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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Mannich Base Curing Agent for Epoxy Coating

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.

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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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/1570	3 M Australia Pty Ltd	Mannich Base Curing Agent for Epoxy Coating	Yes	≤ 60 tonne/s per annum	Component of coatings

^{*}ND = not determined

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
Skin corrosion/irritation (Category 1)	H314 - Causes severe skin burns and eye damage

Based on the available information, the notified chemical is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004), with the following risk phrase(s): R34: Causes burns

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 2	H401 - Toxic to aquatic life
Chronic Category 2	H411 - Toxic to aquatic life with long lasting effects

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

On the basis of the PEC/PNEC ratio and 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:
 - Skin corrosion/irritation (Category 1): H314 Causes severe skin burns and eye damage

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

• Due to the corrosive properties of the notified chemical, the notifier should consider their obligations under the Australian Dangerous Goods Code.

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 prior to its incorporation in coatings:
 - Enclosed and automated processes
 - Local exhaust ventilation where inhalation exposure may occur.
- 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 during reformulation processes:
 - Avoid contact with skin and eyes
 - Avoid inhalation
- 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
 during reformulation and application processes:
 - Coveralls
 - Gloves
 - Safety glasses
 - Respirator

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

- Spray applications should be carried out in accordance with the Safe Work Australia Code of Practice for *Spray Painting and Powder Coating* (SWA, 2015a) or relevant State or Territory Code of Practice.
- A copy of the (M)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.

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, 2012b) 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(1) of the Act; if
 - products containing the notified chemical are intended for public use.

or

- (2) Under Section 64(2) of the Act; if
 - the function or use of the chemical has changed from component of coatings, 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.

(Material) Safety Data Sheet

The (M)SDS of products containing the notified chemical provided by the notifier were reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

This notification has been conducted under the cooperative arrangement with Canada. The health and environmental hazard assessment components of the Canadian report were provided to NICNAS and, where appropriate, used in this assessment report. The other elements of the risk assessment and recommendations on safe use of the notified chemical were carried out by NICNAS.

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
3M Australia Pty Ltd (ABN: 90 000 100 096)
Building A
1 Rivett Road
NORTH RYDE NSW 2113

NOTIFICATION CATEGORY

Standard (Reduced fee notification): Chemical other than polymer (more than 1 tonne per year) – Approved Foreign Scheme.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication: chemical name, other names, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, residual monomers, impurities, additives/adjuvants, use details, and manufacture/import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows: hydrolysis as a function of pH, dissociation constant, flammability limits, autoignition temperature, explosive properties, oxidising properties, reactivity, acute toxicity, eye irritation and skin sensitisation.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S) None.

NOTIFICATION IN OTHER COUNTRIES Canada 2015 EU 2009

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Mannich Base Curing Agent for Epoxy Coating

MOLECULAR WEIGHT > 250 Da

ANALYTICAL DATA

Reference NMR, LC and LC/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

Property	Value	Data Source/Justification	
Melting Point/Freezing Point	0 °C	Measured (pour point)	
Boiling Point	270 °C at 101.3 kPa	Measured. Decomposition of test substance started at 320 °C	
Density	$1034.34 \text{ kg/m}^3 \text{ at } 20 ^{\circ}\text{C}$	Measured	
Vapour Pressure	1.6×10^{-4} kPa at 25 °C	Measured	
Water Solubility	0.02 g/L at 20 °C	Measured	
Hydrolysis as a Function of pH	Not determined	The notified chemical does not contain hydrolysable functionality	
Partition Coefficient (n-octanol/water)	$\log Pow = 2.78 \text{ at } 20 ^{\circ}\text{C}$	Measured	
Surface Tension	62.1 mN/m	Measured	
Adsorption/Desorption	$\log K_{\rm oc} = 5.7$	Measured	
Dissociation Constant	Not determined	The notified chemical contains potential cationic functionalities and is expected to be ionised in the environmental pH range (4 - 9).	
Flash Point	Not determined	(M)SDS. Notified chemical is imported in products with a flash point > 93.3 °C.	
Flammability	Not determined	Not expected to be flammable based on flash point of imported product.	
Autoignition Temperature	Not determined	Not expected to undergo autoignition	
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.	

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 be imported at a concentration of up to 20%.

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

Year	1	2	3	4	5
Tonnes	20 - 60	20 - 60	20 - 60	20 - 60	20 - 60

PORT OF ENTRY Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS 3M (Australia) Pty Ltd

TRANSPORTATION AND PACKAGING

The finished coating products will be imported by sea in dual chamber cartridges (≤ 1 L), cans (≤ 20 L) or 205 L steel drums. The products will be distributed within Australia by road in accordance with the Australian Code for the transport of Dangerous Goods (NTC, 2015).

LICE

The notified chemical will be used as a curing agent in a two-part epoxy amide coating system for the coating of steel structures. The notified chemical will be present in the Part A component at a concentration of $\leq 20\%$. After mixing with Part B, the concentration of the notified chemical in the resulting coating will be $\leq 7\%$.

OPERATION DESCRIPTION

The products containing the notified chemical will be supplied in either dual chamber cartridges, stainless steel cans or steel drums.

The cartridges will be used with either a manual or pressure-assisted dispenser to depress the plunger and slowly extrude the coating onto the surface. The coating will be extruded through a mixing nozzle, which mixes part A containing the notified chemical at $\leq 20\%$ concentration and Part B in a fixed ratio. The coating has a curing and drying time of approximately 2 hours.

Where the product is supplied in cans (up to 20 L), these will be opened and the contents (Part A) manually poured into Part B and mixed prior to application to the surface. Where the product is supplied in 205 L drums, the drums containing Part A and Part B of the coating will be connected to purpose-designed equipment and the coating mixed in-line and applied by airless spray onto the surface.

The coating will only be used in industrial settings with approximately 90% of the import volume applied by spray with the remaining 10% split between roller and brush application.

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 (davs/year)
Transport and Storage	2 - 4	12 - 24
End-use	4 - 8	200

EXPOSURE DETAILS

Transport and storage

Transport and storage workers may come into contact with the notified chemical as a component of the coating finished products at up to 20% concentration only in the event of accidental rupture of containers.

Reformulation into finished products

Dermal, ocular and inhalation exposure to the notified chemical (at a concentration of up to 20%) may occur during opening of cartridges and cans, connection and disconnection of pumping equipment, mixing of coating components (particularly when not using a cartridge or drum) and during equipment cleaning/maintenance. Exposure to the notified chemical is expected to be minimised by the use of personal protection equipment (PPE) including coveralls, boots, gloves, safety glasses and respirator as stated by the notifier.

Application of coatings

The finished coatings containing the notified chemical will be used in industrial applications for use on steel industrial structures, including internal surfaces of pipes for potable water. Dermal, ocular and inhalation exposure to the notified chemical (at a concentration of $\leq 7\%$) may occur when applying the coating to substrates by spray (air-less), brush or roller. Exposure is expected to be minimised by the stated use of PPE (including coveralls, boots, gloves, safety glasses and respirator).

Once the coating has cured, the notified chemical is incorporated into a solid, inert polymer matrix and will not be available for exposure.

6.1.2. Public Exposure

The notified chemical is intended for industrial use only, and will not be available to the public. Direct exposure would therefore not be expected. Indirect exposure from accidental spills or environmental sources may be possible, but are unlikely for the proposed use.

Members of the public may experience dermal contact with industrial items treated with coatings containing the notified chemical. Additionally the notified chemical may be a component of coatings for internal surfaces of pipes for potable water. However, in such coatings the notified chemical will be bound within an inert polymer matrix and will not be available for exposure.

6.2. Human Health Effects Assessment

The results from toxicological investigations were previously assessed by Canada. No additional studies were submitted. The results from the toxicological investigations conducted on the notified chemical are summarised in the following table.

Endpoint	Result and Assessment Conclusion
Skin irritation (in vitro)	inconclusive
Rabbit, skin irritation	corrosive
Rat, repeat dose oral toxicity – 28 days.	NOAEL 50 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro Chromosomal Aberration	non genotoxic
Genotoxicity – in vitro Mammalian cell gene mutation	non genotoxic
assay	_

Toxicokinetics, metabolism and distribution.

No information on the toxicokinetics of the notified chemical was provided. For dermal absorption, molecular weights below 100 Da. are favourable for absorption and molecular weights above 500 Da. do not favour absorption (ECHA, 2014). Water solubility between 1-100 mg/L and log P values between 1 and 4 favour dermal absorption (ECHA, 2014). Therefore, absorption of the notified chemical across biological membranes cannot be excluded based on its water solubility (20.4 mg/L), octanol-water partition coefficient (Log Kow 2.78) and the presence of low molecular weight species (< 500 Da).

Acute toxicity.

No acute toxicity tests were conducted on the notified chemical given its corrosive nature.

Irritation

An *in vitro* skin corrosion test using the EpiskinTM irritation assay (performed according to OECD Test Guideline 431) was inconclusive in determining the skin corrosion potential or to classify the notified chemical as the notified chemical interfered with MTT reduction (demonstrated by the unusually high 3 minute MTT reduction score).

An acute dermal irritation study was performed with the notified chemical in accordance with OECD Test Guideline 404. The notified chemical was applied to three treatment sites on one animal for exposure periods of 3 minutes, 1 hour or 4 hours. Severe erythema and very slight to slight oedema were observed 30-60 minutes after removal of the semi-occlusive dressing at all three treated sites. Blanching of the skin was observed at the 1 and 4 hour exposure sites with large areas of discolouration at the 4 hour exposure site. Based on the severity of the reaction, the experiment was terminated.

Sensitisation

Sensitisation studies were not performed on the notified chemical given its corrosive nature

Repeated dose toxicity.

A 28 day subchronic toxicity assay was performed in F344/DuCrl rats (5/sex/dose). The animals were treated once daily by oral gavage at doses of 15, 50 or 150 mg/kg bw/day for 28 consecutive days (in accordance with OECD Test Guideline 407).

There were no treatment related deaths during the study and no clinical findings. Treatment related decreases in body weight corresponded to decreased feed consumption in animals in the high-dose group. Slight changes in clinical biochemistry parameters were noted in animals in the high-dose group and included decreases in alkaline phosphatase (males only) and increased aspartate aminotransferase (males and females). No other notable biochemical or haematological changes were observed.

Males in the high dose group exhibited lower absolute prostate and spleen organ weights. The study authors considered the histopathologic observation of slight diffuse atrophy of the white pulp of the spleen to correspond to the lower mean absolute spleen weight observed. Histiocytosis in the small intestine (duodenum, jejunum and ileum), mesenteric lymph nodes and spleen, hypertrophy of Kupffer cells in the liver, hyperplasia and hyperkeratosis of the nonglandular mucosa of the stomach, and vacuolisation of tubular epithelial cells in the cortex of the kidneys were observed in males and females in the high-dose group. Males in the high-dose group also exhibited decreased secretory material in the seminal vesicles and coagulating glands. Effects on the small intestine in the mid- and high-dose groups were considered to be point of contact effects due to irritancy from direct exposure to the notified chemical. No treatment related effects were observed in animals in the low dose group.

Based on the reduced body weights in the high dose groups and the histological findings not related to the corrosive nature of the notified chemical in the mid- and high-dose groups, the NOEL is estimated as 15 mg/kg bw/day. The NOAEL for systemic effects is estimated as 50 mg/kg bw/day as the histological effects are likely secondary to the corrosive nature of the notified chemical.

Mutagenicity/Genotoxicity.

The notified chemical was found to be non-mutagenic in a bacterial reverse mutation assay (in accordance with OECD Test Guideline 471).

The notified chemical was found to be non-mutagenic *in vitro* when tested in Chinese Hamster Ovary cells. The *in vitro* mammalian cell gene mutation test was performed (in accordance with OECD Test Guideline 476) in Chinese hamster V79 cells containing the HPRT locus. Following a preliminary cytotoxicity assay, the notified chemical was tested within a concentration range of 12.5 to $80 \mu g/mL$ in the absence of metabolic activation and 12.5 to 150 $\mu g/mL$ and 6.5 to 115 $\mu g/mL$ in the presence of metabolic activation. No precipitation of the test material was noted. No biologically relevant increases in the frequency of mutants in the presence or absence of metabolic activation were observed.

The notified chemical was found to be non-clastogenic *in vitro* when tested in rat lymphocyte cells. A chromosomal aberration assay was performed with the notified chemical utilizing cultured rat lymphocyte cells in the presence and absence of metabolic activation (in accordance with OECD Test Guideline 473). Based on excessive toxicity observed in the initial experiment following exposure to the notified chemical (concentration range of $7.5-1000~\mu g/mL$), the notified chemical was tested within a concentration range of $7.5-50~\mu g/mL$ in the main experiment. No biologically relevant increase in the number of structural chromosomal abnormalities or polyploidy in either the presence or absence of metabolic activation was observed.

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
Skin corrosion/irritation (Category 1)	H314 – Causes severe skin burns and eye damage

Based on the available information, the notified chemical is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004), with the following risk phrase(s): R34: Causes burns

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

Dermal, ocular and inhalation exposure to the notified chemical at a concentration of $\leq 20\%$ may occur during mixing of coating components, during equipment cleaning/maintenance and application of end-use coatings onto industrial items (at a concentration of $\leq 7\%$). Once the coatings containing the notified chemical have cured, the

notified chemical will be incorporated into a polymer matrix and will not be bioavailable. Toxicological studies on the notified chemical indicate that it is corrosive. Therefore, use of the notified chemical is only considered to be reasonable when sufficient engineering controls, safe work practices and personal protective equipment (PPE) are used to reduce the potential for exposure. Dermal, ocular and inhalation exposure is expected to be limited with the use of PPE (gloves, face masks, coveralls and safety glasses/goggles).

Therefore, given the use of sufficient workplace controls, the risk to workers from use of the notified chemical is not considered unreasonable.

6.3.2. Public Health

The notified chemical will only be available to the public when present on industrial items, where it will be bound within a polymer matrix and as such will not be bioavailable. Therefore, the risk to the public is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

No manufacturing or reformulation of the notified chemical will take place in Australia. Release of the notified chemical to the environment during importation, storage, and transport is unlikely. The most likely source of a release to the environment during these activities will be a transport accident. In the event of a spill, the notified chemical is expected to be contained and collected with an inert absorbent material and disposed of in accordance with local regulations.

RELEASE OF CHEMICAL FROM USE

The coatings containing the notified chemical will be used mainly in industrial processes and applications and will not be made available to the public. The notified chemical will be used as one part of a two part epoxy coating system for the coating of steel industrial structures. Therefore, at site two parts of the coating system will be mixed prior to use. Majority of the coating will be applied to the steel structure by spray guns. When coating formulations containing the notified chemical are applied by spray techniques, it is anticipated that between 20-30% of the coating products will form overspray and be collected into drop sheets and/or by using adsorbent material or rags and disposed of to landfill. Application by brush and roller is expected to be efficient, with very little release expected from these application methods. A limited amount of the notified chemical may remain as residues in the product containers, which are expected to be disposed of to landfill. It is estimated that up to 3% of the notified chemical, as a result of splashes, drips and cleaning the application equipment is expected to be treated prior to be released to the sewer.

RELEASE OF CHEMICAL FROM DISPOSAL

The majority of the notified chemical will be cured into an inert polymer matrix expected to be associated with steel structures after application. It is expected to share the fate of the structures to which it is applied and is disposed of to landfill or be subjected to metal recycling processes. Residual notified chemical in empty containers is expected to be disposed of to landfill along with empty cartridges in accordance with local regulations.

7.1.2. Environmental Fate

No environmental fate data were submitted. The majority of the notified polymer is expected to be cured within an inert matrix adhering to articles following its use in coating applications. In its cured form it is not expected to be mobile, bioavailable or biodegradable. Ultimately, the notified chemical is expected to eventually degrade via biotic and abiotic processes in landfill, or by thermal decomposition during metal reclamation processes, to form water and oxides of carbon and nitrogen

A minor amount of the notified chemical may be washed to the sewerage system following spills, or cleaning of residues from application equipment. If released to water, the notified chemical may become distributed in the aquatic environment based on its water solubility. The notified chemical is hydrolytically stable and is not expected to biodegrade rapidly. Adsorption of the substance to dissolved organic matter and sediments is expected to be high based on the log Koc = 5.7. The adsorption is due to ionic interactions of the positively charged moieties on the notified chemical with negatively charged sited on soil. Based on the low log Kow = 2.78 the notified chemical is not expected to bioaccumulate.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) is calculated assuming a worst-case scenario that there is no removal of the notified chemical during sewage treatment plants (STP) processes and 3% of the notified chemical will be washed into sewers per year.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment				
Total Annual Import/Manufactured Volume	60,000	kg/year		
Proportion expected to be released to sewer	3%			
Annual quantity of chemical released to sewer	1,800	kg/year		
Days per year where release occurs	260	days/year		
Daily chemical release:	6.92	kg/day		
Water use	200.0	L/person/day		
Population of Australia (Millions)	22.613	million		
Removal within STP	0%			
Daily effluent production:	4,523	ML		
Dilution Factor - River	1.0			
Dilution Factor - Ocean	10.0			
PEC - River:	1.53	μg/L		
PEC - Ocean:	0.15	μg/L		

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be $1000~L/m^2/year$ (10~ML/ha/year). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 10~cm of soil (density $1500~kg/m^3$). Using these assumptions, irrigation with a concentration of $1.531~\mu g/L$ may potentially result in a soil concentration of approximately 0.01~mg/kg. Assuming accumulation of the notified chemical in soil for 5~and~10~years under repeated irrigation, the concentration of notified chemical in the applied soil in 5~and~10~years may be approximately 0.051~mg/kg and 0.102~mg/kg, respectively.

7.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on the notified chemical are summarised in the table below.

Endpoint	Result	Assessment Conclusion
Acute Toxicity		
Fish	LC50 (96 hours) = 7.90 mg/L	Toxic to fish
Daphnia	EC50 (48 hours) = 8.98 mg/L	Toxic to aquatic invertebrates
Algal	$E_rC50 (72 \text{ hours}) = 4.94 \text{ mg/L}$	Toxic to algae

Based on the acute toxicity for fish, daphnia and algae, the notified chemical is formally classified as "Acute Category 2: Toxic to aquatic life" under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009). On the basis of the acute toxicity and the lack of ready biodegradability, the notified chemical has been formally classified as "Chronic Category 2; Toxic to aquatic life with long lasting effects" under the GHS.

7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) for the notified chemical has been calculated and presented in the table below. An assessment factor of 100 has been used to derive the PNEC as ecotoxicity data for aquatic species at three trophic levels are available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment				
EC50 (Alga).	4.94	mg/L		
Assessment Factor	100			
PNEC:	49.40	μg/L		

7.3. Environmental Risk Assessment

Based on the above PEC and PNEC values, the following Risk Quotient (Q) has been calculated:

Risk Assessment	PEC μg/L	PNEC µg/L	$\boldsymbol{\varrho}$
Q - River:	1.53	49.4	0.031
Q - Ocean:	0.15	49.4	0.003

The Risk Quotients (Q = PEC/PNEC) have been calculated to be < 1 for both river and ocean compartments. Release to the aquatic environment in ecotoxicologically significant quantities is not expected based on its reported use pattern as a component of industrial coating in steel structures. The majority of the notified chemical will be disposed of to landfill as a cured chemical matrix in coated steel articles or degrade by thermal decomposition during metal reclamation processes. The notified chemical bound in coated articles is unlikely to be bioavailable or mobile in this form. Therefore, based on the assessed use pattern, the notified chemical is not considered to pose an unreasonable risk to the environment.

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