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

**PUBLIC REPORT**

**SMA 2625**

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (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 Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of Sustainability, Environment, Water, Population and Communities.

For the purposes of subsection 78(1) of the Act, this Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This Public Report is also available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

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**Director  
NICNAS**

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## SUMMARY

The following details will be published in the NICNAS *Chemical Gazette*:

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1627	Brenntag Australia Pty Ltd	SMA 2625	ND*	≤ 20 tonnes per annum	Ingredient of carpet cleaning products and industrial inks

\*ND = not determined

## CONCLUSIONS AND REGULATORY OBLIGATIONS

### Hazard classification

Based on the limited available information, the notified polymer is not recommended for classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

### Human health risk assessment

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

When used in the proposed manner, the notified polymer 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 polymer is not considered to pose an unreasonable risk to the environment.

### Recommendations

#### REGULATORY CONTROLS

##### Health Surveillance

- As the notified polymer is a potential sensitiser, employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of sensitisation, especially pulmonary sensitisation.

##### (Material) Safety Data Sheet

- The (M)SDS provided by the notifier should be amended as follows:
  - The Engineering Controls subsection in Section 8 should indicate that local exhaust ventilation is needed during weighing and transfer of the powdered material.

#### 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 polymer as introduced:
  - Local exhaust ventilation when weighing and transferring the powder during formulation.

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer as introduced, and as diluted for use:
  - Avoid generation of dust or aerosols
- 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 polymer:
  - Gloves, coveralls and goggles during formulation processes.
  - Respiratory protection during weighing and transferring the polymer powder for formulation.
  - Disposable gloves during printing maintenance and carpet cleaning operations, if dermal exposure is likely to occur.

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

#### Disposal

- The notified polymer should be disposed of to landfill.

#### Emergency procedures

- Spills or accidental release of the notified polymer 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 polymer 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 polymer has a number-average molecular weight of less than 1000;

or

- (2) Under Section 64(2) of the Act; if
  - the function or use of the polymer has changed from being an ingredient in industrial inks and carpet cleaning products, or is likely to change significantly;
  - the amount of polymer being introduced has increased from 20 tonnes per annum, 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 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 the products containing the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

## ASSESSMENT DETAILS

### 1. APPLICANT AND NOTIFICATION DETAILS

#### APPLICANT(S)

Brenntag Australia Pty Ltd, (ABN 84 117 996 595)  
262 Highett Road, Highett VIC 3190

#### NOTIFICATION CATEGORY

Limited: Synthetic polymer with Mn  $\geq$ 1000 Da.

#### EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication: chemical name, CAS number, molecular and structural formulae, analytical data, degree of purity, polymer constituents, residual monomers, impurities, import volume, site of reformulation.

#### VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

No variation to the schedule of data requirements is claimed.

#### PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

#### NOTIFICATION IN OTHER COUNTRIES

Korea (2008)

### 2. IDENTITY OF CHEMICAL

#### MARKETING NAME(S)

SMA 2625P, SMA 2625F

### 3. COMPOSITION

DEGREE OF PURITY > 90%

#### HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

The notified polymer contains hazardous impurities/residual monomers, below the cut-off concentration for classification as a hazardous substance.

#### LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES

No loss of monomers or other reactants is expected.

#### DEGRADATION PRODUCTS

The notified polymer is expected to form oxides of carbon if combusted.

### 4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: White flakes or powder

Property	Value	Data Source/Justification
Glass transition temperature	193.34 °C	Measured (value and graph provided by the notifier)
Boiling Point	Not determined	Estimated to be high, based on the glass transition temperature.
Density	1190 kg/m <sup>3</sup> at 4 °C	Measured (value provided by the notifier)
Vapour Pressure	Not determined	The notified polymer is a solid
Water Solubility	Not determined	Expected to be dispersible in water and soluble under basic conditions
Hydrolysis as a Function of pH	Not determined	Contains side chains which may hydrolyse under environmental pH

Partition Coefficient (n-octanol/water)	Not determined	(4-9) Expected to be influenced by pH. The notified polymer is not expected to bioaccumulate based on its high molecular weight (> 1000)
Adsorption/Desorption	Not determined	Expected to have a low log K <sub>oc</sub> , however due to its high molecular weight (> 1000), it is expected to have low mobility in soils
Dissociation Constant	Not determined	Expected to have pK <sub>a</sub> values ~4 which are consistent with its functional groups
Particle Size	140 µm (average)	Study not provided
Flash Point	< 200 °C	Estimated by the notifier.
Autoignition Temperature	Not determined	Estimated to be high
Explosive Properties	Not determined	Estimated to be not explosive on the basis of structure

#### DISCUSSION OF PROPERTIES

##### *Reactivity*

The notified polymer contains a functional group that may react further in end-use.

##### ***Physical hazard classification***

Based on the submitted physico-chemical data depicted in the above table, the notified polymer is not recommended for hazard classification according to the *Globally Harmonised System for the 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 polymer will be imported at 100%.

#### 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>	< 10	< 10	< 20	< 20	< 20

#### PORT OF ENTRY

The notified polymer will be imported into Melbourne port by sea.

#### TRANSPORTATION AND PACKAGING

The notified polymer will be imported in 22.68 kg paper bags that will be shrink-wrapped onto pallets at the port and transported to storage and formulation sites by road. Formulated ink and cleaning products will be distributed to end-users.

#### USE

Ingredient in industrial inks and carpet cleaning products

## OPERATION DESCRIPTION

*Industrial inks*

At the formulation site, inks are produced in batches of 900 kg to 6,000 kg. The notified polymer is dissolved in a solvent. The resulting solution is then decanted into 180 kg drums for storage or further processed by mixing with additives and pigment dispersions to make finished ink products containing less than 10% notified polymer. The inks are stored in 180 kg drums in a class 3 flammable warehouse and transported by class 3 flammable approved trucks to various industrial customer sites. Transfer from the drums to the printing equipment is carried out using lifting equipment. Approximately 20 – 40 kg would be used to fill each printing unit and, depending on the coverage of the inks on the design, the inks would be replenished as required. Further solvent is added to the inks before printing to make the approximate concentration of the notified polymer < 5% in the final process. The inks are printed onto film and air dried to allow all the solvent to evaporate. The film is then laminated with polyethylene to effectively trap the inks between two layers of plastic. The finished product is generally used for food packaging. The inks remaining at the end of the print job are either used on the next print job or are sealed back into the appropriate drum and stored in the class 3 flammable warehouse. Drum residues are disposed of via a licenced disposal company.

*Carpet cleaning products*

At the formulation site, the notified polymer is dissolved into an alkaline solution. The solution is then further processed by the addition of additives to produce the cleaning products. The cleaning products, containing less than 20% notified polymer, are stored in containers up to 25 kg in size and are sold to qualified cleaners. The cleaning products are further diluted during their use in carpet cleaning operations. Before being released to the environment, the residues of the cleaning products in the carpet are washed down to the drain. Carpet cleaning products (containing < 20% notified polymer) are not available for sale to the public.

**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 workers	4	30
Warehouse staff	0.25	150
Production operators	4	150
Laboratory technicians	0.5	150
Printing operators/Cleaners	8	250

## EXPOSURE DETAILS

*Transport and storage*

There is no expected exposure of transport or warehouse workers to the notified polymer, unless a spill occurs. Warehouse workers may have contact with splashes or spills of inks containing the notified polymer (< 10%), if containers are partly used and returned to the storage area.

*Production Operators*

During formulation, production operators open the bags of notified polymer and pour it into the mixing vessel containing the solvent to make solution. There is potential for dermal, ocular and inhalation exposure to the dust of the notified polymer for the operators. It is mandatory to wear safety Personal Protective Equipment (PPE) including respiratory protection, safety glasses, cotton dust coats or coveralls and disposable gloves when handling the notified polymer (100%). Respirators should be used when handling the notified polymer (100%) in powder form. During the process, the mixing vessel is statically earthed and dust extraction is available. The resulting solution is then decanted into 180 kg drums for storage or further processed by mixing with additives and pigment dispersions to make finished products containing less than 10% notified polymer. Workers may suffer dermal and/or ocular exposure to the solution or inks containing the notified polymer (< 10%) during these processes.

*Laboratory Technicians*

Laboratory technicians are required for quality control of each step of the manufacturing process. They have the potential for dermal and/or ocular exposure to the solution form of the notified polymer (< 10%). The laboratory testing involves checking samples of the solutions for required properties. The laboratory technicians are required to wear cotton dust coats, safety glasses and disposable gloves during the tests.

*Printing operators and technicians*

Printing operators have potential to suffer dermal and/or ocular exposure to the inks containing < 10% notified polymer during ink transfer, printing and printer cleaning processes. Inhalation exposure is not expected unless aerosols are generated during the processes. The printing operators are required to wear safety glasses, coveralls, gloves and anti-static safety boots during ink transfer from storage drums to the printing equipment. Technicians are required to wear disposable gloves during printer cleaning and maintenance operations.

*Cleaners*

Cleaners can suffer dermal and/or ocular exposure to the carpet cleaning products containing the notified polymer at < 20%. The cleaners are supplied with the (M)SDS of the cleaning product and are required to dilute the cleaning product with water before using it. It is recommended that cleaners wear safety glasses, coveralls and disposable gloves when handling cleaning products containing the notified polymer (< 20%).

**6.1.2. Public Exposure***Use in inks*

The public is not expected to be exposed to the notified polymer during its import, formulation or application to substrates as a component of the industrial inks. After application to the substrates and lamination, the dried inks containing the notified polymer will not be bioavailable for exposure. No information is available on whether components of the polymer or impurities can migrate into food from packaging. The potential for migration would be reduced by the high molecular weight of the notified polymer (> 1000) and the lamination, however some low molecular weight species ( $M_n$  < 1000 Da) of the notified polymer are present, as are low levels of residual monomers/impurities. The latter are present at levels below the cut-off concentration for classification as hazardous substances.

*Use in carpet cleaning products*

The public is not expected to have contact with the notified polymer during its import, formulation or application to carpets as a component of cleaning products (< 20% notified polymer). The public may suffer incidental dermal exposure to low levels of product residues (<< 20% notified polymer) that remain in carpets after cleaning them with dilute solutions containing the notified polymer.

**6.2. Human Health Effects Assessment**

The results from toxicological investigations conducted on the notified polymer are summarised in the table below. Details of these studies can be found in Appendix B.

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Rat, acute inhalation toxicity	LC50 > 0.54 mg/L
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	non-irritating

***Toxicokinetics***

Systemic absorption would be limited by the high molecular weight of the notified polymer (> 1000), however low molecular weight species < 1000 and < 500 are present.

*Acute toxicity.*

The notified polymer was tested in an acute inhalation study using an exposure period of 1 hour and a relatively low concentration of 0.54 mg/L. All animals survived the study but showed adverse clinical signs and lung discolouration at necropsy. Based on the relatively low concentration tested and the non-standard protocol, a conclusion cannot be drawn about the polymer's potential for acute inhalation toxicity.

The notified polymer was not tested for its acute toxicity via the oral and dermal routes.

*Irritation and Sensitisation.*



The notified polymer was found to be slightly irritating to the skin and non-irritating to the eyes of rabbits in studies to OECD guidelines. Based on the results of the acute inhalation study, it is likely to be irritating to the respiratory tract.

No information was provided on the skin sensitisation potential of the polymer.

#### *Structural alerts*

The notified polymer contains functional groups that are of potential concern for irritation/corrosion, sensitisation (particularly pulmonary sensitisation), and reproductive and developmental toxicity (US EPA, 2010, Barratt et al, 1994). While the potential for these effects is likely to be limited by the high molecular weight of the notified polymer, they cannot be ruled out, particularly due to the presence of low molecular weight species.

#### *Other endpoints*

Data on other endpoints was not available for the assessment.

#### **Health hazard classification**

Based on the limited available information, the notified polymer is not recommended for classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

### **6.3. Human Health Risk Characterisation**

#### **6.3.1. Occupational Health and Safety**

Limited toxicological data was provided for the notified polymer. It is likely to be irritating to the respiratory tract, and was non-irritating to eyes and slightly irritating to skin in studies carried out to OECD protocols. It contains reactive functional groups that are structural alerts for several adverse health effects. The potential for these effects may be limited by the high molecular weight of the polymer (> 1000), however low molecular weight species are present.

The highest potential for worker exposure is to the polymer as imported in powder form, where inhalation, as well as dermal/ocular exposure may occur. The particle size of the polymer is 140 microns; however the size distribution is not available and it is likely to contain inhalable and respirable fractions. Once incorporated in ink and carpet cleaning products, the concentration of notified polymer would be reduced to < 20% and inhalation exposure would not occur unless aerosols are generated during processing or end-use.

Production operators may suffer inhalation exposure to the dust of the notified polymer in addition to dermal and ocular exposure. Laboratory technicians, printing operators and printing technicians, as well as cleaners may encounter dermal and ocular exposure when handling solutions containing the notified polymer. The production procedures and final applications are not considered to result in an unreasonable risk provided that appropriate controls to reduce exposure are in place.

#### **6.3.2. Public Health**

The notified polymer and ink/cleaning products containing the notified polymer are not intended for direct use by the public. The public may come into contact with the packaging material printed with the inks containing the notified polymer. However, as the polymer would at that stage be incorporated into the ink matrix and the packaging material is laminated after printing, the notified polymer is not bioavailable to the public during handling of the printed packaging, and the lamination layer would act as a barrier and is expected to limit any leaching into food. The public may also come into contact with residues of the notified polymer in carpets cleaned with the cleaning products containing it (<< 20%). Once the cleaning process is finished, incidental exposure of members of the public to cleaning product residues containing low concentration notified polymer are not expected to pose an unreasonable risk. Therefore, based on the proposed uses, the risk of the notified polymer to public health is not considered unreasonable.

## **7. ENVIRONMENTAL IMPLICATIONS**

### **7.1. Environmental Exposure & Fate Assessment**

### 7.1.1. Environmental Exposure

#### RELEASE OF CHEMICAL AT SITE

The notified polymer will be manufactured overseas and imported into Australia in 22.68 kg (50 lb) paper bags. The notified polymer will be formulated into ink and cleaning products. Empty bags containing residues of the notified polymer are expected to be disposed of to landfill. Any spills are expected to be contained and disposed of to landfill.

#### RELEASE OF CHEMICAL FROM USE

##### *Release from use in inks*

Inks containing the notified polymer at a concentration of less than 10% will be used in an industrial environment. Ink remaining at the end of the printing process is used for the next print job or sealed into an appropriate drum and stored in a warehouse. Spills are expected to be absorbed to an appropriate sorbent material and disposed of to landfill. Drum residue containing the notified polymer is expected to be disposed of by a licensed disposal company.

##### *Release from use in carpet cleaning products*

The notified polymer is dissolved in an alkaline solution at a concentration of less than 20% and diluted further during use. The cleaning solution is used for carpet cleaning purposes and residues from the cleaning process are expected to be released directly to sewer or stormwater drains.

#### RELEASE OF CHEMICAL FROM DISPOSAL

##### *Release from disposal of inks*

The majority of notified polymer used in ink formulations will be printed onto plastic film and laminated with polyethylene. The films are generally used for food packaging. Packaging is expected to be disposed of to landfill where the notified polymer is expected to remain bound to the substrate. Residues in empty containers are expected to be disposed of to landfill. Formulated ink products will not be released directly to the environment. Hence, the notified polymer used in the manufacture of inks will predominately be disposed of to landfill.

##### *Release from disposal of carpet cleaning products*

The majority of the notified polymer used in carpet cleaning products is expected to be released to sewer during use and, to a lesser extent, from treated aqueous waste released during formulation. Empty import and product containers containing notified polymer residue are expected to be disposed of to landfill.

### 7.1.2. Environmental Fate

No environmental fate data were submitted.

#### *Fate of inks*

Notified polymer applied to substrates will be laminated with polyethylene and is not expected to be bioavailable. Over time, the notified polymer may leach from the laminated films and is expected to have low mobility in soil. The majority of the contained notified polymer is expected to be disposed of to landfill where it will degrade by biotic and abiotic processes to form water and oxides of carbon.

#### *Fate of carpet cleaning products*

The majority of the notified polymer used in carpet cleaning products is expected to be released to sewer. Because of the notified polymer's dispersibility in water and anionic functionality, it is not expected to be efficiently removed from waste waters by the sewage treatment process. If released to surface waters, the notified polymer is expected to disperse and eventually degrade to form water and oxides of carbon. Due to its high molecular weight (> 1000), the notified polymer has a low potential to bioaccumulate.

### 7.1.3. Predicted Environmental Concentration (PEC)

No estimate for the proportion of the notified polymer used in the manufacture of inks or carpet cleaning products was provided. Therefore, the predicted environmental concentration (PEC) was calculated using the worst-case scenario assumption that all of the notified polymer will be released to sewer over 260 working days per year.

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Predicted Environmental Concentration (PEC) for the Aquatic Compartment

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Total Annual Import/Manufactured Volume	20,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	20,000	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	76.92	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	
Dilution Factor - Ocean	10	
PEC - River:	17.01	µg/L
PEC□ - □cean:	1.70	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m<sup>2</sup>/year (10 ML/ha/year). The notified polymer in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m<sup>3</sup>). Using these assumptions, irrigation with a concentration of 17.0 µg/L may potentially result in a soil concentration of approximately 0.113 mg/kg. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated irrigation, the concentration of notified polymer in the applied soil in 5 and 10 years may be approximately 0.567 mg/kg and 1.134 mg/kg, respectively.

## 7.2. Environmental Effects Assessment

No ecotoxicity data were submitted. Anionic polymers are generally of low toxicity to fish and daphnia, however they are known to be moderately toxic to algae. The mode of toxic action is over-chelation of nutrient elements needed by algae for growth. The highest toxicity is when the acid is on alternating carbons of the polymer backbone. This is unlikely to apply to the notified polymer. Furthermore, the toxicity to algae is likely to be further reduced due to the presence of calcium ions in the aquatic compartment which will bind to the functional groups. A conservative degree of toxicity for the notified polymer was estimated using a nearest analogue approach (Boethling & Nabholz, 1997). The estimated values are reported in the table below.

<i>Endpoint</i>	<i>Result</i>	<i>Assessment Conclusion</i>
<b><u>Acute</u></b>		
Fish Toxicity (96 hour, estimated)	LC50 = 1140 mg/L	Not harmful
Daphnia Toxicity (48 hour, estimated)	LC50 > 339 mg/L	Not harmful
Algal Toxicity (96 hour, estimated)	EC50 = 560 mg/L	Not harmful
<b><u>Chronic</u></b>		
Algal Toxicity (estimated)	ChV = 280 mg/L	Not harmful

The notified polymer is not expected to be harmful to aquatic life on an acute basis, nor harmful to aquatic life with long lasting effects. Therefore, the notified polymer is not formally classified for acute or long-term hazard under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009).

### 7.2.1. Predicted No-Effect Concentration

The endpoint for the most sensitive species from the reported results is used to calculate the predicted no-effect concentration (PNEC). In this case, the chronic algal toxicity estimation was used. Because no ecotoxicity data were submitted and estimates are based on the nearest analogue approach, a conservative assessment factor of 1000 was used. The chronic endpoint for algae was used because it provides the lowest, most conservative PNEC value.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
Algae (Chronic – estimated)	280	mg/L
Assessment Factor	1000	
PNEC:	280	µg/L

### 7.3. Environmental Risk Assessment

Risk Assessment	PEC $\mu\text{g/L}$	PNEC $\mu\text{g/L}$	Q
Q – River	17.01	28	0.061
Q – Ocean	1.70	280	0.006

The Risk Quotients ( $Q = \text{PEC}/\text{PNEC}$ ) for the worst-case discharge scenario have been calculated to be less than 1 for the river and ocean compartments. The notified polymer is not expected to be harmful to aquatic organisms or to bioaccumulate. Therefore, on the basis of the value of Q, the notified polymer is not expected to pose an unreasonable risk to the environment for the assessed use pattern.

**APPENDIX B: TOXICOLOGICAL INVESTIGATIONS****B.1. Acute toxicity – inhalation**

TEST SUBSTANCE	SMA 2625
METHOD	In-house method
Species/Strain	Sprague-Dawley rats
Vehicle	None
Method of Exposure	Whole-body exposure
Exposure Period	1 hour
Physical Form	solid aerosol (particulate)
Particle Size	Particle distribution not stated. Based on the reported results, the test substance contains a respirable fraction.
Remarks - Method	Dry air at a flow rate of 4 L/min was passed through a 500 mL three-neck flask containing the test material. The resulting attainable dust was directed into a 32.2 L glass exposure chamber containing the test animals. A GCA Dust Monitor and a cyclone pre-collector were used to examine the chamber atmosphere samples and the resulting data were used to determine the dust concentrations. The exposure time was recorded as 1 hour. No temperature and humidity of air were recorded.

**RESULTS**

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Concentration &lt;mg/L&gt;</i>			<i>Mortality</i>
		<i>Nominal</i>	<i>Airborne</i>	<i>Respirable</i>	
1	5 M, 5 F	5.42	0.54	0.23	0/10

Signs of Toxicity During the exposure, inactivity was observed in most rats and red nasal discharge was observed in a few of the animals. Upon removal from the exposure chamber, a brown oral discharge was observed in one of ten rats. Post-exposure observation in 14 days found moist rales in one rat and mucoid nasal discharge in two of the animals.

Effects in Organs Lung discoloration was observed in six of ten rats at necropsy.

Remarks - Results

CONCLUSION The notified polymer has a LC50 > 0.54 mg/L via inhalation under the conditions of the test.

TEST FACILITY Bio/dynamics Inc. (1979)

**B.2. Irritation – skin**

TEST SUBSTANCE	SMA 2625A
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	Water
Observation Period	6 days
Type of Dressing	Semi-occlusive.
Remarks - Method	The test substance was applied on a moistened gauze pad. At the end of the exposure period, residual test substance was removed with a gauze pad moistened with water.

**RESULTS**

<i>Lesion</i>	<i>Mean Score*</i> <i>Animal No.</i>			<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
	1	2	3			
<i>Erythema/Eschar</i>	1.0	1.7	0.3	2	< 6 days	0
<i>Oedema</i>	0	0	0	0	0	0

\*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

Remarks - Results	A slight oedema (score of 2) was noted in one animal after 1 hour (data not reflected in the results table). No necrosis or ulceration was observed. One animal showed dryness of the skin on Days 4 and 5.
CONCLUSION	The notified polymer is slightly irritating to the skin.
TEST FACILITY	Centre International de Toxicologie (1994)

### B.3. Irritation – eye

TEST SUBSTANCE	SMA 2625A
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Observation Period	72 hours
Remarks - Method	-

#### RESULTS

<i>Lesion</i>	<i>Mean Score*</i> <i>Animal No.</i>			<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
	1	2	3			
<i>Conjunctiva: redness</i>	0	0	0	1	< 24 hours	0
<i>Conjunctiva: chemosis</i>	0	0	0	0	0	0
<i>Conjunctiva: discharge</i>	0	0	0	0	0	0
<i>Corneal opacity</i>	0	0	0	0	0	0
<i>Iridial inflammation</i>	0	0	0	0	0	0

\*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

Remarks - Results	Slight ocular reactions were observed as conjunctivae in 2 animals, reversing within 24 h.
CONCLUSION	The notified polymer is non-irritating to the eye.
TEST FACILITY	Centre International de Toxicologie (1994)

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