-across where hazard data are lacking. Key results from toxicological investigations conducted on the analogue chemical (1,3-isobenzofuranedione, tetrahydromethyl-) are summarised below.

Endpoint	*Result and Assessment Conclusion*
Acute oral toxicity - rat*	LD50 > 2000 mg/kg bw; low toxicity
Acute oral toxicity - rat*	LD50 = 1900 mg/kg bw
Acute dermal toxicity - rat*	LD50 > 2000 mg/kg bw; low toxicity
Skin irritation - rabbit*	irritating
Eye irritation - rabbit*	irritating
Skin Sensitisation*	sensitiser
Respiratory sensitisation - worker*	evidence of sensitisation
Combined repeat dose oral toxicity and reproductive and developmental toxicity – rat*	repeated dose NOAEL = 100 mg/kg bw/day reproductive/developmental NOAEL = 300 mg/kg bw/day
Mutagenicity – bacterial reverse mutation*	non mutagenic
Genotoxicity – *in vitro* chromosome aberration test*	non genotoxic

* Data on the analogue chemical (1,3-isobenzofuranedione, tetrahydromethyl) derived from the OECD SIDS Initial Assessment Report (OECD 2002)

Absorption, distribution, metabolism and excretion

No information on the toxicokinetics of the notified chemical was provided. For dermal absorption, molecular weights below 500 g/mol are favourable for absorption and molecular weights above 1,000 g/mol do not favour absorption (ECHA, 2017). Dermal uptake is likely to be moderate to high if the water solubility is greater than 0.1 g/L. Dermal uptake through the epidermis is expected if the partition coefficient (log P) values are between -1 and 4 (ECHA, 2017). Gastrointestinal absorption and absorption across the respiratory tract are also likely to be high if the partition coefficient (log P) values are between -1 and 4. Absorption of the notified chemical through the skin, gastrointestinal tract and respiratory tract is expected based on the water solubility (9.5 g/L), low partition coefficient (1.88) and low molecular weight (166.18 g/mol). In humans, following inhalation exposure, the analogue chemical is known to be metabolised to di-carboxylic acids and excreted in the urine. The half-life of the urine concentration of these di-carboxylic acids were 3 - 6 hours (OECD 2002). Based on the information from the analogue chemical, the notified chemical may be expected to be metabolised and excreted similarly.

Acute toxicity

The notified chemical is expected to be of low acute oral, dermal and inhalation toxicity based on information available for the analogue chemical (SIDS 2002), and other cyclic acid anhydrides (WHO 2009).

Irritation

The notified chemical is expected to be a moderate skin irritant based on information available for the analogue chemical (SIDS 2002), and other cyclic acid anhydrides (WHO 2009).

In an eye irritation study conducted in rabbits for the analogue chemical, cloudy cornea and opaque eyeball were noted one minute after administration and congested iris was noted at 24hours (SIDS 2002). On the 10th day, half eye was recovered, reflection to light had normalised and the congestion disappeared (SIDS 2002). The analogue chemical is considered to be a moderate eye irritant (SIDS 2002). Based on this information, the notified chemical is expected to be a moderate eye irritant.

Sensitisation
The notified chemical is expected to have skin sensitisation and respiratory sensitisation effects. Studies on other cyclic anhydrides (WHO 2009) showed antibody responses induced by chemicals in this class via bronchial, subcutaneous, intradermal, and parenteral routes of exposure. Development of allergic respiratory responses following sensitisation with cyclic acid anhydrides was also demonstrated in some studies (WHO 2009). The analogue chemical was reported to cause allergic responses mediated by IgE in workers exposed to this chemical via the inhalation route (SIDS 2002).

Repeated dose toxicity
Based on information available for the analogue chemical, the notified chemical is not expected to cause adverse effects following repeated oral exposure. In a combined repeat dose and reproductive/developmental toxicity screening test conducted in rats, the analogue chemical was administered by oral gavage at doses of 0, 30, 100 and 300 mg/kg bw/day for 49 days in male animals and from 14 days before mating to day 3 of lactation in female animals (SIDS 2002).

All animals in the control and mid-dose groups survived. One animal (male) in the low-dose group and two animals (one male and one female) in the high-dose group died by accident as a result of administering the oral gavage (SIDS 2002). Decreased total cholesterol and blood urea nitrogen (BUN) and increased triglyceride were noted in male animals of the 300 mg/kg bw/day group and mucosal thickening of the forestomach was found in both sexes of this group (SIDS 2002). Histopathological findings in the 300 mg/kg bw/day group included squamous hyperplasia of the forestomach in both sexes, epithelial vascular change, oedema and cellular inflammation of the forestomach in male animals, and erosion of the forestomach in female animals (SIDS 2002). Increased adrenal weights were also noted in male animals of the 300 mg/kg bw/day group (SIDS 2002). The NOAEL for the analogue chemical is considered to be 100 mg/kg bw/day for both sexes based on this study (SIDS 2002).

An increase in stillborns and decrease of birth index was observed in the low-, mid- and high-dose groups, and total litter loss in two dams of the mid-dose group was observed. However, the study authors considered the reproductive and developmental NOAEL of the analogue chemical to be 300 mg/kg/day, as these findings were within the range of historical control data and no dose-response relationship was observed (SIDS 2002).

Mutagenicity/Genotoxicity
The notified chemical is not expected to be genotoxic based on available information for the analogue chemical. In a reverse gene mutation assay conducted using *Salmonella typhimurium* TA100, TA1535, TA98, TA1537 and *Escherichia coli* WP2 *uvr*A, the analogue chemical was not mutagenic at concentrations up to 5 mg/plate and 2 mg/plate, with or without an exogenous metabolic activation system, respectively (SIDS 2002).

In a chromosomal aberration test, structural chromosomal aberrations were not induced at up to 0.30 mg/mL (24 and 48 hours continuous treatment) in the absence of metabolic activation. (SIDS 2002). Polyploidy increased at 0.30 mg/mL with 48 hours continuous treatment in the absence of metabolic activation and increased at 0.11-0.43 mg/mL (all concentrations) with short-term treatment in the presence of an exogenous metabolic activation system (SIDS 2002). The background level of polyploidy in the testing facility was 0-0.5% (48 hours continuous treatment without metabolic activation) and 0-0.75% (short-term treatment with metabolic activation). Genotoxicity of this chemical was equivocal, and toxicological and biological significance were considered to be negligible, based on the results in this study (SIDS 2002).

The SIDS report concludes that the analogue chemical is not genotoxic with or without metabolic activation in bacterial and mammalian cells (SIDS 2002).

Observations on human exposure
The analogue chemical has been reported to cause eye and nasal symptoms (such as pain of eyes, pain of pharynx, sneeze, nose secretion, nose blockage, cough and asthma) in humans (SIDS 2002). Based on these observations, the notified chemical is expected to cause similar symptoms.

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 serious eye damage.

Occupational exposure limits are available overseas for analogue chemicals of the notified chemical. An exposure limit of 3 mg/m^3 time weighted average (TWA) in Denmark and Russia was reported for 1,3-isobenzofurandione, 3a,4,7,7a-tetrahydro- (CAS No. 85-43-8) and an exposure limit of 0.05–1 mg/m^3 TWA in Japan and Russia was reported for 1,3-isobenzofurandione, tetrahydromethyl- (CAS No. 11070-44-3) (NICNAS).

Given the potential for skin and respiratory sensitisation, and serious eye damage, 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 system and sufficient ventilation) and PPE (including protective clothing, impervious gloves, safety glasses and respirator). 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. 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 life.

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 log Pow and chemical instability in water (analogue chemical HMPA), 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 structural similarity, 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 these findings on aquatic ecotoxicity for read-across where hazard data are lacking.

The results from ecotoxicological investigations conducted on the notified chemical and the analogue 1,3-Isobenzofurandione, hexahydromethyl- (MHHPA) are presented below:

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	EC50 > 100 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 endpoints, the notified chemical is expected to be acutely harmful to aquatic life. However, as the notified chemical is highly unstable in water (based on analogue data from HMPA), it is not expected to have chronic toxicity. Therefore, the notified chemical is formally classified under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009) as acute category 3.

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. Using three acute and chronic studies and an assessment factor of 10. The PNEC for the notified chemical is 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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