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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polymer in BYK 9076

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 Full Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This Full 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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FULL PUBLIC REPORT

This assessment report is for an extension of original assessment certificate for Polymer in BYK 9076. Based on the submission of new information by the extension notifier, some sections of the original assessment report have been modified. These modifications have been made under the heading 'Extension Application' in the respective sections.

Polymer in BYK 9076

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Nuplex Industries (Aust.) Pty Ltd (ABN 25 000 045 572)
49-61 Stephen Road
BOTANY NSW 2019

IMCD Australia Ltd (ABN 44 000 005 578) Level 1 372 Wellington Road MULGRAVE, VIC 3170

Akzo Nobel Pty Ltd (ABN 59 000 119 424) 115 Hyde Road YERONGA, QLD 4104

Applicant for an Extension of the Original Assessment Certificate: The Valspar (Australia) Corporation Pty Limited (ABN 82 000 039 396) 13 Webber Parade EAST KEILOR VIC 3033

NOTIFICATION CATEGORY

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

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, Polymer Constituents, Residual Monomers/Impurities, Spectral Data, Introduction Volume, Use Details and Identity of Recipients.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows:

Melting Point/Freezing Point, Boiling Point, Vapour Pressure, Water Solubility, Hydrolysis as a function of pH, Partition Coefficient (n-octanol/water), Adsorption/Desorption, Dissociation Constant, Flash Point, Flammability Limits, Autoignition Temperature, Explosive Properties.

NOTIFICATION IN OTHER COUNTRIES United States of America (1998) Canada (2002) China (2002) Korea (2007)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S) Polymer in BYK 9076

Extension Application:

Porcelain Satin Premium (contains the notified polymer at approximately 2.8%)

OTHER NAME(S)
DISPERBYK-145

MOLECULAR WEIGHT

Mn > 1000 Da

ANALYTICAL DATA

A reference IR spectrum was provided.

3. COMPOSITION

DEGREE OF PURITY > 96%

REACTIVE FUNCTIONAL GROUPS

The notified polymer contains high concern functional groups of unknown functional group equivalent weight (FGEW), possibly FGEW < 5000.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Light yellow liquid

Property	Value	Data Source/Justification
Boiling Point	> 100°C at 101.3 kPa	Estimated
Density	$1070 \text{ kg/m}^3 \text{ at } 20^{\circ}\text{C}$	Measured
Vapour Pressure	< 1.33x10 ⁻⁹ kPa at 25°C	Estimated
Water Solubility	1.55-1.66 g/L at 20°C	Measured
Hydrolysis as a Function of pH	Expected to be slow.	Estimated
Partition Coefficient	$\log P_{\rm ow} > 2.5$ at $20^{\circ} C$	Estimated
(n-octanol/water)		
Adsorption/Desorption	$\log K_{oc} > 3.5$	Estimated
Dissociation Constant	pKa > 9	Estimated
Flash Point	> 100°C at 101.3 kPa	Measured
Flammability	Not expected to be flammable	Estimated
Autoignition Temperature	> 200°C	Estimated
Explosive Properties	Does not contain explosophores	Estimated

DISCUSSION OF PROPERTIES

For full details of tests on physical and chemical properties, please refer to Appendix A.

Reactivity

The notified polymer may react with metals to emit hydrogen gas.

Dangerous Goods classification

Based on the available data the notified polymer is classified as follows according to the Australian Dangerous Goods Code (NTC, 2007):

Environmentally hazardous substance (aquatic environment).

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED POLYMER OVER NEXT 5 YEARS

The notified polymer will not be manufactured in Australia. The notified polymer will be imported into Australia as a < 60% component of polymeric dispersant and wetting agent products in sealed steel 25 kg or 200 kg drums for reformulation into coatings and composites.

Extension Application:

The notified polymer will be imported into Australia at approximately 2.8% as a component of formulated coatings.

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED POLYMER OVER NEXT 5 YEARS

Year	1	2	3	4	5
Tonnes	10 - 30	10 - 30	10 - 30	10 - 30	10 - 30
<u>Extension</u>					
<u>application</u>					
Tonnes	0.65	0.65	0.65	0.65	0.65

PORT OF ENTRY

Melbourne, Sydney, Brisbane

TRANSPORTATION AND PACKAGING

The notified polymer will be transported by road or rail packaged in 25 kg or 200 kg drums. After formulation the coating products containing the notified polymer will be transported in 1 L, 4 L, 10 L and 20 L steel cans and pails. Polyol formulations containing the notified polymer will be transported in 20 L and 200 L steel pails.

USF

It is anticipated that approximately 90% of the imported volume of the notified polymer will be used as a polymeric dispersant (< 30%) in industrial coatings. The remaining 10% of the imported volume of the notified polymer will be used as a dispersant in polyols (< 20%) used in polyurethane foams, PVC and unsaturated polyester composite applications.

Extension Application:

The notified polymer will be used at approximately 2.8% in formulated coatings for metal containers.

OPERATION DESCRIPTION

Coating formulation

At the coating formulation sites, the notified polymer solution (<60%) will be manually weighed or metered directly from the storage drums into a stainless steel blending tank and mixed with pigments and resin to form the mill base. The mill base will then be pumped into a large mixing vessel to which the remaining additives and resin will be added to form the finished product. Samples (<30% notified polymer) will be removed at this stage for quality control testing by laboratory technicians. The finished product (<30% notified polymer) will be fed into product containers by gravity from the bottom of the mixing vessel through a filter and filling lines. Formulation equipment will be cleaned by rinsing with water.

Coating application

The industrial coatings (< 30% notified polymer) will be applied by spray ($\sim 75\%$), brush ($\sim 20\%$) or roller ($\sim 5\%$). Prior to application, the paint will be manually stirred and poured into trays or into the spray guns. Spray application is expected to be conducted in spray booths at industrial sites.

Formulation of polyol and moulded articles manufacture

The notified polymer solution (<60%) will be added to the blending vessel from drums via a pipe attached to the drum. After the addition of further additives to form the polyol resin premix (<20% notified polymer), a small amount will be sampled by laboratory technicians via a sampling valve in the blending vessel for quality control testing. During the polyurethane foaming production process, the resin premix (<20% notified polymer) will be pumped out of the blend tank to a high-pressure mechanical impingement mix head, where the resin premix will be mixed with other components of the polyol. The resulting mixture (<2% notified polymer) will be dispensed from the mix head into an open mould (batch process) or onto a conveyor belt (continuous process).

On occasions, depending on the manufacturer, a closed mould injection system will be employed. In the batch process, the premix resin will be added to heated moulds and allowed to cure for about 5 minutes. In the continuous process, once the composite material is applied to the conveyor belt, the mixture will foam and cure into the final solid product within 3-5 minutes. From the final product, foam blocks will be cut in varying lengths from 3-60 metres for further processing. After production the articles may be painted, fabric wrapped or covered with other components.

Extension Application:

Formulated coatings containing the notified polymer at approximately 2.8% will be manually added to spray guns and applied by spray in a ventilated spray booth.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

Category of Worker	Number	Exposure Duration (hours/day)	Exposure Frequency (days/year)
Transport	6-8	2-3	10-15
Coating formulation			
Blending	4 per site	8	50
Laboratory	2 per site	1	20
Application	100 per site	6	260
Polyol formulation	_		
Blending	1 per site	2	260
Laboratory	1 per site	1	260
Moulded article manufacture	100 per site	1	260

EXPOSURE DETAILS

Transport and storage

Transport and storage workers are not expected to be exposed to the notified polymer (< 60%) except in the event of an accident.

Coating formulation

Dermal and accidental ocular exposure to the notified polymer (< 60%) may occur when manually weighing, connecting and disconnecting pumps, charging the blending vessels and when laboratory technicians sample the coating formulation. Similar exposure may also occur during routine cleaning and maintenance of equipment, and cleaning up of spills or leaks. Inhalation exposure to vapours and aerosols is not likely during blending due to the anticipated low vapour pressure of the notified polymer.

Personal protective equipment (PPE) such as coveralls, safety glasses, and gloves is expected to be used by workers to minimise exposure. Local exhaust ventilation is expected to be employed in areas where weighing and charging of the blending vessels occur to limit the potential for inhalation exposure.

Application of coatings

Dermal and accidental ocular exposure to the notified polymer (< 30%) may occur during the manual addition of coatings to spray guns, as well as during spray application, roller and brush application, and when cleaning equipment. Inhalation exposure to aerosols is also possible during spraying.

Spray applications are expected to be conducted within spray booths at industrial manufacturing facilities to minimise inhalation exposure. Exposure during application by roller or brush is expected to be minimised by the use of safety glasses, coveralls, and gloves, and if necessary an air respirator. Workers may make dermal contact with the notified polymer once the coating (< 30% notified polymer) has dried on the substrate. However once dried the coating will form an inert matrix and further exposure to the notified polymer is not anticipated.

Formulation of polyol and moulded article manufacture

Dermal and accidental ocular exposure to the notified polymer (<60%) may occur when connecting and disconnecting transfer lines from drums to the blending vessels and when taking samples from the blending vessel by laboratory technicians. Following the charging of the equipment the process is fully automated and therefore exposure is not expected.

During moulded article manufacture, exposure is not anticipated as it will take place via an automated process. Once moulded into the final article the notified polymer will be reacted into the moulded matrix within the article and will not be bioavailable. However, dermal and ocular exposure may occur to the notified polymer (< 20%) when cleaning the used drums prior to recycling.

Exposure to the notified polymer during formulation of polyols and moulded article manufacture is expected to be minimised by the use of PPE, such as coveralls, safety eyewear and gloves.

Extension Application:

Dermal and accidental ocular exposure of workers to the notified polymer (approximately 2.8%) may occur during the manual addition of coatings to spray guns, as well as during spray application, and when cleaning equipment. Inhalation exposure to aerosols is also possible during spraying.

Spray applications are expected to be conducted within spray booths at industrial facilities to minimise inhalation exposure and PPE including gloves, glasses and coveralls are expected to be used to minimise dermal and ocular exposure.

6.1.2. Public exposure

Public exposure to the notified polymer is not expected. Following application of coatings containing the notified polymer (< 30%), it will become trapped within an inert matrix and will not be bioavailable. Similarly, once the notified polymer has been incorporated into an inert matrix as part of moulded articles (< 20%), it will no longer be bioavailable.

Extension Application:

Public exposure to metal containers coated with the notified polymer (approximately 2.8%) may occur. However, the notified polymer is expected to be trapped within an inert matrix and will not be bioavailable.

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.

Endpoint	Result and Assessment Conclusion
Rat, acute oral toxicity	oral LD50 > 5000 mg/kg bw
	low toxicity
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating

Toxicokinetics

The notified polymer has a relatively high molecular weight (> 1000 Da.) and is charged, and therefore is unlikely to cross biological membranes. No signs of toxicity were evident in the acute oral toxicity study (Pharmatox - Beratung and Forschung GmbH, 1998a) which may be indicative of the inability of the notified polymer to be absorbed.

Acute toxicity

The notified polymer was found to be of low toxicity via the oral route, based on no toxicological effects observed in an acute oral toxicity test conducted similar to the method described by OECD TG 401 (Pharmatox - Beratung and Forschung GmbH, 1998a).

Irritation and Sensitisation

The notified polymer contains several reactive functional groups which are known to cause irritation to mucous membranes, eyes and skin. (Kirk-Othmer, 1995).

The notified polymer was found to be slightly irritating to the skin in a skin irritation study conducted in rabbits according to OECD TG 404 (see Appendix B for further details). Slight to clear erythema and very slight oedema were observed up to 3 days following treatment. All signs of irritation had cleared by the Day 7 observation point. The effects observed were not sufficient for classification as an irritant according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

The notified polymer was found to be slightly irritating to the eye in an eye irritation study conducted in rabbits according to OECD TG 405 (see Appendix B for further details). Slightly injected blood vessels were observed in the animals for 4 days following treatment. In addition, swelling of the eyelid until it was half-closed was observed within 48 hours of treatment in 2 animals. All effects cleared by day 5. The effects observed were not sufficient for classification as an irritant according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

The notified polymer contains a reactive functional group similar to a known skin sensitiser (Barratt et al.,

1994). A skin sensitisation test was not conducted on the notified polymer. Even though the notified polymer has a relatively high molecular weight (Mn > 1000 Da.), with low levels of low molecular weight species anticipated, the risk of skin sensitisation cannot be ruled out.

Repeated Dose Toxicity

No repeated dose toxicity studies were conducted on the notified polymer. However, absorption across biological membranes is not considered to be significant given the relatively high molecular weight and ionic nature of the notified polymer.

Genotoxicity

The notified polymer was not tested for mutagenicity or genotoxicity.

Health hazard classification

Based on the available data the notified polymer is not classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

The notified polymer is not classified as hazardous, however, the effects observed in skin and eye irritation studies in rabbits indicate some potential for irritation in humans. It also contains functional groups which may be irritating to the respiratory tract (Kirk-Othmer, 1995). In addition, the potential for skin sensitisation, while not expected to be significant, cannot be ruled out.

Coating formulation

Dermal and ocular exposure is possible during manual weighing of the notified polymer (< 60%), connection and disconnection of hoses to reaction vessels, charging of reaction vessels, sampling and cleaning and maintenance of equipment. The use of safety glasses and protective gloves is expected to reduce exposure so that the risk of skin and eye irritation is not considered significant.

Coating application

Dermal and ocular exposure to the notified polymer (< 30%) may occur during the manual addition of coating to spray guns, spray application and cleaning of spray equipment. However, exposure during spray application, preparation and cleaning is expected to be minimised by using a spray booth for application and the use of appropriate PPE such as, safety glasses, protective gloves and coveralls.

Workers applying coatings by roller and brush are expected to wear safety glasses, protective gloves and coveralls to minimise exposure to the notified polymer and therefore the risk of skin and eye irritation is not considered to be unacceptable.

Inhalation exposure to aerosols of coatings containing the notified polymer (< 30%) during spray application may lead to irritation of the respiratory tract. Therefore, spray application should take place in ventilated spray booths and workers should wear respirators to ensure the risk is minimised.

Formulation of polyol

Dermal and ocular exposure to the notified polymer (< 60%) is possible during connecting and disconnecting transfer lines from the drums to the blending vessels, taking samples from the blending vessels, cleaning and maintenance of equipment. The use of safety glasses, protective gloves and coveralls during these processes is expected to reduce exposure so that the risk of skin and eye irritation is not considered significant.

Moulded article manufacture using polyols containing the notified polymer (< 20%) is not expected to result in exposure given the processes are automated.

Overall, the risk to occupational health is not considered to be unacceptable provided that the appropriate PPE (safety glasses, protective gloves, coveralls and respirators where appropriate) and engineering controls (ventilated spray booths) are used.

Extension Application:

The potential for exposure to the notified polymer in coatings during spray application and cleaning of equipment is expected to be low due to the relatively low concentration (approximately 2.8%) of the notified

polymer in the coatings, as well as the use of a ventilated spray booth and PPE. Therefore, based on the low potential for exposure and the relatively low concentration of the notified polymer in coating products, the risk to occupational health and safety from the notified polymer is not considered unacceptable.

6.3.2. Public health

The public may make dermal contact with articles coated with coatings containing the notified polymer (< 30%) or plastic articles containing the notified polymer (< 20%). However, the notified polymer will be trapped within an inert matrix and will not be bioavailable. Therefore, based on the very low potential for exposure to the notified polymer, the risk to public health is not considered unacceptable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The most likely source of a release to the environment during importation, storage, and transport will be a transport accident. However, the capacity and specifications of the import containers are likely to minimise the extent of any such releases. Releases that do occur as a result of accidents are expected to be physically contained, absorbed on inert material, and either reused or sent for safe disposal.

An estimated 135 kg of the annual introduction volume of notified polymer $(0.5\% \times 90\%)$ of annual import volume) will be lost as a result of spillages that occur during coating manufacture. The spillages will be absorbed and the materials collected will be disposed of to landfill or thermal decomposition. A maximum of 270 kg of notified polymer $(1\% \times 90\%)$ of annual import volume) will remain in import drums that will be collected by licensed waste contractors. The residues in storage containers will be cured prior to disposal to landfill.

Coating use will be exclusively in solvent free coatings. It is estimated that less than 1% of the notified polymer (270 kg of the annual use in coatings) may be lost due to cleaning of the manufacturing equipment, with potential release to the sewer as the equipment will be washed with water. However, these washes will undergo treatment whereby the notified polymer is removed and disposed of to landfill. In some situations, the manufacturing equipment will be washed with wash solvent (reclaimed mineral spirits) which will be collected and disposed to landfill or by thermal decomposition.

The release of the notified polymer at the polyol reformulation site is likely to be limited by the engineering controls that are employed. For example, only 0.2% of formulated liquid polyol product is expected to remain as residues in the lines at the end of blending. This quantity of residual product is equivalent to 6 kg of notified polymer $(0.2\% \times 10\%$ of annual import volume), which will be either recycled or removed by a waste disposal company for thermal decomposition or, more likely, disposal to landfill. Any spills that may occur during formulation will be contained in the existing bunded areas of the production facility and will be removed by a waste disposal company for disposal by thermal decomposition, or to landfill. Leaking drums and any clean-up material such as rags are likely to be stored on-site in oversized containers or drums until they are removed by a waste disposal company for landfill disposal.

It is estimated that up to 2% of the formulated product, equivalent to 60 kg of notified polymer ($2\% \times 10\%$ of annual import volume), will be discharged to the sewer with the wash waters (after on-site treatment to remove organic solvents and insoluble substances including the notified polymer) as a result of spill clean up and equipment cleaning.

Residues in import drums may be either removed by the waste disposal company for thermal decomposition or landfill disposal, or the drums may be recycled with the contents mostly likely being discharged to a sewage treatment plant after on-site treatment. The washes will undergo treatment whereby the notified polymer is removed and disposed of to landfill (maximum 30 kg, $1\% \times 10\%$ annual import volume).

RELEASE OF CHEMICAL FROM USE

When coating formulations containing the notified polymer are applied by spray techniques, it is anticipated that approximately 20-30% of the coating product will form overspray and be collected as waste material. As the application of coatings will be conducted at industrial sites in designated spray booths, the overspray will be

captured in the spray booth and on kraft paper or newspaper. The product will then dry onto the paper and be disposed to landfill or thermal decomposition.

During industrial use of the notified polymer, it is estimated that < 1% of the notified polymer will be spilt. These spills will be contained and disposed to landfill or thermal decomposition. Less than 1% of the notified polymer may remain as residues in the product containers. These will be disposed to landfill or thermal decomposition.

Equipment used to apply the coating formulations may be rinsed with water. It is estimated that 1% of notified polymer used in water-based coatings (up to 270 kg) may be released to sewer due to rinsing of equipment. These washes will undergo a treatment during which time the notified polymer will be removed and disposed to landfill. In some situations, the equipment used to apply the coating formulation may be rinsed with cleaning solvent. The wash will be removed and disposed to landfill or by thermal decomposition.

The manufacture of moulded articles from the polyol product containing the notified polymer are expected to take place on an industrial scale using various blending, pumping and injection processes. The release of the notified polymer from the manufacture of polyurethane is expected to be limited to accidental spills of liquid polyol formulations, the disposal of liquid residues from blending vessels and liquid transfer lines, and the disposal of residual polyol formulation present in drums. Based on a typical wastage figure of 2% for clean up of processing equipment and 1% residues in drums, up to 90 kg of notified polymer (3% ×10% of annual import volume) may require disposal from the manufacture of polyurethane articles. It is expected that these liquid wastes will be stored on-site for subsequent disposal. This may involve thermal decomposition of the organic components or, again more likely, disposal to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

The notified polymer will be disposed of predominantly to landfill or by thermal decomposition. Residues in aqueous waste streams will be largely removed by treatment before discharge to sewer.

7.1.2 Environmental fate

The notified polymer will be irreversibly combined with other chemical substances as part of the manufacture of articles. In the case of polyurethane manufacture, polyol products containing the notified polymer will be completely reacted by cross-linking, which leaves no residual material in the finished article. The finished polyurethane articles will be disposed of to landfill at the end of their useful life. In the case of coating applications, the notified polymer will be immobilised within a polymeric film on coated articles.

The notified polymer did not meet criteria for ready biodegradability in standard testing, but underwent some degradation. Residues of the notified polymer that are not consumed during the application of coatings and manufacture of articles can therefore be expected to slowly degrade if disposed of to landfill. The notified polymer is not expected to reach surface waters because of its tendency to associate with soils and sludge. Any residues that may enter aquatic environments would not be expected to bioconcentrate in fish because the high molecular weight will preclude absorption. For the details of the environmental fate studies please refer to Appendix C.

7.1.3 Predicted Environmental Concentration (PEC)

It is neither necessary nor meaningful to determine a PEC as the notified polymer is not expected to reach natural surface waters when it is used, handled and disposed of as proposed. The PEC can be expected to remain very low.

7.2. Environmental effects assessment

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

Endpoint	Result	Assessment Conclusion
Fish Toxicity (96 hours)	EC50 = 8 mg/L	Toxic
Algal Toxicity (72 hours)	$E_rC50 > 1 \text{ mg/L}$	Toxic

Results from testing in fish and algae indicate that the notified polymer is toxic to aquatic life.

7.2.1 Predicted No-Effect Concentration (PNEC)

The PNEC can be calculated by application of a thousand-fold assessment factor to the algal endpoint, as tabulated below.

Predicted No-Effect Concentration (PNEC) for	the Aquatic Compartment	
E _r C50 (algae)	> 1	mg/L
Assessment Factor	1000	
PNEC:	> 1	μg/L

7.3. Environmental risk assessment

Risk quotients cannot be calculated as the PEC is expected to be very low.

The notified polymer is not expected to present a risk to the environment when it is handled, used and disposed of as proposed by the notifier.

8. RISK ASSESSMENT AND RECOMMENDATIONS RELATING TO EXTENSION APPLICATION

The proposed use, introduction volume and fate of the notified polymer will not change significantly under the proposed extension. Under the extension application, product containing the notified polymer will not be available for public use. The circumstances in the extension application are not expected to impact on the original human health and environmental risk assessment and recommendations.

9. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available data the notified polymer is not classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

and

As a comparison only, the classification of the notified polymer using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

	Hazard category	Hazard statement
Skin irritant	3	Warning: causes mild skin irritation
Aquatic toxicity	Acute 2	Toxic to aquatic life

Human health risk assessment

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

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

Environmental risk assessment

On the basis of the reported use pattern, the notified polymer is not considered to pose a risk to the environment.

Recommendations

- The notified polymer should be classified as follows under the ADG Code:
 - Class 9: Environmentally Hazardous Substance (aquatic environment), Packing Group III

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer:
 - Spray application should be carried out in accordance with the Safework Australia *National Guidance Material for Spray Painting* [NOHSC (1999b)].
- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer as introduced and when used in products containing it:
 - Avoid contact with skin and eyes
 - Avoid inhalation of vapours, mists and aerosols
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer and when used in products containing it:
 - Wear suitable protective clothing (eg. overalls and gloves)
 - Organic vapour respirator (as needed)

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

- A copy of the MSDS should be easily accessible to employees.
- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Environment

Disposal

• The notified polymer should be disposed of to landfill.

Storage

- The following precautions should be taken by IMCD Australia Limited, Nuplex Industries (Aust) Pty Ltd, Akzo Nobel Pty Ltd and The Valspar (Australasia) Corporation Pty Ltd regarding storage of the notified polymer:
 - Keep only in the original container.

Emergency procedures

• Spills or accidental release of the notified polymer should be handled by 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 polymer, 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 chemical has changed from a component of industrial coatings and polyols, or is likely to change significantly;
 - the amount of chemical being introduced has increased from 31 tonnes, or is likely to increase, significantly;
 - the chemical has begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

Material Safety Data Sheet

The MSDS of the notified polymer and products containing the notified polymer provided by the notifier were reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

Extension Application

The MSDS of the notified polymer and products containing the notified polymer provided by the extension notifier were reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the extension applicant.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Boiling Point > 100°C at 101.3 kPa

Remarks Estimate based on molecular weight and structural formula.

Density $1070 \text{ kg/m}^3 \text{ at } 20^{\circ}\text{C}$

Method DIN EN ISO 2811-3
Remarks Test report not provided

Source MSDS

Vapour Pressure < 1.33x10⁻⁹ kPa at 25°C

Method Based on the molecular weight and structural formula.

Remarks US EPA, 2007

Water Solubility 1.66 (pH 1), 1.66 (pH 7), 1.55 (pH 10) g/L at 20°C

Method OECD TG 105 Water Solubility.

Remarks Flask Method. The test substance was analysed by gel permeation chromatography with

detection by evaporative light scattering.

Test Facility Springborn Smithers Laboratories (2005a)

Hydrolysis as a Function of pH Not determined.

No hydrolysis test was conducted. The notified polymer contains groups that could hydrolyse, but hydrolysis is expected to be slow under environmental conditions.

Partition Coefficient (n- $\log P_{ow} > 2.5$ at 20°C octanol/water)

Method The value above is an estimate based on the solubilities in water and in n-octanol

(> 522 g/L). Standard testing using the shake flask method tends to give unreliable results

for polymeric dispersants.

Adsorption/Desorption Not determined

The notified polymer is expected to sorb strongly to soil (log $K_{oc} > 3.5$) because of its

ionic nature.

Dissociation Constant Not determined.

The notified polymer contains functional groups with a typical pKa of > 9.

Flash Point > 100°C at 101.3 kPa

Method DIN EN 2719, ISO 2719. Remarks Test report not provided

Source MSDS

Flammability Not expected to be flammable

Remarks Estimated based on molecular weight and structural formula

Autoignition Temperature > 200°C

Method Not expected to auto-ignite based on practical experience.

Remarks Test report not provided

Source MSDS

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

Acute oral toxicity study: See summary in 6.2. Human health effects assessment

B.1. Irritation – skin

TEST SUBSTANCE Notified polymer

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.

EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).

Species/Strain Rabbit/New Zealand White

Number of Animals

Vehicle Administered as supplied

Observation Period 7 days

Type of Dressing Semi-occlusive.

ease of application. At time of application the notified polymer was similar to the body temperature of the animals. No significant protocol

deviations.

RESULTS

Lesion		ean Sco Inimal N	-	Maximum Value	Maximum Duration of Any Effect	Maximum Value at End of Observation Period
	1	2	3			
Erythema/Eschar	1	1.67	1.67	2	< 7 days	0
Oedema	1	1.33	1	1	< 7 days	0

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

Remarks - Results At one hour, slight erythema only was noted in all animals. At 24 hours,

slight to clearly visible erythema and very slight to slight oedema were observed in all test animals. Slight to clearly visible erythema and very slight oedema were observed at 48 hours. At 72 hours, slight erythema and very slight oedema were observed. No effects were observed at 7 days. The Primary Irritation Index (PII) was found to be 2.17 based on scoring of the skin reactions at 1, 24, 48 and 72 hours following treatment and

therefore classified as a moderate irritant.

CONCLUSION The notified polymer is slightly irritating to the skin.

TEST FACILITY Pharmatox (1998b)

B.2. Irritation – eye

TEST SUBSTANCE Notified polymer

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.

EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).

Species/Strain Rabbit/New Zealand White

Number of Animals 3 Observation Period 7 day

Remarks - Method The notified polymer was heated to approximately 37°C immediately prior

to treatment for ease of application. No significant protocol deviations.

RESULTS

Lesion	Mean Score* Animal No.	Maximum Value	Maximum Duration of Anv	Maximum Value at End of Observation Period
			Effect	J

	1	2	3			
Conjunctiva: redness	1.67	1.33	2	3	< 5 days	0
Conjunctiva: chemosis	1.33	1	1	3	< 72 hours	0
Conjunctiva: discharge	1	1.33	1.33	2	< 4 days	0
Corneal opacity	0	0	0	0	-	0
Iridial inflammation	0	0	0	0	-	0

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

Remarks - Results

Slight to diffuse blood red colouring of the conjunctivae were observed in the test animals clearing by 5 days after application. In the 48 hours following application the chemosis observed varied from slight swelling to swelling with the eyelid half closed. Discharge varied from slight lacrimation to lacrimation that moistened the eyelids in the first 3 days. All effects were resolved by day 5. No corneal or iris effects were observed.

CONCLUSION

The notified polymer is slightly irritating to the eye.

TEST FACILITY

Pharmatox (1998c)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE Notified polymer

METHOD OECD TG 301 B Ready Biodegradability: CO₂ Evolution Test.

Inoculum Activated sludge (local wastewater treatment plant, Massachusetts, USA)

Exposure Period 43 days Auxiliary Solvent None

Analytical Monitoring ThermoGlas Model 1200 Carbon Analyzer

Remarks - Method The test period was extended beyond the normal 28 days because the

degradation appeared not to have reached a plateau.

RESULTS

Test	substance	Sodiu	ım benzoate
Day	% Degradation	Day	% Degradation
2	-1.82	2	4.25
4	-5.28	4	20.57
7	-6.93	7	50.21
10	-4.99	10	74.46
14	-0.49	14	76.72
19	6.38	19	85.20
23	13.24	23	71.90
28	20.45	28	69.24
43	22.08	43	66.24

Remarks - Results

The net mean cumulative carbon dioxide evolved (percentage biodegradation) from the aqueous test medium fortified with 10 mg C/L was 20.5% on day 28. The value for the toxicity control on day 28 was 40.7% which indicates the notified polymer was not inhibitory to the microbial population in the test medium.

At day 43 the CO₂ evolution value was 22.1% and indicated that no further significant biodegradation of the notified polymer occurred during the 15 day extension of the test.

The net cumulative CO₂ evolved from the sodium benzoate reference was 74.5% by day 10, satisfying the pass criterion for the test. The rapid biodegradation of the reference substance confirmed the presence of active microbial population and system integrity.

CONCLUSION The notified polymer cannot be classed as readily biodegradable.

TEST FACILITY Springborn Smithers Laboratories (2004)

C.1.2. Bioaccumulation

The notified polymer is unlikely to bioaccumulate. Due to its molecular weight, it is not expected to be able to cross biological membranes. Although it is not readily biodegradable, the notified polymer is expected to undergo abiotic and biotic degradation over time.

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE Notified polymer

METHOD OECD TG 203 Fish, Acute Toxicity Test - static.

Species Rainbow trout (Oncorhynchus mykiss)

Exposure Period 96 hours Auxiliary Solvent None.

Water Hardness 42-46 mg CaCO₃/L

Analytical Monitoring Gel Permeation Chromatography with Evaporative Light Scattering

Detection (GPC/ELSD).

Remarks – Method All test solutions were observed to be clear and colourless with no visible

undissolved test substance.

RESULTS

Concentration mg/L		Number of Fish	Mortality (%)			
Nominal	Actual	•	24 h	48 h	72 h	96 h
0	0	10	0	0	0	0
0.63	0.73	10	0	0	0	0
1.3	1.1	10	0	0	0	0
2.5	2.1	10	0	0	0	0
5.0	4.5	10	0	0	0	0
10	8.7	10	0	40	60	60

LC50 > 8.7 mg/L at 24 hours.

> 8.7 mg/L at 48 hours. 8.0 mg/L at 72 hours. 8.0 mg/L at 96 hours. 4.5 mg/L at 96 hours.

Remarks – Results Mortality reached 100% after 96 hours in preliminary testing at 10 and

100 mg/L. Surviving fish were asymptomatic.

CONCLUSION The notified polymer is toxic to fish.

TEST FACILITY Springborn Smithers Laboratories (2005c)

C.2.2. Algal growth inhibition test

NOEC (or LOEC)

TEST SUBSTANCE Notified polymer

METHOD OECD TG 201 Alga, Growth Inhibition Test.

Species Pseudokirchneriella subcapitata

Exposure Period 72 hours

Concentration Range Nominal: 0.063, 0.13, 0.25, 0.50, and 1.0 mg/L

Auxiliary Solvent None

Water Hardness Typical algal assay medium.

Analytical Monitoring GPC/ELSD

Remarks - Method Only the two highest test concentrations were analysed. The

measurements showed considerable variability as the limit of quantitation was 0.6 mg/L, and are regarded as a qualitative indicator that solutions

were dosed correctly, rather than quantitative measurements.

RESULTS

Biomass		Growth			
E_bC50	NOEC	E_rC50	NOEC		
mg/L at 72 h	mg/L at 72 h	mg/L at 72 h	mg/L at 72 h		
0.47 (0.40-0.55)	0.25	> 1	0.25		
Remarks - Results	No abnormal morphology was seen in the algal cells. Algal growth met the validity criterion of a 16-fold increase.				
CONCLUSION	The notified polymer is toxic to green algae.				
TEST FACILITY	Springborn Smithers Laboratories (2005d)				

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