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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME
(NICNAS)**

PUBLIC REPORT

Chemical in MasterSeal CR 195

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**

TABLE OF CONTENTS

SUMMARY	3
CONCLUSIONS AND REGULATORY OBLIGATIONS	3
ASSESSMENT DETAILS	6
1. APPLICANT AND NOTIFICATION DETAILS	6
2. IDENTITY OF CHEMICAL.....	6
3. COMPOSITION.....	6
4. PHYSICAL AND CHEMICAL PROPERTIES	6
5. INTRODUCTION AND USE INFORMATION	7
6. HUMAN HEALTH IMPLICATIONS	8
6.1. Exposure Assessment.....	8
6.1.1. Occupational Exposure.....	8
6.1.2. Public Exposure.....	8
6.2. Human Health Effects Assessment	8
6.3. Human Health Risk Characterisation	9
6.3.1. Occupational Health and Safety	9
6.3.2. Public Health	10
7. ENVIRONMENTAL IMPLICATIONS.....	10
7.1. Environmental Exposure & Fate Assessment	10
7.1.1. Environmental Exposure	10
7.1.2. Environmental Fate	10
7.1.3. Predicted Environmental Concentration (PEC).....	10
7.2. Environmental Effects Assessment.....	10
7.2.1. Predicted No-Effect Concentration	10
7.3. Environmental Risk Assessment	11
BIBLIOGRAPHY	12

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
LTD/2046	BASF Australia Ltd	Chemical in MasterSeal CR 195	Yes	≤ 1 tonne per annum	Component of waterproofing products used in construction

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.

<i>Hazard classification</i>	<i>Hazard statement</i>
Flammable liquid (Category 4)	H227 – Combustible liquid
Acute oral toxicity (Category 4)	H302 – Harmful if swallowed
Serious eye damage (Category 1)	H318 – Causes serious eye damage
Skin sensitisation (Category 1)	H317 – May cause an allergic skin reaction

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 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:
 - Flammable liquid (Category 4): H227 – Combustible liquid
 - Acute oral toxicity (Category 4): H302 – Harmful if swallowed
 - Serious eye damage (Category 1): H318 – Causes serious eye damage
 - Skin sensitisation (Category 1): H317 – May cause an allergic skin reaction

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 sensitizer, employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of allergic skin reaction.

CONTROL MEASURES

Occupational Health and Safety

- 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 or 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:
 - Impervious gloves
 - Coverall
 - Safety glasses or goggles
 - Respiratory protection if used in poorly ventilated areas

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.

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.

Transport and Packaging

- Due to the notified chemical being a flammable liquid, introducers of the chemical should consider their obligations under *Australian Code for the Transport of Dangerous Goods by Road and Rail* (ADG code) (NTC, 2017).

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
- the importation volume exceeds one tonne per annum notified chemical;
 - the notified chemical is intended to be used in products available to the public.

or

- (2) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from component of waterproofing products used in construction, 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 products 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

APPLICANT(S)

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

NOTIFICATION CATEGORY

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

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, impurities, additives/adjuvants and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed for all physical-chemical properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

Canada (1991)
China (2013)
Europe (2017)
Japan (2002)
Malaysia
New Zealand (2013)
Philippines (2000)
USA (2018)
Taiwan (2015)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

MasterSeal CR 195 AluGry (product containing the notified chemical)
MasterSeal CR 195 Wht (product containing the notified chemical)

MOLECULAR WEIGHT

< 500 g/mol

ANALYTICAL DATA

Reference IR and GC/MS spectra were provided.

3. COMPOSITION

DEGREE OF PURITY

> 90%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Pale amber liquid with sweetish odour

Property	Value	Data Source/Justification
Melting Point	< -20 °C	Data provided by a third party
Boiling Point	226 °C at 101.3 kPa	Data provided by a third party
Density	1,020 kg/m ³ at 20 °C	Data provided by a third party
Vapour Pressure	8.0 × 10 ⁻⁵ kPa at 25 °C	Data provided by a third party

Water Solubility	612 g/L at 20 °C	Calculated by WSKOW v1.42 (US EPI, 2012)
Hydrolysis as a Function of pH	Not determined	Likely to undergo hydrolysis based on the structure
Partition Coefficient (n-octanol/water)	log P _{ow} = 0.06	Estimated by KOWWIN v1.68 (US EPI, 2012)
Adsorption/Desorption	log K _{oc} = 0.51 (MCI method) log K _{oc} = 0.39 (log P _{ow} method)	Estimated by KOCWIN v2.00 (US EPI, 2012)
Dissociation Constant	Not determined	Hydrolytically unstable; pKa indeterminable
Flash Point	67 °C	Data provided by a third party
Flammability	Flammable liquid (Category 4)	Based on flash point
Autoignition Temperature	239 – 249 °C	Data provided by a third party
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidative properties

DISCUSSION OF PROPERTIES

No test details were provided for physical-chemical properties of the notified chemical.

Reactivity

The notified chemical is expected to be stable under normal conditions of transport and storage. The notified chemical reacts slowly with moisture forming a hydrolysis product, which can react with other ingredients in the final product during the curing process and will be bound in an inert matrix.

Physical hazard classification

Based on the submitted physical-chemical data depicted in the above table, 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.

<i>Hazard classification</i>	<i>Hazard statement</i>
Flammable liquid (Category 4)	H227 – Combustible liquid

5. INTRODUCTION AND USE INFORMATION

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

The notified chemical will not be manufactured in Australia. The notified chemical will be imported into Australia as a component of waterproofing products at < 1% concentration and will be used without any local reformulation or repackaging.

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED 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

Sydney, Melbourne and Brisbane

IDENTITY OF RECIPIENT

BASF Australia Ltd

TRANSPORTATION AND PACKAGING

The products containing the notified chemical will be imported into Australia by sea in 0.7 kg caulking gun cartridges with 20 cartridges per fibreboard box packed in shipping containers and transported by road to warehouses for storage. The products will be distributed to customers by pallet sized loads and divided into smaller packages for delivery to construction sites.

USE

The notified chemical will be used as a component in waterproofing products at concentration < 1% and will be used by professional construction workers.

OPERATION DESCRIPTION

Manufacture, reformulation and repackaging of the notified chemical or products containing the notified chemical will not occur in Australia.

End Use

Waterproofing products containing the notified chemical will be used by professional users for manual application to indoor or outdoor surfaces and for structural joinery using a caulking gun. A clean cloth will be used to remove excess products and to clean application equipment. Wastes will be collected for disposal. For application in poorly ventilated areas, individual respirators will be available for professional users.

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 – 60
Professional construction applicators	5	150

EXPOSURE DETAILS

Transport and Storage

Transport and storage workers may come into contact with the notified chemical (at < 1% concentration) only in the event of an accident where the containers are breached.

End Use

Dermal and ocular exposure of workers to the notified chemical at < 1% concentration may occur during application and cleaning processes. Based on the low vapour pressure (8.0×10^{-5} kPa at 25 °C) of the notified chemical with no spray application proposed, inhalation exposure to the notified chemical under normal use conditions is expected to be limited.

6.1.2. Public Exposure

The products containing the notified chemical will only be used by professional construction workers and will not be sold to the public for do-it-yourself (DIY) use.

Once applied to surfaces, the waterproofing products containing the notified chemical will be cured within 48 hours and the notified chemical is expected to be reacted and bound within the inert matrix. It is not expected to be available for further exposure after curing.

6.2. Human Health Effects Assessment

No toxicology study data were provided for the notified chemical. Available information on European Chemicals Agency web site (ECHA, 2018; Exempt Information) indicates the following results from toxicological investigations conducted on the notified chemical:

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Rat, acute oral toxicity	LD50 > 300 but < 2,000 mg/kg bw; harmful
Eye irritation (<i>in vitro</i> enucleated rabbit eye)	Corrosive/irritating
Mouse, skin sensitisation – local lymph node assay	Evidence of sensitisation

Toxicokinetics, metabolism and distribution

No toxicity data were submitted for the notified chemical. The notified chemical is expected to be readily absorbed across biological membranes, based on the low molecular weight (< 500 g/mol) and high water solubility.

Acute toxicity

In an acute oral toxicity study conducted in rats, the notified chemical at a dose level of 2,000 mg/kg bw caused mortality. Abnormally red lungs, dark liver and kidneys, and slight haemorrhage of the gastric mucosa were noted at necropsy of the animals. Signs of systemic toxicity included hunched posture, ataxia, prostration, decreased respiratory rate, laboured respiration, pilo-erection and occasional body tremors. The study authors concluded that the acute oral median lethal dose (LD50) of the notified chemical was in the range of 300 – 2,000 mg/kg bw. The notified chemical is harmful if swallowed (ECHA, 2018; Exempt Information).

Irritation

The notified chemical contains chemical structures that may have potential to cause serious eye damage.

In an eye irritation study using rabbit enucleated eyes conducted on the notified chemical, significant corneal opacity and swelling, fluorescein uptake and sloughing of the corneal epithelium were noted in the eyes, persisting till the end of the study period. These effects were not reversible. The notified chemical was considered by the study authors to have the potential to cause severe ocular damage and to be a Category 1 eye irritant (ECHA, 2018; Exempt Information).

Sensitisation

In a local lymph node assay (LLNA) in mice conducted on the notified chemical, stimulation indexes (SI) of > 3 were recorded for all concentrations tested at $\geq 25\%$. The SI at 25% test concentration was approximately 15. There were no signs of systemic toxicity noted in the test. The results clearly indicated evidence of skin sensitisation and therefore the notified chemical was considered by the study authors to be a Category 1 skin sensitiser according to GHS (ECHA, 2018; Exempt Information).

Health hazard classification

Based on the above 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.

<i>Hazard classification</i>	<i>Hazard statement</i>
Acute oral toxicity (Category 4)	H302 – Harmful if swallowed
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Skin sensitisation (Category 1)	H317 – May cause an allergic skin reaction

6.3. Human Health Risk Characterisation**6.3.1. Occupational Health and Safety**

Based on the use patterns assessed, the main concerns to workers posed by the notified chemical are potential for eye irritations and skin sensitisation. However, the notified chemical is only to be imported and used at < 1% concentration in ready-for-use waterproofing construction products. At this relatively low final use concentration, significant eye irritation effects are not expected. The use of appropriate PPE including impervious gloves and safety glasses, will reduce the potential for exposure during the operations, and hence reduce the risk of possible adverse skin and eye effects.

The inhalation toxicity of the notified chemical is not determined. However, based on the assessed use patterns, inhalation exposure to the notified chemical is expected to be limited for workers due to the low vapour pressure of the notified chemical with no spray applications. Use of the notified chemical in well ventilated areas may further reduce the risk of potential inhalation effects.

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 products containing the notified chemical will only be used by professional construction workers and will not be sold to the public for DIY use.

Once applied to surfaces, the waterproofing product containing the notified chemical will be cured and the notified chemical is expected to be reacted and trapped within the inert matrix. It is not expected to be available for exposure after curing.

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 into Australia as a component of waterproofing products at < 1% concentration. Manufacture, reformulation and repackaging of the products containing the notified chemical will not occur in Australia. Accidental spills of the notified chemical during import, transport, or storage only occur if the cartridges are breached. These spills are expected to be adsorbed onto a suitable material for disposal in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE

Waterproofing products containing the notified chemical will be used by professional construction workers for manual application to indoor and outdoor surfaces or for structural joinery using a caulking gun. The notifier estimates that up to 1% of the import volume of the notified chemical could be released as waste during use. This waste will form an inert solid matrix on exposure to ambient conditions, and the cured mass will be disposed of to landfill in accordance with local government regulations.

RELEASE OF CHEMICAL FROM DISPOSAL

The notified chemical in cured sealants is expected to share the fate of the construction materials to which it has been applied and is expected to be predominantly disposed of to landfill at the end of their useful lives. Residual notified chemical in empty containers is expected to be cured into an inert solid matrix and be disposed of to landfill along with the empty containers.

7.1.2. Environmental Fate

No environmental fate data were submitted. The majority of the notified chemical is expected to share the fate of the construction materials to which it has been applied, and be disposed of to landfill at the end of their useful lives. In landfill, the notified chemical will be present as cured solids and will be neither mobile nor bioavailable. Based on predicted low log P_{ow} , the notified chemical is not expected to be bioaccumulative. The notified chemical is expected to eventually degrade via biotic and abiotic processes to form water and oxides of carbon and nitrogen.

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 as a component of waterproofing products.

7.2. Environmental Effects Assessment

No ecotoxicity data were submitted. Release of the notified chemical to the aquatic environment will be limited based on its reported use pattern as a component of waterproofing products.

7.2.1. Predicted No-Effect Concentration

The Predicted No-Effect Concentration (PNEC) has not been calculated since no ecotoxicological data were submitted.

7.3. Environmental Risk Assessment

The risk quotient ($Q = PEC/PNEC$) for the notified chemical has not been calculated as release to the aquatic environment in ecotoxicologically significant concentration is not expected based on its reported use pattern. Therefore, on the basis of this assessed use pattern as a component of waterproofing products, the notified chemical is not considered to pose an unreasonable risk to the environment.

BIBLIOGRAPHY

- NTC (2017) Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG code), Edition 7.5, National Transport Commission, Commonwealth of Australia
- 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 >
- US EPA (2012) Estimation Programs Interface (EPI) Suite™ for Microsoft® Windows, v 4.10. United States Environmental Protection Agency. Washington DC, USA.