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

FULL PUBLIC REPORT

Polymer in Disperbyk-2012

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:

Street Address:	Level 7, 260 Elizabeth Street, SURRY HILLS NSW 2010, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL: + 61 2 8577 8800	
FAX: + 61 2 8577 8888	
Website:	www.nicnas.gov.au

**Director
NICNAS**

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FULL PUBLIC REPORT**Polymer in Disperbyk-2012****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

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

Nuplex Industries (Aust) Pty Limited (ABN 25 000 045 572)
49-61 Stephen Road
BOTANY, NSW 2019

PPG Industries Australia Pty Limited (82 055 500 939)
14 McNaughton Road
CLAYTON, VIC 3168

NOTIFICATION CATEGORY

Limited: Synthetic polymer with $M_n \geq 1000$ 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, analytical data, degree of purity, polymer constituents, residual monomers, impurities, use details, manufacture/import volume and site of manufacture.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows: Melting Point, Boiling Point, Vapour Pressure, Water Solubility, Hydrolysis as a Function of pH, Partition Coefficient (n-octanol/water), Adsorption/Desorption, Dissociation Constant, Flammability Limits, and Autoignition Temperature.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

USA (2009)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Disperbyk-2012 (contains $\leq 60\%$ notified polymer)

MOLECULAR WEIGHT

$> 10,000$ Da

ANALYTICAL DATA

Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY $> 98\%$

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

Below classification cut-off levels

ADDITIVES/ADJUVANTS

None

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
Not expected to occur under normal conditions of use.

DEGRADATION PRODUCTS
Not expected to occur under normal conditions of use.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Amber liquid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	< 20°C	Estimated based on the state of the polymer at room temperature.
Boiling Point	> 200°C at 101.3 kPa	Estimated, the notified polymer is expected to decompose prior to boiling
Density*	1,050 kg/m ³ at 20°C	MSDS
Viscosity*	7,100 mm ² /s at 20°C (kinematic) 7,500 mPa.s at 20°C (dynamic)	MSDS
Vapour Pressure	< 1.3 × 10 ⁻⁹ kPa	Estimated based on the NAMW > 1,000 Da (US EPA, 2007).
Water Solubility	Not determined	Expected to be dispersible in water based on its structure and experience in use
Hydrolysis as a Function of pH	Not determined	The notified polymer has functional groups that are susceptible to hydrolysis. However, hydrolysis is expected to be slow at environmental pH (4-9).
Partition Coefficient (n-octanol/water)	Not determined	The notified polymer may partition from octanol into water based on its hydrophilicity
Adsorption/Desorption	Not determined	Based on its ionic nature and high molecular weight, the notified polymer is expected to adsorb strongly to soil and sediment and have low mobility in the environment
Dissociation Constant	Not determined	The notified polymer will be ionised in the environmental pH range (4-9) based on the presence of a cationic functional group in the polymer structure
Flash Point*	> 150°C	MSDS
Autoignition Temperature	Not determined	Expected to be high based on the flash point.
Explosive Properties	Not expected to be explosive	The structural formula contains no explosives.

* For product containing ≤ 60% notified chemical.

DISCUSSION OF PROPERTIES

Reactivity

Stable under normal conditions of use.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) 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 a wetting and dispersing additive for reformulation into paints.

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>	2-5	4-7	4-7	4-7	4-7

PORT OF ENTRY

Melbourne and Sydney

TRANSPORTATION AND PACKAGING

The product containing the notified polymer at $\leq 60\%$ will be imported in sealed 25 kg or 200 kg drums and will be transported by road and rail. The reformulated end use products containing $< 5\%$ notified polymer will be transported to end use sites by road.

USE

Polymeric wetting and dispersing additive for resin and resin-free water-borne pigment concentrates, for use in inks and surface coatings at $< 5\%$.

OPERATION DESCRIPTION

The notified polymer will not be manufactured within Australia.

Reformulation

The product Disperbyk-2012 (containing $\leq 60\%$ notified polymer) will be manually weighed or metered directly from the imported drums into the mixing tank. The mixing facilities are expected to be automated, well ventilated (local exhaust ventilation) and closed systems. After being reformulated, the finished products containing the notified chemical at concentrations up to 5% will undergo further quality assurance tests before being packaged into containers.

End use

The notified polymer will predominantly be used as a component in surface coatings (95%) with the remainder (5%) used in ink products. The products containing the notified chemical will not be sold to the public. Of the surface coatings containing the notified polymer 70% is expected to be applied to metal substrates with the remainder applied to plastic or other substrates. The surface coatings containing the notified polymer will be applied by spray (90%), brush (5%) and roller (5%) with manual transfer to the spray painting equipment expected. Spray application will be conducted within spray booths with a down draft, by workers using protective equipment including vapour masks and full protective clothing. Ink products containing the notified polymer are expected to be used in equal proportions on plastic and paper substrates. During printing, the ink will be transferred directly from the container to the printing head via automated lines.

6. HUMAN HEALTH IMPLICATIONS**6.1. Exposure Assessment****6.1.1. Occupational Exposure**

EXPOSURE DETAILS

Transport and warehousing

It is expected that transport and warehouse workers handling the imported solution containing $\leq 60\%$ notified polymer will only be exposed to the notified chemical in the event of spills due to an accident or as a result of a drum leakage. Following reformulation of the imported solution into inks and surface coatings, transport and warehouse workers handling products will be exposed to concentrations of up to 5% notified polymer in the case of an accident when packaging is breached. The main route of exposure in these situations will be dermal.

Reformulation

During reformulation, dermal and ocular exposure of workers to the product containing the notified chemical (at $\leq 60\%$) may occur when weighing and transferring to the mixing tank. It is expected that there will be a low potential for exposure during the fully automated and closed blending process. Workers involved in the reformulation process are expected to wear impermeable gloves, goggles or face shield and protective clothing to further minimise exposure. Exposure to the notified chemical at concentrations up to 5% during transfer of the formulated product to packaging is expected to be low due to the largely automated processes used.

Inhalation exposure is expected to be negligible given the very low estimated vapour pressure of the notified chemical. In addition, blending and packaging facilities are expected to be well ventilated and generally will also use local exhaust ventilation.

End use

Exposure to the notified polymer ($< 5\%$) when used in printing inks may result via the dermal or ocular routes when the ink formulation is transferred to the printing machine. However, exposure to the notified polymer

should be limited by the proposed use of PPE (protective clothing, safety goggles and impermeable gloves) by these workers. Dermal, ocular and inhalation exposure of workers to the notified polymer (< 5%) may occur during spray application of surface coatings to plastic or metal substrates, and when cleaning up application equipment. Exposure during spray operations should be reduced as all spray applications will be within spray booths at industrial manufacturing facilities. In addition, workers will wear, as a minimum, eye protection, coveralls, and impermeable gloves; if necessary an air respirator will also be worn. Dermal and ocular exposure of workers to the notified polymer may occur during brush and roller applications, particularly during manual decanting and manual application. Exposure should be reduced by the wearing of PPE, including protective clothing, eye protection and impermeable gloves. Workers may make dermal contact with the notified polymer once the ink or coating formulation is dried to the substrate. Once dried, the coating or ink will form an inert film that will contain and immobilise the notified polymer, making it unavailable for dermal absorption.

6.1.2. Public Exposure

The finished products containing the notified polymer (< 5%) will not be sold to the public. The public may come into contact with the inks and coatings containing the notified polymer after application to substrates. However, once the inks and coatings are dried, the notified polymer will be bound within an inert film that will contain and immobilise it and hence will not be bioavailable.

6.2. Human Health Effects Assessment

No toxicity data were submitted.

Toxicokinetics, metabolism and distribution.

The notified polymer is not expected to be absorbed across biological membranes, based on the high molecular weight (> 10,000 Da) and low percentage of low molecular weight species (< 1,000 Da).

Irritation and Sensitisation.

The notified polymer contains quaternary ammonium functional groups (FGEW ~ 2,000) which are a structural alert for corrosion and skin sensitisation. However, given the high molecular weight, the lack of low molecular weight (< 1,000 Da) species and the relatively high FGEW the potential for corrosion and skin sensitisation is expected to be significantly reduced.

Health hazard classification

Based on the limited data available the notified polymer cannot be classified as hazardous according to 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 has the potential to be both corrosive and a skin sensitiser. However, the risk of these adverse health effects from exposure to the notified polymer is expected to be reduced by the relatively high FGEW, the high molecular weight (> 10,000 Da) and the lack of low molecular weight (< 1,000 Da) species. During reformulation workers will handle the notified polymer at concentrations of ≤ 60%, however exposure is expected to be low given the proposed use of PPE and largely enclosed, automated processes. During end use workers will be exposed to products containing the notified polymer at concentrations up to 5%. Exposure to the notified polymer during end use is also expected to be low due to the reduced concentration and the use of engineering controls and appropriate PPE. Exposure of workers to the notified polymer through dried inks and coatings is expected to be negligible. Given the expected low potential hazard, the proposed use of PPE and the engineering controls in place, the risk to workers of the notified polymer is not considered to be unreasonable.

6.3.2. Public Health

The finished printing inks and surface coatings containing the notified polymer will not be sold to the public. The public may have dermal exposure to printing inks and surface coatings containing the notified polymer; however, once the inks and coatings are cured or dried, the notified polymer will be bound within a polymer matrix and will not be bioavailable. Therefore the risk to the public from the notified polymer is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

No manufacturing of the notified polymer will take place in Australia. The release of the notified polymer to the environment during importation, storage, and transport is unlikely. The most likely source of a release to the environment during these activities will be a transport accident. Releases that do occur as a result of accidents are expected to be physically contained, absorbed into inert material and sent for disposal to landfill.

During the reformulation of the notified polymer into coating and ink products, an estimated 1% of the total importation volume of the notified polymer may be released due to spills. The spills will be readily contained and collected for disposal to landfill. At most, 1% of the total import volume of the notified polymer is anticipated to remain in storage containers as residues. Import drums will be collected by licensed waste contractors and the residue in storage containers will be cured prior to disposal to landfill. Equipment will be cleaned by rinsing with water and the washings are expected to be treated prior to release to sewer treatment plants, resulting in the collection and disposal of the notified polymer to landfill.

RELEASE OF CHEMICAL FROM USE

Application of coatings

Approximately 95% of the notified polymer will be used in coating preparations which will be mainly applied to metal articles but also other surfaces such as plastics. The coatings will primarily be applied by spray and it is anticipated that up to 30% of the coating product will be accounted for as 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. Waste material containing the notified polymer will be disposed of to landfill. Equipment used to apply the coating formulations may be rinsed with water and these washes will undergo a treatment during which time the notified polymer will be removed and disposed to landfill.

During industrial use of the notified polymer, it is estimated that < 0.5% of the notified polymer will be spilt. These spills are expected to be contained and disposed of to landfill. Less than 1% of the notified polymer may remain as residues in the product containers and these are also anticipated to be disposed of to landfill.

Ink Preparations

Approximately 5% of the notified polymer will be used in ink preparations. During use of the ink products containing the notified polymer, some release is expected to occur during the printing process via cleaning and maintenance operations and small spills (< 0.5%). It is expected that these residues will be disposed of to landfill. The inks containing the notified polymer will be applied to paper and plastic. The applied notified polymer is expected to be trapped in the ink matrix with other components of the ink.

RELEASE OF CHEMICAL FROM DISPOSAL

The majority of notified polymer in coatings is expected to share the fate of the articles to which it has been applied. Therefore, the notified polymer is expected to be either thermally decomposed during metal reclamation processes at the end of the articles' useful lives, or disposed of to landfill.

It is anticipated that half of the ink containing the notified polymer will be applied to plastic. The remainder will be applied to paper, half of which is expected to be recycled.

7.1.2. Environmental Fate

No environmental fate data were submitted. The majority of the notified polymer will be bound in either an inert print matrix on various substrates or immobilised within a polymeric film on coated articles and is therefore not expected to be bioavailable nor mobile. The majority of articles containing the notified polymer are anticipated to be disposed of to landfill or sent to metal recyclers. The notified polymer is expected to degrade by biotic and abiotic processes, or by thermal decomposition, to form water and oxides of carbon and nitrogen.

An estimated maximum of 3.25% of the imported notified polymer may be disposed of to the sewer due to washing of reformulation and coating equipment (2%) and paper recycling (1.25%). During paper recycling processes, waste paper is repulped using a variety of chemical agents which, amongst other things, enhance detachment of ink from the fibres. Some of the notified polymer may partition to the supernatant water which is released to sewer. However, the notified polymer would be expected to be efficiently removed from influent in sewage treatment plants through adsorption of this ionic polymer to sludge or by flocculation (Boethling and Nabholz, 1997). The notified polymer is therefore expected to be concentrated in the sludge fraction of on-site or municipal waste water treatment plants. Sludge generated during the washing process will be sent to landfill for disposal or to agricultural land for remediation. The notified polymer will be bound to soil and sludge due to its ionic functions and is not expected to be mobile in the environment (Boethling and Nabholz, 1997).

7.1.3. Predicted Environmental Concentration (PEC)

The Predicted Environmental Concentration (PEC) was calculated assuming that 3.25% of the total import volume of polymer would be released to sewer annually from paper recycling (1.25%) and the washing of reformulation and coating equipment (2%).

A worst case scenario was considered, assuming no removal of the notified polymer in sewage treatment plants (STPs) and the release of the notified polymer will occur over 260 days per annum into the total Australian effluent volume. This corresponds to release only on working days, based on a 5 day work week. The results of the calculation are shown in the table below.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	7,000	kg/year
Proportion expected to be released to sewer	3.25%	
Annual quantity of chemical released to sewer	227.5	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	0.88	kg/day
Water use	200	L/person/day
Population of Australia (Millions)	21.161	million
Removal within STP	0%	
Daily effluent production:	4,232	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.21	µg/L
PEC - Ocean:	0.021	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m²/year (10 ML/ha/year). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m³). Using these assumptions, irrigation with a concentration of 0.207 µg/L may potentially result in a soil concentration of approximately 1.378 µg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 6.892 µg/kg and 13.78 µg/kg, respectively. However, based on the likely high sorption to sludge of the notified polymer due to its cationicity, these values represent maximum concentrations only.

7.2. Environmental Effects Assessment

No ecotoxicity data were submitted. Ecotoxicological endpoints for the notified polymer were calculated based on SAR equations assuming a worst case cation charge density for the polymer (Boethling and Nabholz, 1997). The endpoints are summarised in the table below.

Endpoint	Result	Assessment Conclusion
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Fish Toxicity	LC50 = 9.7 mg/L	Toxic
Daphnia Toxicity	EC50 > 100 mg/L	Not harmful
Algal Toxicity	EC50 = 12.7 mg/L	Harmful

The notified polymer is potentially toxic to aquatic organisms in environmental waters. The SAR estimation procedure used here is a standard approach and is considered reliable to provide general indications of the likely environmental effects of the polymer. However, this method is not considered sufficient to formally classify the acute and long term hazard of the notified polymer to aquatic life under the Globally Harmonised System for the Classification and Labelling of Chemicals (United Nations, 2009).

7.2.1. Predicted No-Effect Concentration

The estimated hazard data for the notified polymer indicates that the most sensitive species is fish. The endpoint for fish was therefore selected for the calculation of the PNEC below. A conservative assessment factor of 1000 was applied since ecotoxicity endpoints were calculated using SAR equations based on groupings of broadly related polymers.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
Fish (LC50, 96 h)	9.7	mg/L
Assessment Factor	1000	
PNEC:	9.7	µg/L

7.3. Environmental Risk Assessment

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	0.21	9.7	0.02
Q - Ocean	0.021	9.7	0.002

The risk quotient ($Q = \text{PEC}/\text{PNEC}$) for aquatic exposure is calculated to be < 1 based on the above calculated PEC and PNEC. The Q value of < 1 indicates the notified polymer is not expected to pose an unreasonable risk to the aquatic environment from its proposed use pattern at the proposed maximum import volume.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available data the notified polymer is not classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(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 assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer during reformulation and handling:
 - Gloves, overalls and goggles. Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards. Spray applications should be carried out in accordance with the Safe Work Australia *National Guidance Material for Spray Painting* [NOHSC (1999)] or relevant State and Territory Codes of Practice.

- 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.

Disposal

- The notified chemical 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 in inks and surface coatings in industrial settings, or is likely to change significantly;
 - the amount of polymer being introduced has increased from 7 tonnes, 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 products containing the notified chemical provided by the notifier were reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

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