File No.: LTD/2157

October 2020

AUSTRALIAN INDUSTRIAL CHEMICALS INTRODUCTION SCHEME (AICIS)

PUBLIC REPORT

Phenol, 4,4'-(1-methylethylidene)bis-, polymer with 2-(chloromethyl)oxirane and 4-methylbenzenamine

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 human health. 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:

Street Address:	Level 7, 260 Elizabeth Street, SURRY HILLS NSW 2010, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
Email:	assessments@industrialchemicals.gov.au
Website:	www.industrialchemicals.gov.au

Executive Director
AICIS

TABLE OF CONTENTS

SUMMARY

The following details will be published on our website:

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/2157	Scott Bader Australia Pty Ltd	Phenol, 4,4'-(1-methylethylidene)bis-, polymer with 2-(chloromethyl)oxirane and 4-methylbenzenamine	ND*	< 10 tonnes per annum	Component of industrial resins, coatings and fillers

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard Classification
As only limited toxicity data were provided, the assessed polymer cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia.

Human Health Risk Assessment
Under the conditions of the occupational settings described, the assessed polymer is not considered to pose an unreasonable risk to the health of workers.

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

Environmental Risk Assessment
Based on the assumed low hazard and reported use pattern, the assessed polymer 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 assessed polymer during final use:
  - Automated processes where possible
  - Exhaust ventilation if aerosols are generated

- 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 polymer during final use:
  - Avoid contact with skin and eyes
  - Avoid inhalation exposure

- 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 polymer during final use:
  - Gloves
  - Goggles
  - Protective clothing
  - Respiratory protection if inhalation exposure may occur

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 polymer 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.

Emergency procedures

- Spills or accidental release of the assessed polymer should be handled by physical containment, collection and subsequent safe disposal.

Disposal

- Where reuse or recycling are not appropriate, dispose of the assessed polymer 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 introducer 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 polymer has a number-average molecular weight of less than 1,000 g/mol;
- the function or use of the polymer has changed from component of industrial resins, coatings and fillers, or is likely to change significantly;
- the amount of polymer being introduced has increased, or is likely to increase, significantly;
- the polymer has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the polymer 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 a product containing the assessed polymer provided by the applicant was reviewed by AICIS. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

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

1. APPLICANT AND APPLICATION DETAILS

APPLICANT(S)
Scott Bader Australia Pty Ltd (ABN: 640 312 170)
Level 27, 123 Pitt St
SYDNEY NSW 2000

APPLICATION CATEGORY
Limited (reduced fee application): Synthetic polymer with Mn ≥ 1,000 g/mol) – Approved Foreign Scheme – Canada

PROTECTED INFORMATION (SECTION 38 OF THE TRANSITIONAL ACT)
Data items and details taken to be protected information include: specific other names, structural formula, molecular weight, analytical data, degree of purity, polymer constituents, residual monomers, impurities, additives/adjuvants, use details, and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 6 OF THE TRANSITIONAL RULES)
Schedule data requirements are varied for partition coefficient, hydrolysis as a function of pH, dissociation constant, flammability, and autoignition temperature.

PREVIOUS APPLICATION IN AUSTRALIA BY APPLICANT(S)
None

APPLICATION IN OTHER COUNTRIES
Canada (2013)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Crystic D3726A (product containing the assessed polymer at < 60%)

CAS NUMBER
164254-94-8

CHEMICAL NAME
Phenol, 4,4'-(1-methylethylidene)bis-, polymer with 2-(chloromethyl)oxirane and 4-methylbenzenamine

OTHER NAMES
Products containing the assessed polymer include:
Crystic PD10491A
Crystic RTR 4010 White
Crestafix 630 PA
Crystic Gelcoat 15 PA (B)
Prime Coat
Gloss Coat
BP 621 CC-45
RTR 4010
GC 15 PA
BP 90-84

MOLECULAR FORMULA
$(C_{15}H_{16}O_2.C_7H_9N.C_3H_5ClO)_x$

MOLECULAR WEIGHT
Number average molecular weight (Mn) is > 1,000 g/mol.

ANALYTICAL DATA
Reference GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 70%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: viscous amber liquid

Property	*Value*	*Data Source/Justification*
Boiling Point*	136.16 °C at 101.3 kPa	SDS
Density*	1,100 – 1,200 kg/m^3	SDS
Vapour Pressure	Not determined	Expected to be low, based on molecular weight
Water Solubility	< 0.05 g/L at 20 °C	Measured
Hydrolysis as a Function of pH	Not determined	Stable to hydrolysis except terminal epoxy groups
Partition Coefficient (n-octanol/water)	Not determined / log Pow > 3.5	Expected to partition to organic phase due to low water solubility / Calculated
Adsorption/Desorption	log K_{oc} > 5.63 (excluding impurities)	Measured
Dissociation Constant	Not determined	Contains no dissociable functional groups
Flash Point*	32 °C	SDS
Autoignition Temperature	Not determined	-
Explosive Properties	Not determined	Contains no functional groups that imply explosive properties.
Oxidising Properties	Not determined	Contains no functional groups that imply oxidative properties.

*Values are for product containing the assessed polymer

DISCUSSION OF PROPERTIES
The water extractability of the assessed polymer was below the method detection limit of 50 mg/L.

Reactivity
The assessed polymer is expected to be stable in air and under normal conditions of use. The assessed polymer contains terminal epoxy groups that may hydrolyse to alcohol groups in the presence of water.

Physical Hazard Classification
Based on the limited physico-chemical data depicted in the above table, the assessed polymer 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.

However, the product containing the assessed polymer has been classified by the applicant as a flammable liquid (Category 3), based on other ingredients of the product.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF ASSESSED CHEMICAL (100%) OVER NEXT 5 YEARS
The assessed polymer will not be manufactured or reformulated in Australia. It will be imported at < 60% concentration as a component of products for resins and coatings/fillers.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 10	< 10	< 10	< 10	< 10

PORT OF ENTRY
Perth, Brisbane, Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
Scott Bader Australia Pty Ltd

TRANSPORTATION AND PACKAGING
The assessed polymer at < 60% concentration will be introduced into Australia by sea as finished products, in 225 kg steel drums, 1,000 kg IBCs and in 25 kg kegs. These products will be transported to manufacturers and distributors of fibre reinforced plastics (FRP) and glass reinforced plastics (GRP).

USE
The products containing the assessed polymer at concentrations of < 60% will be used as a component of glass-reinforced plastics (GRP) or fibre-reinforced plastics (FRP) "body" fillers and coatings, or in the industrial manufacture of various glass-reinforced or fibre-reinforced articles.

OPERATION DESCRIPTION
The assessed polymer will not be manufactured or reformulated in Australia. The products containing the assessed polymer (at < 60% concentration) will be used for coatings/fillers or resins. Prior to end use, a small amount (1 – 2% concentration) of catalyst will be added to the product via manual stirring or a powered mixer, depending on the scale of use.

For coating or filler use, the products containing the assessed polymer will be directly applied to any vessel, vehicle or structure that requires treatment. For resin use, the products containing the assessed polymer will be infused into a closed mould, and solid fillers, such as glass fibres or silica particles, will be added into the mixture. Examples of articles that could be made with this process include basins, vanity units, profiled panels, vessels, and vehicle components.

The coating/fillers or articles would then be chemically cured at room temperature for up to 24 hours, with some possible additional post-curing at high temperatures (up to 80°C) if necessary.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Shipper/receiver	1	3 – 4
Quality control	8	3 – 4
Production worker	2 – 5	150 – 200

EXPOSURE DETAILS

Transport and storage
Transport, storage and warehouse workers may come into contact with the assessed polymer at < 60% concentration only in the event of accidental breaching of containers.

End-use
Workers using products containing the assessed polymer may have dermal or ocular exposure during use. Inhalation exposure may also occur if aerosols are generated during processes such as spray application. Exposure to the assessed polymer in end-use products (at < 60% concentration) may occur for workers during the mixing of catalyst into the products prior to use, during manual loading of the resin into the manufacturing equipment, or

when products are applied to a substrate as a coating or filler. According to the applicant, appropriate PPE is expected to be used by workers during use, which would reduce the potential for exposure. Local exhaust ventilation will also be provided if required. Exposure may also occur during cleaning of equipment. Once the assessed polymer has been cured, it is not expected to be available for exposure.

6.1.2. Public Exposure

The assessed polymer is intended only for use in industrial settings as a component of resins, coatings and filler products. Public exposure to the assessed polymer is not expected.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the assessed polymer are summarised in the following table.

Endpoint	*Result and Assessment Conclusion*
Acute oral toxicity – rat	LD50 > 2,000 mg/kg bw; low toxicity

The assessed polymer has a high molecular weight >1000 g/mol, with a substantial percentage of oligomers < 1,000 g/mol and a low percentage of oligomers < 500 g/mol. Molecular weights above 500 g/mol do not favour dermal absorption, which is also likely to be reduced by low water solubility (ECHA, 2017). Based on the molecular weight profile and low water solubility (0.05 g/L) of the assessed polymer, absorption across biological membranes is expected to be limited.

The assessed polymer was found to have low acute oral toxicity in rats in a study carried out to OECD TG 425. No information was submitted on other endpoints.

The assessed polymer contains epoxide functional groups that may cause skin irritation/corrosion, skin sensitisation, and carcinogenicity or reproductive toxicity (Gerner 2004, Hulzebos 2005, US EPA 2010). The potential for adverse effects would be reduced by the molecular weight profile of the polymer, but cannot be ruled out entirely. These functional groups will be reacted during end use.

Health Hazard Classification

As only limited toxicity data were provided, the assessed polymer cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia.

However, the imported product containing the assessed polymer has been classified as a hazardous substance by the applicant, based on other ingredients in the product.

6.3. Human Health Risk Characterisation

The assessed polymer contains functional groups associated with skin corrosion/irritation, skin sensitisation, carcinogenicity and reproductive effects. Potential systemic effects are likely to be mitigated by the high molecular weight and low water solubility of the polymer, reducing systemic absorption.

6.3.1. Occupational Health and Safety

During end-use, production workers may come into contact with the assessed polymer at < 60% concentration during incorporation of catalyst, application of the product onto a surface, or during the loading and cleaning of moulding equipment used for making articles containing the assessed polymer. It was stated by the applicant that workers would wear appropriate personal protective equipment (e.g. protective clothing, respirators, gloves and goggles) during the mixing process and that local exhaust ventilation would be used when necessary. Once the product containing the assessed polymer has been applied or moulded and cured, the assessed polymer will be bound into an inert adhesive matrix and is not expected to be available for exposure. The assessed polymer is imported as part of a product which is classified as a hazardous substance. The workplace controls in place for the other ingredients are expected to reduce exposure to the assessed polymer.

Under the conditions of the occupational settings described, the assessed polymer is not considered to pose an unreasonable risk to the health of workers.

6.3.2. Public Health

The products containing the assessed polymer will not be available for use to the general public, but the public will come into contact with substrates or articles containing the assessed polymer. After application and curing, the assessed polymer is expected to be reacted and will not be available for further exposure.

When used in the proposed manner, the assessed polymer 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 assessed polymer will be imported into Australia as a component of resins and coatings for use in various fibre reinforced plastics (FRP) and glass reinforced plastics (GRP). Release of products containing the assessed polymer to the environment will be limited to accidental spills or leaks during storage and transport where the packaging is breached and is expected to be absorbed on suitable materials and disposed of to landfill in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE

Upon application as coatings and resins in the industrial manufacture of various FRP and GRP articles, the assessed polymer will be cured and chemically consumed to form an inert solid matrix and significant releases to the environment are not expected. Wastes and residues in empty containers are expected to be collected and disposed of to landfill according to local government regulations. Wastewater from the application equipment cleaning is expected to be released to the sewer. In the wastewater treatment systems, the sludge containing the assessed polymer is expected to be removed and disposed of to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

The assessed polymer is chemically reacted in the curing process and is not expected to be present in the finished end use products or applications such as body fillers. These products are expected to be disposed of to landfill at the end of their useful life. Residual assessed polymer in empty end-use containers is expected to be cured into solids and be disposed of to landfill along with the empty containers.

7.1.2. Environmental Fate

No environmental fate study was provided. The majority of the assessed polymer is cured and chemically reacted to form an inert solid matrix that will neither be bioavailable nor mobile. The assessed polymer is not expected to be bioaccumulative due to its high molecular weight of > 1,000 g/mol. In landfill, the assessed polymer 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 for the assessed polymer, as no significant aquatic release is expected from the proposed use pattern.

7.2. Environmental Effects Assessment

No ecotoxicity data were submitted for the assessed polymer. High molecular weight polymers with low water solubility are not expected to be harmful to aquatic life.

7.2.1. Predicted No-Effect Concentration

The predicted no-effects concentration (PNEC) has not been calculated.

7.3. Environmental Risk Assessment

The Risk Quotient, Q (= PEC/PNEC), has not been calculated since neither a PEC nor PNEC is available. However, the assessed polymer is not expected to be harmful to aquatic life and will not be released to the environment in significant quantities. Therefore, based on the assumed low hazard and reported use pattern, the assessed polymer is not considered to pose an unreasonable risk to the environment.

BIBLIOGRAPHY

ECHA (2017) Guidance on Information Requirements and Chemical Safety Assessment Chapter R.7c: Endpoint specific guidance, June 2017, version 3.0. European Chemicals Agency, see https://echa.europa.eu/documents/10162/13632/information_requirements_r7c_en.pdf.

Gerner, I.; Barrat, M.D.; Zinke, S.; Schlegel, K.; Schlede, E. (2004) Development and Pre-validation of a list of Structure-Activity Relationship Rules to be used in Expert Systems for Prediction of the Skin-sensitising Properties of Chemicals. Alternatives to Laboratory Animals, 32: 487-509.

Hulzebos, E.; Walker, J.D.; Gerner, I.; Schlegel, K. (2005) Use of structural alerts to develop rules for identifying chemical substances with skin irritation or skin corrosion potential. QSAR Combinatorial Science, 24: 332-342.

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

US EPA (2010), TSCA New Chemicals Program (NCP) Chemical categories, Washington, D.C., http://www.epa.gov/oppt/newchems/pubs/npcchemicalcategories.pdf