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**AUSTRALIAN INDUSTRIAL CHEMICALS INTRODUCTION SCHEME
(AICIS)**

PUBLIC REPORT

New Chemical in MasterProtect® 8500 CI

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals Act 2019 (the IC Act)* and *Industrial Chemicals (General) Rules 2019 (the IC Rules)* by following the *Industrial Chemicals (Consequential Amendments and Transitional Provisions) Act 2019 (the Transitional Act)* and *Industrial Chemicals (Consequential Amendments and Transitional Provisions) Rules 2019 (the Transitional Rules)*. The legislations are Acts of the Commonwealth of Australia. The Australian Industrial Chemicals Introduction Scheme (AICIS) 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 Agriculture, Water and the Environment.

This Public Report is available for viewing and downloading from the AICIS website. For enquiries please contact AICIS at:

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**Executive Director
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SUMMARY

The following details will be published on our website:

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/2145	BASF Australia Ltd	New Chemical in MasterProtect® 8500 CI	Yes	≤ 1 tonne per annum	A component of corrosion inhibitor in concrete

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard Classification

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

<i>Hazard Classification</i>	<i>Hazard Statement</i>
Acute Toxicity, Dermal (Category 4)	H312 - Harmful in contact with skin
Acute Toxicity, Inhalation (Category 4)	H332 - Harmful if inhaled
Specific Target Organ Toxicity (Repeated Exposure) (Category 2)	H373 - May cause damage to organs through prolonged or repeated dermal and inhalation exposure
Reproductive Toxicity (Category 1B)	H360D - May damage the unborn child

Human Health Risk Assessment

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

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

Environmental Risk Assessment

Based on the proposed use pattern, the assessed chemical is not expected to pose an unreasonable risk to the environment.

Recommendations

Hazard Classification and Labelling

- The assessed chemical should be classified as follows:
 - Acute Toxicity, Dermal (Category 4): H312 - Harmful in contact with skin
 - Acute Toxicity, Inhalation (Category 4): H332 - Harmful if inhaled
 - Specific Target Organ Toxicity (Repeated Exposure) (Category 2): H373 - May cause damage to organs through prolonged or repeated dermal and inhalation exposure
 - Reproductive Toxicity (Category 1B): H360D - May damage the unborn child

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

Safety Data Sheet

- The SDS provided by the applicant should be amended as follows:
 - Hazard classifications for the assessed chemical should be included in the SDS;
 - Identity of assessed chemical should be included in the SDS available to workers.

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 assessed chemical during use:
 - Use the assessed chemical in well ventilated areas
- 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 assessed chemical during use:
 - Avoid skin and eye contact
 - Avoid inhaling vapour
- 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 assessed chemical during use:
 - Impervious gloves
 - Protective clothing
 - Respiratory protection if ventilation is inadequate

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 assessed 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.

Storage

- The handling and storage of the assessed 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 assessed chemical should be handled by physical containment, collection and subsequent safe disposal.

Disposal

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

Regulatory Obligations

Specific Requirements to Provide Information

This risk assessment is based on the information available at the time of the application. The Executive Director may initiate an evaluation of the chemical based on changes in certain circumstances. Under Section 101 of the IC

Act the applicant of the assessed chemical has post-assessment regulatory obligations to provide information to AICIS when any of these circumstances change. These obligations apply even when the assessed chemical is listed on the Australian Inventory of Industrial Chemicals (the Inventory).

Therefore, the Executive Director of AICIS must be notified in writing within 20 working days by the applicant or other introducers if:

- the importation volume exceeds one tonne per annum assessed chemical;
- the function or use of the chemical has changed from a component of corrosion inhibitor in concrete for industrial use, or is likely to change significantly;
- the end use products are made available for public use;
- the chemical has begun to be manufactured or reformulated in Australia;
- additional information has become available to the person as to an adverse effect of the chemical on human health, or the environment.

The Executive Director will then decide whether an evaluation of the introduction is required.

Safety Data Sheet

The SDS of the products containing the assessed chemical provided by the applicant was reviewed by AICIS. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND APPLICATION DETAILS

APPLICANT(S)

BASF Australia Ltd (ABN: 62 008 437 867)
Level 12, 28 Freshwater Place
SOUTHBANK VIC 3006

APPLICATION CATEGORY

Limited-small volume: Chemical other than polymer (1 tonne or less per year)

PROTECTED INFORMATION (SECTION 38 OF THE TRANSITIONAL ACT)

Data items and details taken to be protected information include: chemical name, other names, CAS number, molecular and structural formulae, molecular weight, details of analogue chemical, degree of purity, impurities, additives/adjuvants and use details.

VARIATION OF DATA REQUIREMENTS (SECTION 6 OF THE TRANSITIONAL RULES)

Schedule data requirements are varied for all physical and chemical endpoints.

PREVIOUS APPLICATION IN AUSTRALIA BY APPLICANT(S)

None

APPLICATION IN OTHER COUNTRIES

EU (2009), USA (2019), Canada (2020), China (2019), Japan (2019), South Korea (2019), Taiwan (2015) and Vietnam (2018)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

MasterProtect® 8500 CI (containing the assessed chemical at < 2%)

MOLECULAR WEIGHT

< 500 g/mol

3. COMPOSITION

DEGREE OF PURITY

> 95%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: colourless liquid (assessed chemical)

<i>Property</i>	<i>Value</i>	<i>Data Source/Justification</i>
Melting Point/Freezing Point	-32 °C	Chemical book
Boiling Point	90 - 92 °C at 1.1 kPa	SDS
Relative Density	924 kg/m ³ at 25 °C	SDS
Vapour Pressure	0.034 kPa at 25 °C	Calculated
Water Solubility	189.2 g/L at 20 °C	Calculated using Episuite
Hydrolysis as a Function of pH	Not determined	Contains functional groups expected to slowly hydrolyse under environmental conditions
Partition Coefficient (n-octanol/water)	log Pow = - 0.21	Calculated using Episuite
Adsorption/Desorption	log K _{oc} = 0.78	Calculated using Episuite
Dissociation Constant	Strongest pKa(Acid): 15.1 Strongest pKa(Base): -0.3	Calculated using ACD/iLabs 2.0
Flash Point	107 °C (closed cup)	SDS
Autoignition Temperature	Not determined	Not expected to Autoignite

Property	Value	Data Source/Justification
Explosive Properties	Not determined	Contains no functional groups that imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that imply oxidising properties

Reactivity

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

Physical Hazard Classification

Based on the physico-chemical data depicted in the above table, the assessed 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 ASSESSED CHEMICAL (100%) OVER NEXT 5 YEARS**

The assessed chemical will not be manufactured in Australia. It will be imported at < 2% concentration in a finished ready-to-use product for professional construction workers to use. It will not be reformulated or repackaged in Australia.

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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	≤ 1	≤ 1	≤ 1	≤ 1	≤ 1

PORT OF ENTRY

Melbourne, Sydney, Brisbane

IDENTITY OF MANUFACTURER/RECIPIENTS

BASF Australia Ltd

TRANSPORTATION AND PACKAGING

The product containing the assessed chemical (at a concentration of < 2%) will be imported into Australia by sea in 200 L closed head steel drums and 1,000 L intermediate bulk containers. The imported solution containing the assessed chemical will be transported within Australia by road to construction sites.

USE

The assessed chemical will be used as a component of a dual-phase corrosion inhibitor for reinforced concrete structures.

OPERATION DESCRIPTION

The corrosion inhibitor product containing the assessed chemical at < 2% concentration will not be manufactured, reformulated or repackaged in Australia. The product containing the assessed chemical will be used by professional construction workers for manual application to indoor and outdoor surfaces. The product will be applied with low pressure non-atomising spray equipment or brush or roller to dry concrete surfaces. The product can also be poured when pre-treating cracks in horizontal surfaces. Applications of the product will require two or three coats applied at a rate of 180 – 230 mL/m² depending on the concrete porosity, application environment and the degree of corrosion, chloride content of the concrete and the severity of expected service conditions.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

<i>Category of Worker</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Transport	3	10-20
Storage	1	50-70
Professional construction	5-8	150-200

EXPOSURE DETAILS

Transport and Storage

Transport and storage workers may come into contact with the assessed chemical (at < 2 % concentration) only in the event of accidental spill or breach of the containers.

End-use

Dermal, ocular and inhalation exposure of workers to the assessed chemical at < 2% concentration may occur during application and cleaning processes. The use of appropriate PPE including impervious gloves, protective clothing and safety glasses, will reduce any potential dermal and/or ocular exposure to the chemical during these operations. Based on the low vapour pressure of the assessed chemical (0.034 kPa), inhalation exposure to the assessed chemical is expected to be limited. Use of the assessed chemical in well ventilated areas may further reduce the potential inhalation exposure to the chemical vapour. Respiratory protection is expected to be worn if ventilation is inadequate.

6.1.2. Public Exposure

The product containing the assessed chemical at < 2% concentration will only be used by professional construction workers and will not be sold or made available to the public such as for do-it-yourself (DIY) users. Once applied to surfaces, the corrosion inhibitor product containing the assessed chemical will be cured within 48 hours and the assessed chemical is not expected to be available for further exposure as it will be reacted, bound and cured within the inert matrix of the concrete.

6.2. Human Health Effects Assessment

No toxicity data were submitted for the assessed chemical. However, toxicity information on a suitable analogue chemical (an isomer of the assessed chemical with a similar structure) was available (reference 2001 and reference 2013).

Toxicokinetics

The assessed chemical has a molecular weight of < 500 g/mol, very high water solubility (calculated 189.2 g/L at 20 °C) and a log Pow of - 0.21 (calculated), indicating potential for absorption. The analogue chemical can be absorbed by oral, inhalation or dermal routes of exposure.

Acute Toxicity

The analogue chemical is reported to have low acute toxicity via the oral route (median lethal dose (LD50) > 2,000 mg/kg bw in rats and mice). Based on available data, the analogue chemical is classified as harmful for the acute dermal (the LD50 was 940 mg/kg bw in guinea pigs) and inhalation toxicity. In an acute inhalation toxicity test using OECD 403, rats were exposed to vapour of the analogue chemical for 4 hours at 10.7 or 32.0 mg/L. Two out of 6 animals in the lower dose group and all animals in the higher dose group died. The LC50 was established as 10.7–32 mg/L.

Irritation and Sensitisation

The analogue chemical is reported to slightly irritate the skin in animal studies. Based on the limited data available, the analogue chemical is not considered to cause eye irritation at a level that warrants a hazard classification.

The analogue chemical was not considered to be a skin sensitizer based on the results of a guinea pig test with direct application of a 50% solution to guinea pig abraded skin.

Repeated Dose Toxicity

Based on the data available, the analogue chemical is not considered to cause serious damage to health through repeated oral exposure up to 300 mg/kg bw/day.

Although the analogue chemical is not considered to cause serious damage to health through repeated dermal exposure in animals (up to 95 mg/kg bw/day), human epidemiological/occupational data indicate adverse effects to the liver with repeated dermal exposure. Therefore, a hazard classification is warranted (reference 2013).

Based on the data available from repeat-dose inhalation toxicity studies in rats and mice (with a NOAEC of 0.09 mg/L being established for male and female rats and male mice), and also based on the epidemiological/occupational exposure studies with liver as the main organ being targeted, repeated inhalation exposure to the analogue chemical may cause serious damage to health.

Mutagenicity/Genotoxicity

The analogue chemical showed negative results in several *in vitro* gene mutation and clastogenicity tests (bacterial reverse mutation assays with *Salmonella typhimurium*; DNA damage and repair assay with human embryonic intestinal cells) and in some *in vivo* tests (rodent dominant lethal tests with mice and rats, mammalian bone marrow chromosome aberration assays with rats and a gene mutation sex-linked recessive lethal test with *Drosophila melanogaster*). There were positive results in an *in vitro* sister chromatid exchange assay with Chinese hamster ovary cells (reference 2001). Based on the data available, the analogue chemical is not considered genotoxic.

Reproductive and Developmental Toxicity

The analogue chemical is classified as a substance toxic to reproduction, given the malformations observed in foetuses and young animals in rabbit developmental studies, at doses with no maternal toxicity (reference 2013). The analogue chemical is not considered to affect fertility.

Carcinogenicity

The analogue chemical was not carcinogenic in rats (2-year study) and mice (18-month study) when exposed to the vapour in whole body exposures at concentrations up to 1.26 mg/L. The analogue chemical was not carcinogenic in rats at concentrations up to 1,000 mg/kg bw/day by oral exposure in drinking water (2-year study) (reference 2013).

Dermal application of the analogue chemical did not result in carcinogenicity in hamsters. The analogue chemical appeared to lower the incidence of tumours in hamsters that had resulted from other chemicals (reference 2001).

Based on the data available, the analogue chemical is not considered carcinogenic.

Health Hazard Classification

Based on the available information for the analogue chemical, the assessed chemical is considered a hazardous chemical according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia. The hazard classification applicable to the analogue chemical (reference 2013) is applicable for the assessed chemical and is presented in the following table.

<i>Hazard Classification</i>	<i>Hazard Statement</i>
Acute Toxicity, Dermal (Category 4)	H312 - Harmful in contact with skin
Acute Toxicity, Inhalation (Category 4)	H332 - Harmful if inhaled
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Reproductive Toxicity (Category 1B)	H360D - May damage the unborn child

6.3. Human Health Risk Characterisation

Based on toxicological data available on the analogue chemical, the critical health effects of the assessed chemical for risk characterisation include acute toxicity by the dermal and inhalation routes of exposure, reproductive toxicity and harmful effects following repeated dermal or inhalation exposure.

6.3.1. Occupational Health and Safety

Professional end-users may be exposed to the assessed chemical at < 2% concentration during end-use. The proposed use of PPE including impervious gloves, protective clothing and safety glasses during use is expected to minimise dermal and accidental ocular exposure. Use of the assessed chemical in well ventilated areas and possible use of respiratory protection if ventilation is inadequate will minimise the inhalation exposure.

Provided that the stipulated control measures are in place and the proposed PPE is used, the risk to workers from use of the assessed chemical is not considered unreasonable.

6.3.2. Public Health

The assessed chemical is only intended for use in industrial settings, and hence public exposure is not expected. Therefore, when used in the proposed manner, the risk to public health from the assessed chemical 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

The assessed chemical is imported as a part of a finished product and therefore no release will occur from these processes. Accidental spills may occur during transport and storage. Any accidental spills are to be collected and disposed of in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE

The assessed chemical is used as a corrosion inhibitor coating which will be applied by brush, roller or spray (low pressure non-atomising) methods by professional users only. It is expected that some of the assessed chemical will be lost to overspray during the application process. Overspray is expected to be primarily be deposited onto the adjacent concrete substrate. The applicant estimates that up to 1% of the import volume of the assessed chemical may be released during its application. Any wastes are expected to be collected and disposed of to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

The assessed chemical is expected either to eventually degrade in situ or share the fate of the concrete substrate it is applied to, which is expected to be eventually disposed of to landfill at the end of its useful life. Residues of the assessed chemical may remain in the packaging containers. Empty containers containing the residual assessed chemical are to disposal to landfill.

7.1.2. Environmental Fate

No environmental fate data were submitted. The assessed chemical is expected to be mobile in soil based on its low calculated Log K_{oc} value (log K_{oc} = 0.78) and high calculated water solubility. The assessed chemical is not expected to bioaccumulate due to its low log P_{ow} (calculated as - 0.21). The majority of the assessed chemical is expected to either eventually degrade in situ or share the fate of the articles which it is applied to. These will eventually be disposed of to landfill as a part of the cured coating matrix. In landfill, the assessed chemical is expected to ultimately degrade via biotic and abiotic processes to form water and oxides of carbon and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

A Predicted Environmental Concentration (PEC) could not be calculated as based on the proposed use pattern, no aquatic exposure is expected.

7.2. Environmental Effects Assessment

No ecotoxicity data were submitted.

7.2.1. Predicted No-Effect Concentration

The Predicted No-Effect Concentration (PNEC) could not be calculated as no ecotoxicological endpoints were provided.

7.3. Environmental Risk Assessment

The Risk Quotient, Q ($= \text{PEC}/\text{PNEC}$), has not been calculated since neither a PEC nor PNEC is available. The majority of the assessed chemical will be incorporated in a coating matrix and bound to the substrate after application and is not expected to be exposed to the aquatic environment. Therefore, based on the proposed use pattern, the assessed chemical is not expected to pose and unreasonable risk to the environment.

BIBLIOGRAPHY

SWA (2012) Code of Practice: Managing Risks of Hazardous Chemicals in the Workplace, Safe Work Australia, <https://www.safeworkaustralia.gov.au/doc/model-code-practice-managing-risks-hazardous-chemicals-workplace>

United Nations (2009) Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 3rd revised edition. United Nations Economic Commission for Europe (UN/ECE), http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html >