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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polymer in Autoclear LV Scratchguard

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 the Environment, Water, Heritage and the Arts.

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 334-336 Illawarra Road, Marrickville NSW 2204.

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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Polymer in Autoclear LV Scratchgaurd

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Akzo Nobel Car Refinishes Australia Pty Ltd (ABN 26 087 571 882)
269 Williamstown Road
PORT MELBOURNE VIC 3207

NOTIFICATION CATEGORY
Limited: Synthetic polymer with Mn ≥ 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, Use details and Import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: Melting point, Boiling point, Density, Vapour pressure, Water solubility, Hydrolysis as a Function of pH, Partition coefficient, Adsorption/desorption, Dissociation constant, Particle size, Flash point, Flammability limits and Autoignition temperature.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA
Canada

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Polymer in Autoclear LV Scratchguard

MOLECULAR WEIGHT
NAMW >1000 Da

ANALYTICAL DATA
Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY 70-80%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Liquid*

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Imported in solvent solution only.
Density	986 kg/m^3 at 20°C*	MSDS
Vapour Pressure	Not determined	Expected to be low based on high molecular weight.
Water Solubility	69.5 g/L at 20°C at pH ~6	Acceptable analogue data. The notified polymer is therefore expected to be readily soluble in water. Hydrolysis is expected to occur during the test.
Hydrolysis as a Function of pH	$t_{½}$ = 3.3 hours at pH 4, 67 days at pH 7 and > 1 year at pH 9, 25°C.	Acceptable analogue data. The notified polymer is expected to be readily hydrolysable under acidic conditions and hydrolytically stable under basic conditions.
Partition Coefficient (n-octanol/water)	Not determined	The notified polymer is expected to have a low P_{OW} based on its molecular structure and the estimated high water solubility.
Adsorption/Desorption	Not determined	Given the presence of weakly basic groups and the hydrophilic nature of the structure, the notified polymer is expected to be mobile in soil.
Dissociation Constant	Not determined	The notified polymer is not expected to be ionised in the environmental pH range (4-9).
Particle Size	Not determined	Imported in solution only.
Flash Point	Expected to be high	Based on high molecular weight.
Flammability	Not expected to be highly flammable	Based on estimated flash point.
Autoignition Temperature	Not determined	Not expected to autoignite under normal conditions of use.
Explosive Properties	Not expected to be explosive	The structural formula contains no explosophores.

* For Autoclear LV Scratchguard containing up to 30% notified polymer in solvent solution.

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

Reactivity
The notified polymer is expected to be stable under normal storage and handling conditions.

Dangerous Goods classification
Based on the submitted physical-chemical data in the above table the notified polymer is not classified according to the Australian Dangerous Goods Code (NTC, 2007). However the data above do not address all Dangerous Goods endpoints. Therefore consideration of all endpoints should be undertaken before a final decision on the Dangerous Goods classification is made by the introducer of the polymer.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will be imported at up to 30% in solvent-based paint products.

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

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

PORT OF ENTRY
Melbourne and Sydney

TRANSPORTATION AND PACKAGING
The notified polymer will be imported by sea in up to 5 L steel cans and transported from the wharf to the notifiers warehouses and then to distribution outlets across Australia by road.

USE
Component of automotive refinish paints.

OPERATION DESCRIPTION
The coatings containing the notified polymer at up to 30% will be used at car repair shops as received, or manually mixed with an appropriate thinner to reduce viscosity, and transferred to a reservoir for spray equipment application. It is expected that the coatings for the most part will be applied in ventilated spray booths. However, in smaller automotive refinish repair shops spray applications may occur outside of a spray booth.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

EXPOSURE DETAILS
Transport and storage
Exposure to the notified polymer (at up to 30%) during transport and storage is not expected except in the unlikely event of an accident where the containers are breached.

End-use
Dermal and ocular exposure to the notified polymer (at up to 30%) may occur during mixing and transfer of the paint to the spraying equipment, spray application, and equipment cleaning and maintenance. Inhalation exposure to the notified polymer (at up to 30%) is also likely during spray application. In the majority of car repair shops exposure is expected to be minimal as the coatings will be applied in a ventilated spray booth by workers using personal protective equipment. In car repair shops where spray booths are not used the level of inhalation exposure is expected to be greater. Exposure should be minimised if conducted in a well-ventilated area using personal protective equipment that includes respiratory protection.

6.1.2. Public exposure
The products containing the notified polymer will not be sold to the public. However, the public may come into contact with surfaces coated with products containing the notified polymer. Once cured and dried the notified polymer will be reacted into a polymer matrix and will not be bioavailable.

6.2. Human health effects assessment

No toxicity data were submitted for the notified polymer. However data were submitted for an acceptable "analogue mixture" of the notified polymer that comprises a structurally related polymer and its monomer. The toxicity data on the analogue mixture are summarised in the table below.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 > 2000 mg/kg bw; low toxicity LD50 = 1600 (females) and 2000 (males) mg/kg bw; harmful LD50 = 7,400 mg/kg bw; low toxicity
Rat, acute dermal toxicity	LD50 > 7,900 mg/kg bw; low toxicity
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Rat, repeat dose oral toxicity – 28 days.	NOAEL = 250 mg/kg/day
Rat, repeat dose dermal toxicity – 28 days	NOAEL = 1000 mg/kg/day
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro CHO Cell Assay	genotoxic
Genotoxicity – in vivo bone marrow chromosomal aberration	non genotoxic
Reproductive/developmental toxicity	NOAEL = 500 mg/kg bw/day

Toxicokinetics
Dermal absorption of the notified polymer is not expected given its high water solubility and expected low lipophilicity. This is supported by the low acute dermal toxicity (LD50 > 7,940 mg/kg bw) observed in a study conducted on the analogue. However, there is potential for toxicity via the oral route given there is a high percentage of low molecular weight species (23% < 1000 Da) and hydrolysis is likely to occur in the acidic environment of the GI tract that also might potentially form further low molecular weight species.

Acute toxicity
The analogue mixture of the notified polymer was found to be of low acute dermal toxicity (LD50 > 7,940 mg/kg bw) in a study conducted on New Zealand white rabbits (n=2; 1M/1F).

On the other hand, the analogue mixture has shown some toxicity when administered orally to rats in multiple tests with LD50 values ranging from 1600-7400 mg/kg bw. For example, in a study conducted to the OECD test guideline 401 (Limit Test), 1/5 males and 3/5 females died during the study (total of 4/10). Gross internal observations for the animals that died included foci on the thymus, dark red lungs, blackish-purple spleen, abnormal content of the bladder, and abnormal content of the digestive system. No significant gross internal findings were observed in surviving animals on study day 14. The LD50 value for this study was therefore determined to be > 2000 mg/kg bw. However in another study groups of 10 rats (5 male/ 5 female) dosed with 625, 1250, 2500 and 5000 mg/kg bw gave LD50 values of 1600 mg/kg bw for females and 2000 mg/kg bw for males (overall LD50 = 1800 mk/kg bw). The analogue mixture therefore may have some toxicity via the oral route. Given the result of the test conducted according to the OECD test guideline (LD50 > 2000 mg/kg bw) and the weight of evidence from the other tests, the analogue mixture is considered to be of low toxicity.

Given the results of these studies conducted with the analogue mixture, the notified polymer is expected to have low acute oral and dermal toxicity.

Acute inhalation toxicity data are not available for the notified polymer or the analogue mixture.

Irritation and Sensitisation
In a study similar to that described in the OECD test guideline TG104, the analogue mixture was found to be slightly irritating to the skin of rabbits. The analogue mixture produced very mild and transient dermal irritation for 5/6 of the animals in the first 48 hours after the removal of the occlusive patch but all animals were free of irritation at 72 hours.

In a study similar to that described in the OECD test guideline TG405, the analogue mixture was found to be slightly irritating to rabbit eyes. Ocular exposure produced immediate discomfort. Moderate degrees of redness and copious ocular discharge were seen up to 24 hours of the observation period. By 48 hours, there was gradual improvement and by 72 hours, there were no signs of irritation. No corneal or iridial inflammation was noted at any time.

Given the results of the irritation studies on the acceptable analogue mixture, the notified polymer is expected to be only slightly irritating to the skin and eyes.

No data on sensitisation is available for an analogue or the notified polymer. However, the notified polymer does not contain any structural alerts for sensitisation and therefore is not expected to be a sensitiser.

Repeated Dose Toxicity (oral)
A combined repeated-dose reproductive/developmental toxicity test was conducted according to the OECD test guideline TG422 on Sprague-Dawley rats using the analogue mixture. Animals were dosed at 0, 250, 500 or 1000 mg/kg bw/day. One high-dose female was euthanized in extremis on gestation day 21 and one high-dose recovery group female was euthanized on day 2. One mid-dose female died during parturition due to difficult delivery. Mean body weights and body weight gain of high-dose males were decreased during the first four weeks of the study. Food consumption was also decreased in high-dose males during the first week of the study. Clinical signs including prostration, impaired mobility and increased salivation were noted in high-dose males on study days 5 and 6 and lethargy, brown staining around the mouth and salivation were noted in mid- and high-dose males intermittently on days 1 – 26. Prostration, lethargy, rocking, lurching or swaying with ambulating, red material around the nose, splayed limbs and labored respiration were noted in high-dose females within 1 hour of dosing. Mean absolute and relative adrenal weights were increased in high-dose males and absolute adrenal weights were increased in females. An increase in relative thyroid/parathyroid weight was observed in high-dose recovery phase males. Mean red blood cell count, hematocrit, hemoglobin and reticulocyte counts were decreased in males and females at the high-dose. In high-dose male and female rats, microscopic changes were observed in the glandular (minimal neutrophils infiltration, erosion and eosinophilic chief cells) and non-glandular (minimal to mild hyperplasia of the limiting ridge) portion of the stomach. At the mid- and low-doses, similar changes were observed in the non-glandular portion of the stomach. This histopathological effect was considered to be a sign of gut irritation and not reflective of systemic toxicity. The NOAEL for systemic toxicity via the oral route for the analogue mixture was determined to be 250 mg/kg bw/day based on minor histopathological effects seen at this dose level.

Repeated Dose Toxicity (dermall)
A 28-day repeated dose dermal toxicity test was conducted on Sprague-Dawley rats using the analogue mixture. Rats (10 sex/dose) were administered the test substance via unoccluded, dermal applications at 0, 250, 750 or 1000 mg/kg-bw/day for 6 hours/day, 5 days/week for approximately 4 weeks. There were no deaths during the study and body weights and food consumption of treated animals were comparable to controls. No clinical signs of dermal irritation or toxicity were observed. There were no significant changes in hematological parameters. Increases in serum glutamic oxaloacetic transaminase (mid- and high-dose females) and serum glutamic-pyruvic transaminase (high-dose females) were observed as well as increases in absolute and relative liver weights (mid- and high-dose males) and spleen weights (high-dose males). However, in the absence of supportive microscopic findings, the biological significance of these changes are unclear, hence the NOAEL for systemic toxicity via the dermal route for the analogue mixture was considered to be 1000 mg/kg bw/day. There were no treatment-related gross lesions observed at necropsy.

Mutagenicity
The analogue mixture was found to be not mutagenic in an Ames Plate Incorporation Assay when tested in *Salmonella typhimurium* (TA1538, TA1535, TA1537, TA98, TA97) with and without metabolic activation at the test concentration range of 167-10,000 µg per plate. However the analogue mixture did induce chromosomal aberrations in a test conducted with Chinese hamster ovary cells both with and without metabolic activation at the test concentrations 87.5, 350 and 900 µg/ml (without S9) and 292, 1000 and 2500 µg/ml (with S9). Significant increases in aberrations/cell and proportions of cells with aberrant metaphases at 900 µg/ml without S9 and at 1000 and 25,000 µg/ml with S9 were observed. An *in vivo* chromosome aberration test (bone marrow cytogenetics rat metaphase analysis) on the analogue mixture was negative. In this study, male rats (number unknown) were dosed with 1700 mg/kg bw of the analogue and bone marrow cells harvested at 6, 18 and 30 hours post-dose. Two rats died and a few more exhibited severe pharmacotoxic signs. No significant increases in the incidence of aberrations or in the number of cells with one or more aberrations were observed.

Although the analogue mixture did not induce gene mutations *in vitro* or chromosomal aberrations *in vivo*, it did induce chromosomal aberrations in mammalian cells *in vitro*, hence the genotoxic potential of the analogue mixture, and by inference the notified polymer, can not be ruled out.

Carcinogenicity
No data on carcinogenicity is available for an analogue or the notified polymer. However, the notified polymer does contain at up to 3 wt.% the methoylol-amine group (FGEW = 3600 Da) that is a structural alert for carcinogenicity (Benigni et al, 2008). Given the high percentage of low molecular weight species passage across biological membranes may occur. In addition a mutagenic effect was observed in an *in vitro* chromosomal aberration test with the analogue which is likely to contain a percentage of methoylol groups. Therefore, the carcinogenicity potential of the notified polymer can not be totally ruled out.

Developmental/Reproductive Toxicity
Reproductive and developmental toxicity was evaluated on the analogue mixture (described under repeated-dose toxicity) in rats. There were no effects on reproductive performance parameters including mating index, fertility index, number of days between pairing and coitus, mean lengths of gestation, number of F1 pups born, live litter sizes, percentage of males at birth and postnatal survival through postnatal day 4 in any of the dose groups up to 1000 mg/kg bw/day. One female at 500 mg/kg bw/day died during parturition and death was attributed to difficult delivery. This female delivered 3 pups and had 16 fetuses with no apparent malformations *in utero*. One high-dose female died on gestation day 21. This female had 17 fetuses with no apparent malformations and two early resorptions. The numbers of pups found dead during lactation period were two, two, one and four in the control, low-, mid- and high-dose groups, respectively. One pup each in the mid- and high-dose groups was missing and presumed cannibalized. The general physical condition of F1 pups during lactation was similar in all groups. Mean male and female pup body weights in the 1000 mg/kg-bw/day groups were slightly reduced during postnatal days 1 – 4. On postnatal day 1, the mean body weight for the high-dose male pups was below the minimum value for historical controls. The NOAEL for reproductive/developmental toxicity for the analogue mixture was determined to be 500 mg/kg bw/day based on decreased pup weights at 1000 mg/kg bw/day.

Given the result of this study on the analogue mixture, the notified polymer is expected to have a NOAEL of 500 mg/kg bw/day for reproductive/developmental toxicity.

Summary
In summary based on the toxicity data for the analogue mixture, the notified polymer is expected to have low acute oral and dermal toxicity. It is not expected to be a sensitiser but may be a slight eye and skin irritant. However, based on a structural alert and high percentage of low molecular weight species and positive result in an *in vitro* chromosomal aberration assay on an acceptable analogue mixture, the notified polymer may have mutagenic and/or carcinogenic properties.

Health hazard classification
Based on the analogue data provided, the notified polymer can not be classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004). However the carcinogenic and/or mutagenic potential of the notified polymer can not be totally ruled out based on the presence of a structural alert and high percentage of low molecular weight species, and positive result in an in vitro chromosomal aberration assay on an acceptable analogue mixture.

6.3. Human health risk characterisation

6.3.1. Occupational health and safety
The notified polymer may have a mutagenic or carcinogenic potential. Given exposure is expected to be minimal provided all workers wear personal protective equipment and spray application is conducted in a spray booth or well-ventilated area using appropriate respiratory protection, the risk to workers from use of the notified polymer is not considered unacceptable.

6.3.2. Public health
Based on the expected minimal exposure to the cured notified polymer, the risk to the health of the public is not considered unacceptable under normal use conditions.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer will be imported as a component of an oil based coating for clear coat car refinishes. The coating containing the notified polymer can be either used as received or further manually diluted before use by professional operators. It is estimated that a maximum of 0.2% of the notified polymer will be lost during spillage in storage. Spills will be contained and soaked up with inert adsorbent material (sand, soil, vermiculite etc) and placed in sealable container for appropriate disposal to landfill.

RELEASE OF CHEMICAL FROM USE

Significant release of the notified polymer from the diluting of the product (if required) with organic solvents is not expected since this will be performed by trained professional operators. The majority of the chemical will be released as overspray during automotive spray painting operations. It is estimated that up to 35% of the applied notified polymer will be lost during the spray application. The majority of spray painting is expected to be performed in spray booths, where the overspray will be collected using filters and water scrubbers. The filters will be disposed of to landfill. The polymer in the scrubber water is likely to cure as a component of the paint and be removed periodically for disposal to landfill. In smaller smash repair workshops, which may not have spray booths, the overspray will be collected on newspaper sheet and be disposed of as domestic waste to landfill. Approximately 1% of the notified polymer is likely to be lost from cleaning of equipment and is expected to be collected for disposal to landfill. The residue in the containers is approximately 0.2% of the total amount imported and is expected to be sent to landfill with the containers.

RELEASE OF CHEMICAL FROM DISPOSAL

Most of the wastes containing the notified polymer resulting from the coating application are expected to be sent to landfill. No significant release of the coating containing the notified polymer to the sewage system is expected from the use. In addition, most of the wasted notified polymer is expected to be cross-linked with another component in the coating application. Therefore, if any polymer is released to sewer, it is likely to adsorb to the sewage sludge in the Sewage Treatment Plant (STP) due to the cross-linked and higher molecular weight structure and will be collected for disposal to landfill.

7.1.2 Environmental fate

The notified polymer is not expected to be readily biodegradable but is expected to be inherently biodegradable. However, it is not expected to be bioaccumulative or bioavailable to the aquatic organisms due to its high molecular weight and predicted high water solubility. For the details of the environmental fate studies, refer to Appendix C. The majority of the notified polymer will be bound to the car bodies via coating application and share the fate of the coated automotive panels. The panels may either be landfilled or be recycled for reuse of the metal material via thermal decomposition. A small amount of the notified polymer will be sent to landfill via wastes disposal.

In landfill, the notified polymer is not expected to leach due to the expected cross-linked and higher molecular weight structure and will undergo slow biotic or abiotic degradation processes. During metal reclamation, the notified polymer will be thermally decomposed. In both processes, the notified polymer will be converted into small molecules including water and oxides of carbon and nitrogen.

7.1.3 Predicted Environmental Concentration (PEC)

A PEC has not been calculated due to the limited release that is expected based on the proposed use application.

7.2. Environmental effects assessment

The results from ecotoxicological investigations conducted on mixtures that are considered acceptable as analogues of 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 h LC50 > 1000 mg/L	Not harmful
Daphnia Toxicity	48 h EC50 > 1000 mg/L	Not harmful
Algal Toxicity	E_rC50 > 100 mg/L	Not harmful

Based on the above ecotoxicity data for the tested analogue mixtures, the notified polymer is not classified as harmful to the aquatic life.

7.2.1 Predicted No-Effect Concentration

A PNEC of > 100 µg/L has been calculated based on the lowest endpoint E_rC50 > 100 mg/L for algae. An assessment factor of 1000 has been used since all the original reports were not available for review, despite endpoints for three species are available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (Alga).	> 100	mg/L
Assessment Factor	1000	
PNEC:	> 100	µg/L

7.3. Environmental risk assessment

The Risk Quotient (Q = PEC/PNEC) has not been calculated since the PEC has not been calculated due to the low release of the notified polymer to the aquatic environment.

The notified polymer is not expected to pose any unacceptable risk to the environment based on its reported use pattern.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available data the notified polymer can not be classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004). However the carcinogenic and/or mutagenic potential of the notified polymer can not be totally ruled out based on the presence of a structural alert and high percentage of low molecular weight species, and positive result in an *in vitro* chromosomal aberration assay on an acceptable analogue mixture.

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 expected to pose a risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer during spray application:
  - Use of spray paints containing the notified polymer should be in accordance with the NOHSC National Guidance Material for Spray Painting (NOHSC, 1999)

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer as introduced:
  - Avoid contact with eyes and skin
  - Do not inhale spray, mist or vapour
  - A shower station should be available

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced:
  - Coveralls
  - Safety glasses
  - Impermeable gloves
  - Respirator

  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 chemical 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.

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 chemical is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(1) of the Act; if
  - the 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 a component of automotive refinish paints at concentrations up to 30%, or is likely to change significantly;
- the amount of polymer being introduced has increased from 10 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 MSDS of the notified polymer and product 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.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Water Solubility 69.5 g/L at pH ~ 6 and 20ºC for an analogue mixture

Method OECD TG 105 Water Solubility

Remarks The test substance is a mixture that is considered an acceptable analogue. Following a preliminary test, the test substance was mixed with distilled water for 24 hours at 20º C, and centrifuged for HPLC analysis. It is believed that hydrolysis occurred during the course of the water solubility test.

The test substance, and by inference, the notified polymer, are considered to be readily soluble based on the test results.

Test Facility IUCLID

Hydrolysis as a Function of pH $t_{½}$ = 3.3 hours at pH 4, 67 days at pH 7 and > 1 year at pH 9, 25°C, for an analogue mixture.

Method OECD TG 111 Hydrolysis as a Function of pH.

pH	*T (°C)*	$t_{½}$
4	25	3.3 hours
7	25	67 days
9	25	> 1 year

Remarks The test substance is a mixture that is considered an acceptable analogue. Following a preliminary test, the final test was conducted at pH 4 with solutions maintained at 30 and 40°C, and at pH 7 with the temperature maintained at 50, 60 and 70°C. The rate constants (s^{-1}) at 25°C were determined to be 5.84 at pH 4 and 1.21 $\times 10^{-7}$ at pH 7. The test substance reached 11.3% degradation after 24 hours at pH 1.2 and 37°C.

The test substance, and by inference, the notified polymer, are considered to be rapidly hydrolysed under acidic conditions and hydrolytically stable under basic conditions.

Test Facility IUCLID

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Analogue mixture
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test
Inoculum	Activated sludge, domestic
Exposure Period	29 days
Auxiliary Solvent	None
Analytical Monitoring	CO_2 produced was collected using NaOH solutions. Samples were analysed for CO_2 using a TOC analyzer
Remarks - Method	The test substance contained the main monomer and a polymer that is structurally similar to the notified polymer, and it is considered to be an acceptable analogue of the notified polymer. The test was conducted at a concentration of 22.1 mg test substance/L, equivalent to 10 mg carbon/L. Sodium benzoate was used as the reference control at 17.1 mg/L, equivalent to 10 mg carbon/L. A toxicity control was also conducted at a concentration of 22.1 mg test substance/L and 17.1 mg sodium benzoate/L, equivalent to a total of 20 mg carbon/L. Observations made throughout the test indicated that the control, test, toxicity and positive control vessels contained light brown dispersions. No undissolved test or positive control material was visible.

RESULTS

Test substance		*Sodium Benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
3	3	14	82
16	15	29	94
29	23		

Remarks - Results	The test substance is not expected to be readily biodegradable, but is expected to be inherently biodegradable based on the test results.
CONCLUSION	The test substance, and by inference, the notified polymer is not readily biodegradable.
TEST FACILITY	IUCLID

C.1.2. Bioaccumulation

A test was not conducted. The notified polymer is not expected to be readily biodegradable. However, it is not considered to be bioaccumulative based on its high molecular weight and predicted low P_{OW}.

CONCLUSION	The notified polymer is not expected to be bioaccumulative or bioavailable to the aquatic organisms.

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Analogue Mixture
METHOD	OECD TG 203 Fish, Acute Toxicity Test - static
Species	*Lepomis macrochirus*
Exposure Period	96 hours
Auxiliary Solvent	None

Water Hardness	72-84 mg $CaCO_3$/L
Analytical Monitoring	Information for concentration monitoring during the test was not available.
Remarks – Method	The test substance was a mixture containing the main monomer and a polymer that is similar in structure to the notified polymer, which is considered to be an acceptable analogue of the notified polymer. Six groups of 10 bluegill sunfish were exposed in duplicates to test solutions of nominal concentrations at 60, 120, 250, 500, 1,000 mg/L, and laboratory dilution water (blank control). Test conditions were controlled at pH 7.0 – 7.6, 22.3°C, and dissolved oxygen levels from 8.4 mg/L (day 0) to 6.5 mg/L (day 4). Individual test solutions were prepared by adding the appropriate amount of test substance to laboratory dilution water which was stirred for 1 hour and 20 minutes until treatment solutions appeared clear.

RESULTS

LC50	> 1000 mg/L at 96 hours.
LC0	≥ 603.1 mg/L at 96 hours.
Remarks – Results	No mortality occurred during the 96-hour period up to the test concentration of 1000 mg/L.

CONCLUSION	The test substance, and by inference, the notified polymer, is not considered harmful to *Lepomis macrochirus*.
TEST FACILITY	IUCLID

C.2.2. Acute toxicity to fish

TEST SUBSTANCE	Analogue Mixture
METHOD	Methods for Acute Toxicity Tests with Fish, Macroinvertebrates and Amphibians (1975). EPA Guideline 660/3-75-009 - static
Species	*Lepomis macrochirus*
Exposure Period	96 hours
Auxiliary Solvent	Acetone
Water Hardness	40-45 mg $CaCO_3$/L
Analytical Monitoring	Information for concentration monitoring during the test was not available.
Remarks – Method	The test substance was a mixture that is considered to be an acceptable analogue to the notified polymer. Following a range-finding test, groups of 10 bluegill sunfish were exposed to test solutions of nominal concentrations at 100, 180, 320, 560, 1,000 mg/L, and dilution water control and solvent control. Test conditions were controlled as pH 7.0 – 7.2, 22°C, and the dissolved oxygen levels from 7.4 mg/L to 9.7 mg/L. Acetone was used in preparation of all test concentrations.

RESULTS

LC50	> 1000 mg/L at 96 hours
NOEC	320 mg/L at 96 hours
Remarks – Results	None of the fish in at any test concentration died by 96 hours. Abnormal effects of surfacing, dark discoloration and/or fish on bottom were observed in the 560 and 1,000 mg/L test concentrations. Therefore, the NOEC and LC50 values in terms of the formulation were 320 mg/L and > 1,000 mg/L, respectively.

CONCLUSION	The test substance, and by inference, the notified polymer, is not considered harmful to *Lepomis macrochirus*.

TEST FACILITY	IUCLID

C.2.3. Acute toxicity to fish

TEST SUBSTANCE	Analogue Mixture
METHOD	Methods for Acute Toxicity Tests with Fish, Macroinvertebrates and Amphibians (1975). EPA Guideline 660/3-75-009 - static
Species	*Salmo gairdneri*
Exposure Period	96 hours
Auxiliary Solvent	Acetone
Water Hardness	40-45 mg $CaCO_3$/L
Analytical Monitoring	Information for concentration monitoring during the test was not available.
Remarks – Method	The test substance was a mixture that is considered to be an acceptable analogue to the notified polymer. Following a range-finding test, groups of 10 fish were exposed to test solutions of nominal concentrations at 100, 180, 320, 560, 1,000 mg/L, and dilution water control and solvent control. Test conditions were controlled at pH 7.0 – 7.6, 12°C, and the dissolved oxygen levels from 7.6 mg/L to 9.5 mg/L. Acetone was used in preparation of all test concentrations.

RESULTS

LC50	> 1000 mg/L at 96 hours
NOEC	560 mg/L at 96 hours
Remarks – Results	None of the fish at any test concentration died by 96 hours. Abnormal effects of surfacing and fish on bottom were observed at 1,000 mg/L test concentration. Therefore, the NOEC and LC50 values in terms of the formulation were 560 mg/L and > 1,000 mg/L, respectively.

CONCLUSION	The test substance, and by inference, the notified polymer, is not considered harmful to *Salmo gairdneri*.
TEST FACILITY	IUCLID

C.2.4. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Analogue Mixture
METHOD	Methods for Acute Toxicity Tests with Fish, Macroinvertebrates and Amphibians (1975). EPA Guideline 660/3-75-009 - static
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	Acetone
Water Hardness	255 mg $CaCO_3$/L
Analytical Monitoring	Information for concentration monitoring during the test was not available.
Remarks - Method	The test substance was a mixture that is considered to be an acceptable analogue to the notified polymer. Following a range-finding test, groups of 10 daphnids were exposed to test solutions of nominal concentration at 100, 180, 320, 560, 1,000 mg/L, and blank control and solvent control. Test conditions were controlled at pH 8.2 – 8.7, 20°C, and the dissolved oxygen levels from 8.0 to 8.1 mg/L. Acetone was used in preparation of all test concentrations.

RESULTS

EC50	> 1000 mg/L at 48 hours
NOEC	320 mg/L at 48 hours
Remarks - Results	Although no immobility was observed in the test concentrations of 100-1,000 mg/L, abnormal effects of surfacing and daphnids lying on the bottom of the test chambers were observed at the 1,000 and 560 mg/L test concentrations. Therefore, the NOEC and EC50 values were 320 mg/L and > 1,000 mg/L, respectively.
CONCLUSION	The test substance, and by inference, the notified polymer, is not considered harmful to *Daphnia magna*.
TEST FACILITY	IUCLID

C.2.5. Algal growth inhibition test

TEST SUBSTANCE	Analogue Mixture
METHOD	OECD TG 201 Alga, Growth Inhibition Test.
Species	*Desmodesmus subspicatus*
Exposure Period	72 hours
Concentration Range	Nominal: 100 mg/L
Auxiliary Solvent	Acetone
Water Hardness	Not reported
Analytical Monitoring	The cell densities at 0, 48 and 72 hours were determined using a Coulter® Multisizer Particle Counter. Due to a malfunction of the counter at 24 hours, cell densities at this time were determined using a hemocytometer and light microscope.
Remarks - Method	The test substance was a mixture that is considered to be an acceptable analogue to the notified polymer. Following a range-finding test, algae (at nominal cell density of 1 x 10^4 cells/mL, in triplicates) were exposed to the test substance at 100 mg/L and incubated at 24˚C under continuous illumination (approximately 7,000 lux) and constantly shaken at approximately 150 rpm for 72 hours. The pH values of controls increased from pH 7.6 at 0 hours to 8.5 at 72 hours. The test substance was heated to approximately 60˚C before addition to culture medium to aid dissolution.

RESULTS

Biomass		*Growth*	
E_bC50	*NOEC*	*E_rC50*	*NOEC*
mg/L at 72h	*mg/L*	*mg/L at 72 h*	*mg/L*
> 100	100	> 100	100

Remarks - Results	The cell density of the control cultures was increased by a factor of 68 by 72 hours. No abnormalities were detected in any of the cultures upon microscopic evaluation at 72 hours. All control and test cultures were clear and colourless at the start of the test. At 72 h, all cultures appeared to be green dispersions. Neither the growth nor the biomass was affected by the presence of 100 mg/L test substance.
CONCLUSION	The test substance, and by inference, the notified polymer, is not considered harmful to algae.
TEST FACILITY	IUCLID

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