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September 2019

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

REOLOSIL MT

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	APPLICANTS	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
STD/1692	Dow Performance Materials (Australia) Pty Ltd. Lincoln Sentry Group Pty Ltd.	REOLOSIL MT	ND*	≤ 40 tonnes per annum	Component of industrial adhesive and sealant products

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard Classification
As no toxicity data were provided, the notified chemical cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia. However, based on the available information, the notified chemical may cause skin and serious eye irritation and may cause respiratory irritation. In powder form the notified chemical may be toxic if inhaled and the potential for the chemical as nano-size particles to be able to penetrate skin cannot be fully ruled out. There is currently insufficient information to fully determine the toxicity profile of the notified chemical. The chemical is not introduced into Australia in powder formulations and therefore full assessment of hazards from inhalable nano-size particles is not included in this report.

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 patterns, the notified chemical is not considered to pose an unreasonable risk to the environment.

Recommendations

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 as introduced in end use products:
  - Adequate ventilation

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical in end use products:
  - Avoid generation of aerosols/dusts at all times
  - Avoid inhalation of aerosols/dusts
  - Avoid contact with skin and eyes

- 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 as introduced in end use products:
  - Impervious gloves
  - Safety glasses or goggles
  - Respiratory protection if inhalation exposure to dust may occur during application and cleaning steps
  - Protective clothing

  Selected personal protective equipment should be capable of protecting workers from exposure to nano-size particles. 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 are not appropriate, dispose of the notified chemical in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

Regulatory Obligations
This chemical has been assessed by NICNAS and there are specific secondary notification obligations that must be met. Potential introducers should contact NICNAS before introduction.

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(1) of the Act; if
  - the end use concentration of the notified chemical in industrial adhesive and sealant products exceeds 5%;
  - the notified chemical has begun to be imported for reformulation into end-use products in Australia;
  - the notified chemical has begun to be imported in a powder formulation;
  - the notified chemical is intended to be used in products available to the public;
  - the notified chemical is intended to be used in products involving spray application;
  - additional information has become available to the person as to an adverse effect of the notified chemical due to its nano-size particle properties;

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the chemical has changed from component of industrial adhesive and sealant products, 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 the notified chemical and product containing the notified chemical provided by the notifier were reviewed by NICNAS. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANTS
Dow Performance Materials (Australia) Pty. Ltd. (ABN: 29 004 513 188)
Level 29
367 Collins Street
MELBOURNE VIC 3000

Lincoln Sentry Group Pty. Ltd. (ABN: 59 010 624 389)
76 Postle Street
COOPERS PLAINS QLD 4108

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details exempt from publication include: chemical name, other names, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, impurities, additives/adjuvants, and identity of manufacturer.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Schedule data requirements are varied for all physical and chemical properties, toxicity and ecotoxicity endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANTS
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAMES
REOLOSIL MT
DOWSIL™ 2100-S (Product containing the notified chemical at ≤ 5% concentration)
DOWSIL™ 580 (Product containing the notified chemical at ≤ 5% concentration)
DOWSIL™ 793T (Product containing the notified chemical at ≤ 5% concentration)

MOLECULAR WEIGHT
< 1,000 g/mol

ANALYTICAL DATA
Reference NMR and IR spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 98%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: white amorphous powder

Property	*Value*	*Data Source/Justification*
Melting Point	> 1,600 °C	SDS
Boiling Point	2,230 °C	SDS
Density	Not determined	No data available (SDS)
Vapour Pressure	Not determined	Not expected to be volatile based on boiling point

Property	*Value*	*Data Source/Justification*
Water Solubility	Not determined	Expected to be insoluble in water
Hydrolysis as a Function of pH	Not determined	Does not contain functionalities hydrolysable in environmental conditions.
Partition Coefficient (n-octanol/water)	Not determined	Not expected to have significant solubility in water or octanol
Adsorption/Desorption	Not determined	Expected to sorb to soil based on its low water solubility
Dissociation Constant	Not determined	Does not contain dissociable functionalities
Particle Size	15 nm	Calculated based on particle surface area (120 ± 20 m^2/g) using Brunauer-Emmet-Teller theory
Flash Point	Not determined	Solid with high melting point
Flammability	Predicted to be non-flammable	Not expected to be flammable based on chemical structure
Autoignition Temperature	Not predicted to auto-ignite	Not expected to auto-ignite based on chemical structure
Explosive Properties	Predicted non-explosive	Contains no functional groups that would imply explosive properties
Oxidising Properties	Predicted non-oxidising	Contains no functional groups that would imply oxidative properties

DISCUSSION OF PROPERTIES
The notified chemical has an estimated particle size in the nanoscale.

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 or reformulated within Australia. It will be imported as a component of finished adhesive and sealant paste products at a concentration of ≤ 5%. The notified chemical will not be introduced in powder formulations.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	10 – 20	20 – 25	25 – 30	30 – 35	35 - 40

PORT OF ENTRY
Brisbane, Melbourne and Sydney

IDENTITY OF RECIPIENTS
Lincoln Sentry Group Pty. Ltd.

TRANSPORTATION AND PACKAGING
The finished adhesive and sealant paste products containing the notified chemical at ≤ 5% concentration will be imported into Australia by sea and transported by road in sealed 400 g cartridges. The products containing the notified chemical will be distributed to industrial users in the construction sector.

USE
The notified chemical will be used as an adhesive and sealant agent for glass, metal or masonry in one-pack neutral-cured silicon based adhesives and sealants at ≤ 5% concentration.

OPERATION DESCRIPTION
The imported adhesive and sealant paste products containing the notified chemical at ≤ 5% concentration will be supplied in 400 g cartridges. The finished products will be applied in well ventilated areas to surfaces or cavities using either a manual application gun or a compressed air-assisted caulking gun. Any excess product will be removed using a scraper and cloth. No spray application will be involved.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

EXPOSURE DETAILS
Transport and storage
Transport and storage workers, and retail workers may come into contact with the notified chemical at ≤ 5% concentration only in the unlikely event of an accidental breach of the cartridges.

End use
At end use sites, dermal and perhaps accidental ocular exposure to the notified chemical at ≤ 5% concentration may occur during application of adhesives/sealants containing the notified chemical. Inhalation exposure is not expected given the use of the notified chemical in end use adhesive and sealant paste products with no spray involved. The potential for exposure to the notified chemical should be minimised through the use of personal protective equipment (PPE) including coveralls, gloves, and goggles.

Once the product containing the notified chemical has cured, the notified chemical will be bound within a polymer matrix and is not expected to be available for exposure.

6.1.2. Public Exposure
Products containing the notified chemical at ≤ 5% concentration are for industrial use only, and will not be available to the public. The public may come into contact with the cured adhesives/sealants containing the notified chemical after application. However, once the adhesives/sealants are cured, the notified chemical will be bound within a polymer matrix and is not expected to be available for exposure.

6.2. Human Health Effects Assessment
No toxicological data were provided for the notified chemical. The notified chemical is a surface modified silica with particle sizes at the nanoscale (15 nm). Several analogues for the notified chemical were proposed for the purposes of human health effects assessment. Analogue 1 is a non-surface modified silica that includes crystalline silica, amorphous silica and synthetic amorphous silica (SAS). Analogue 2 is the surface treatment agent used to modified silica to form the notified chemical. Since the toxicological properties of the notified chemical may be significantly affected by its surface functionalisation, a surface modified silica containing similar functional groups to the notified chemical was also selected as analogue 3. In addition, analogue 2 and the surface treatment agent used on analogue 3 have been assigned the same hazard classifications in the HCIS by Safe Work Australia. All three analogues are expected to give a reasonable indication of the toxicological properties of the notified chemical.

No toxicity studies were submitted for any of the analogues proposed. However, published or provided summary information from toxicological investigations conducted on the analogue chemicals are discussed below.

Toxicokinetics, metabolism and distribution
The notified chemical is a substance of unknown, of variable composition, or of biological origin (UVCB) and contains molecular weight species < 500 g/mol which may favour dermal or gastrointestinal absorption (ECHA, 2017). However, given the notified chemical's expected poor solubility in either water or octanol, absorption through the skin and gastrointestinal tract may be limited.

In vitro and *in vivo* studies on the cellular uptake and tissue distribution of SAS have shown that it can be absorbed and distributed through the body (Fruijtier-Pölloth, 2012). However, even after prolonged exposure to high doses, there were no signs of SAS accumulating in the body. There were also no indications of SAS being metabolised in the body (ECETOC 2006).

The main route of exposure during use of the notified chemical is expected to be dermal. The Scientific Committee on Consumer Safety (SCCS) of the European Commission has reviewed the toxicity of various nano-forms of silica used in cosmetics and regarded the information available on skin penetration of silica nanoparticles/clusters as insufficient and inconclusive (SCCS 2015, SCCS 2016). Further studies on the dermal penetration of silica nanoparticles may be required to address the uncertainties (Nafisi *et al* 2015; Ngo *et al* 2013). Based on the available information, the potential for nano-size particles of the notified chemical to be able to penetrate the skin cannot be completely ruled out.

Acute toxicity
Summary information on the acute toxicity is available for SAS and analogue 3.

SAS (including surface-treated forms) are expected to be of low acute oral and dermal toxicity based on studies in rats (ECETOC, 2006, Fruijtier-Pölloth, 2012). Analogue 3 is also expected to be of low acute oral toxicity (EPA, 2011).

In studies conducted in rats, an oral LD_{50} of greater than 5,000 mg/kg bw was recorded for analogue 3 (EPA, 2011) and SAS (ECETOC, 2006). Mortality was observed where animals were exposed to doses of SAS > 10,000 mg/kg bw. In an acute dermal toxicity study for SAS in rabbits, LD_{50} values greater than 5,000 mg/kg bw was also recorded with local effects including slight erythema and oedema following 24 hours after exposure. These effects were reversible within 5 days.

Results on studies in rats indicate that the acute inhalation toxicity of SAS and surface modified SAS can vary depending on their forms. SAS forms, such as precipitated silica, silica gel, pyrogenic silica and hydrophilic SAS, have been shown not to cause adverse effects in rats when inhaled (ECETOC, 2006, Fruijtier-Pölloth, 2012). However, hydrophobic SAS may exhibit high acute inhalation toxicity due to suffocation and lung overloading effects. The study authors considered that the adverse effects observed under the test conditions were not reflective of occupational exposure conditions where SAS are expected to form agglomerates of sizes outside the respirable and inhalable range (ECETOC, 2006).

In studies conducted in rats, analogue 3 was considered fatal if inhaled. Following a 4-hour exposure, mortalities were observed within one day in 7 of 10 animals exposed to a dose of 0.54 mg/L and all 10 animals exposed to a dose of 2.1 mg/L. LC_{50} was considered to be 0.45 mg/L/4-hour. No mortalities were observed in a study where rats (5 male, 5 female) were exposed to 2.8 mg/L of analogue 3 for an hour exposure period (EPA, 2011).

Analogue 2 has been classified under the GHS criteria for specific target organ toxicity (single exposure) having the potential to cause respiratory irritation as listed in *Hazardous Chemical Information System* (HCIS).

Therefore, based on the information available for the analogue chemicals, the notified chemical may be expected to be of low acute oral and dermal toxicity, but may be highly toxic if inhaled.

Irritation and sensitisation
SAS is hygroscopic and as such tends to absorb moisture from the air. Therefore, SAS may cause drying and cracking of the skin following repeated exposure, and may cause irritation to the skin, eye, nose and throat through mechanical action (ECETOC, 2006, Fruijtier-Pölloth, 2012). However, SAS is not expected to be a skin or eye irritant based on studies in rabbits (ECETOC, 2006).

Analogue 2 is listed on the HCIS with hazard classification for serious eye damage/eye irritation and skin corrosion/ irritation.

SAS is not expected to cause skin sensitisation based on its chemical structure. Analogue 3 is also not expected to be a skin sensitiser based on a lack of reported human cases following occupational exposure (Fruijtier-Pölloth, 2012).

Based on the available information on analogues, the notified chemical may be expected to be irritating to the eyes and skin, but is not likely to cause skin sensitisation.

Repeated dose toxicity
SAS is not expected to cause significantly toxic effects following repeated oral or dermal exposure (ECETOC, 2006) and a No Observed Adverse Effects level (NOAEL) of 2,500 mg/kg bw/day was reported (Takizawa 1988,

OECD, 2004) based on a study in mice and rats orally exposed to food-grade micronized SAS (particle size not provided) for 93 and 103 weeks respectively.

In two repeated dose oral toxicity studies in rats exposed to analogue 3 (particle size not provided) by gavage or diet, no treatment related effects were observed. In one study, animals were exposed to 0 or 500 mg/kg bw/day of analogue 3 for 6 months, and, in a separate study, female rats were exposed to 0, 500 or 1,000 mg/kg bw/day over 19 or 39 days. A NOAEL of 1,000 mg/kg bw/day was reported (EPA, 2011).

However, SAS and analogue 3 are expected to cause adverse effects following repeated inhalation exposure. In studies on animals (ECETOC, 2006; Fruijtier-Pölloth, 2012), inhalation of SAS (particle size not provided) in rats resulted in a time- and dose-related inflammation response in the lung tissue. Following subacute or sub-chronic inhalation exposure to SAS (particle size not provided) in rats, transient increases in inflammation markers associated with cell injury and lung collagen were observed. Accumulation of macrophages, reticulin fibre formation, nodule formation and some alterations in pulmonary function were obvious. However, the alterations in pulmonary function reduced over time and silica was rapidly cleared from the lungs during recovery periods. No indication of systemic toxicity was recorded. NOAEL or NOEL were reported varying between 1 mg/m^3 and ≥ 50 mg/m^3 (particle size not provided) (Fruijtier-Pölloth, 2012).

Adverse effects following subacute, sub-chronic and chronic inhalation exposure to analogue 3 were reported in studies in rats. Transient effects on the lungs were observed, including an increase in weight and histopathological changes such as granulomata or similar lesions, interstitial fibrosis, granular phagocytes, epithelial desquamation, dust cell granulomata, local perivascular and peribronchiolar dust deposits with slight to moderate formation of fibrous tissue and thickening of the alveolar wall, and accumulation of alveolar macrophages. Recovery from these effects was indicated in studies where a recovery period was included in the study design (EPA, 2011).

Based on the information available for the analogues, the notified chemical may be expected to be of low oral and dermal toxicity following repeated exposure, but may be expected to cause lung overloading effects upon repeated or prolonged inhalation.

Reproductive and developmental toxicity
Two repeated dose toxicity studies in rats with analogue 3 reported no effects on the male and female reproductive organs at dose levels of 500 mg/kg bw/day via oral route and 0.35 mg/L via inhalation (EPA, 2011). Based on developmental toxicity and teratogenicity studies in rats via oral route, SAS is not expected to cause adverse effects on fertility or development (ECETOC, 2006).

Mutagenicity/Genotoxicity
No data are available on the potential for mutagenicity or genotoxicity of the notified chemical. Information available for SAS and analogue 3 indicates that they are not mutagenic and do not induce chromosomal aberration (ECETOC, 2006; Fruijtier-Pölloth, 2012). Therefore, the notified chemical is not expected to be mutagenic or genotoxic.

Carcinogenicity
No significant toxicological changes were observed in mice or rats in chronic toxicity and carcinogenicity studies following exposure to SAS gel in the diet. No evidence of cancer or other long-term respiratory health effects have been reported in workers involved in the manufacturing of SAS (ECETOC, 2006; Fruijtier-Pölloth, 2012). Tumour responses were observed in 5/53 female rats following repeated intratracheal instillation to amorphous silica. However, this effect was attributed to lung overloading effects due to the high doses tested (15 mg/day). The International Agency for Research on Cancer (IARC) recorded that there was inadequate evidence in humans for the carcinogenicity of amorphous silica and that there was inadequate evidence in experimental animals for the carcinogenicity of SAS (IARC, 1997).

Health Hazard Classification
As no toxicity data were provided, the notified chemical cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia. However, based on the available information, the notified chemical may cause skin and serious eye irritation effects and may cause respiratory irritation. In powder form the notified chemical may be toxic if inhaled and the potential for the notified chemical as nano-size particles to be able to penetrate skin cannot be fully ruled out. There is currently insufficient information to fully determine the toxicity profile of the notified chemical.

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

The notified chemical will only be imported in end use products at up to 5% concentration. During end-use, workers may come into contact with the notified chemical at up to 5% concentration. Inhalation exposure to the chemical is not expected as the end-use product containing the notified chemical is presented and applied as a paste and, the end-use products will not be applied to surfaces by spray. The notified chemical will not be available in a powder form for end-use applications and therefore exposure to single nano-size particles is not expected. Workers may be at risk of skin or eye irritation effects caused by the notified chemical. The use of suitable PPE, including impervious gloves, safety glasses or goggles, and protective clothing is expected to minimise the exposure and hence reduce the risk to workers.

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 use in industrial applications only. The public may come into contact with building or article surfaces treated with products containing the notified chemical. However, once the sealants/adhesives containing the notified chemical has cured, the notified chemical is expected to be trapped in an inert matrix.

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 is not manufactured, reformulated or repackaged in Australia. The notified chemical is only imported as a part of an end-use product.

RELEASE OF CHEMICAL FROM USE

The notified chemical is not expected to be released into the aquatic environment under the proposed use scenarios. Some release of the notified chemical may occur due to spills of equipment wash water.

RELEASE OF CHEMICAL FROM DISPOSAL

The notified chemical is expected to share the fate of the substrate it is applied to, which is to be disposed of by landfill at the end of its useful life. Residues of the notified chemical are expected to remain in the packaging which are to be disposed of by a licensed waste contractor.

7.1.2. Environmental Fate

No environmental fate data were provided. The notified chemical is not expected to be bioaccumulative or readily biodegradable in the environment based on the structural similarity to amorphous silica. During use the notified chemical will be cured and incorporated into an inert solid matrix.

7.1.3. Predicted Environmental Concentration (PEC)

A Predicted Environmental Concentration was not calculated as the notified chemical is not expected to be released into the aquatic environment under the proposed use patterns.

7.2. Environmental Effects Assessment

No ecotoxicity data were submitted. The ecotoxicity endpoints in the table below are derived from an SDS provided for the product containing the notified chemical. The results provided are based on silicon dioxide, which is considered to be similar to the notified chemical for ecotoxicity.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	96 h LC50 > 100 mg/L	Not harmful to fish
Daphnia Toxicity	24 h EC50 > 100 mg/L	Not harmful to aquatic invertebrates

Endpoint	*Result*	*Assessment Conclusion*
Algal Toxicity	72 h EC50 > 100 mg/L	Not harmful to algal growth

The notified chemical is not expected to be harmful to aquatic species.

7.2.1. Predicted No-Effect Concentration

The Predicted No-Effect Concentration was not calculated as the notified chemical is not expected to be toxic to aquatic species.

7.3. Environmental Risk Assessment

On the basis that there is limited release to the aquatic environment under the proposed use pattern and the low expected toxicity to aquatic species, the notified chemical is not considered to pose an unreasonable risk to the environment.

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