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August 2015

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Polymer in Dispex® Ultra PA 4530

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (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 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.

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

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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SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1848	BASF Australia Ltd	Polymer in Dispex® Ultra PA 4530	ND*	≤ 40 tonnes per annum	Dispersing agent in industrial and automotive paints

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
As no toxicity data were provided, the notified polymer cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

Human health risk assessment
Provided that the recommended controls are being adhered to, 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 its limited aquatic exposure and assessed use pattern, the notified polymer is not considered to pose a risk to the environment.

Recommendations

REGULATORY CONTROLS

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified polymer as introduced in the product:
  - Enclosed and automated reformulation processes, where possible
  - Spray booths if spray applications occur

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer as introduced in the product:
  - Avoid contact with skin and eyes
  - Avoid breathing aerosols and mists
  - Ensure compliance with the exposure standard for benzene in the atmosphere

- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced in the product:
  - Protective clothing/coveralls
  - Impervious gloves
  - Eye protection
  - Respiratory protection

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 Code of Practice for *Spray Painting and Powder Coating* (SWA, 2012) or relevant State or Territory Code of Practice.

- A copy of the (M)SDS should be easily accessible to employees.

- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Public Health

- The following measures should be taken by formulators to minimise public exposure to the notified polymer:
  - Adequately label the products containing the notified polymer to use formulated paints in well ventilated areas and avoid inhalation of mists or aerosols

Disposal

- Where reuse or recycling are not appropriate, dispose of the notified polymer in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

Emergency procedures

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

Regulatory Obligations

Secondary Notification
This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified polymer is listed on the Australian Inventory of Chemical Substances (AICS).

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

(1) Under Section 64(1) of the Act; if
  - the polymer has a number-average molecular weight of less than 1000;

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the polymer has changed from a dispersing agent in industrial and automotive paints, or is likely to change significantly;
  - the amount of polymer being introduced has increased, or is likely to increase, significantly;
  - the polymer has begun to be manufactured in Australia;
  - additional information has become available to the person as to an adverse effect of the polymer on occupational health and safety, public health, or the environment.

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

(Material) Safety Data Sheet

The (M)SDS of the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
BASF Australia Ltd (ABN: 62 008 437 867)
Level 12, 28 Freshwater Place
SOUTHBANK, VIC 3006

NOTIFICATION CATEGORY
Limited: Synthetic polymer with Mn ≥ 1,000 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, additives/adjuvants, use details, import volume, and identity of recipients.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed for all physico-chemical endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Canada (2012), China (2013), US (1994)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Dispex® Ultra PA 4530 (≤ 75% notified polymer)

MOLECULAR WEIGHT
> 1,000 Da

ANALYTICAL DATA
Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 95%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
The notified polymer contains hazardous impurities and/or residual monomers at levels above the concentration cut-offs for classification. The impurities and/or residual monomers may cause cancer, heritable genetic damage or skin sensitisation (R45, R46 and R43 classifications).

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Yellowish liquid*

Property	Value	Data Source/Justification
Boiling Point*	~ 119 °C	(M)SDS
Density*	990 kg/m^3 at 20 °C	(M)SDS
Vapour Pressure	< 1.3 × 10^{-9} kPa	Estimated, based on the NAMW > 1,000 Da (US EPA, 2013)
Water Solubility	46 – 377 mg/L at 20 °C	Measured (similar substance)
Hydrolysis as a Function of pH	Not determined	Contains functional groups that are expected to hydrolyse very slowly in the environmental pH range of 4-9

Partition Coefficient (n-octanol/water)	log Pow ≥ 3.4 at 20 °C	Measured (similar substance)
Adsorption/Desorption	Not determined	Expected to adsorb to soil, sediment and sludge based on its high molecular weight and low water solubility
Dissociation Constant	Not determined	Contains basic functionality (pKa ~ 7) which has the potential to be cationic under environmental conditions (pH 4-9)
Flash Point/Flammability	Not determined	Imported in flammable solvent
Autoignition Temperature	Not determined	Imported in flammable solvent
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not determined	Contains no function groups that would imply oxidative properties.

*Dispex® Ultra PA 4530 (≤ 75% notified polymer)

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 conditions of use.

Physical hazard classification
Based on the limited submitted physico-chemical data depicted in the above table, the notified polymer is not recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

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 at ≤ 75% concentration for reformulation into paints, or at < 15% concentration as a component of paints.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	≤ 20	≤ 30	≤ 30	≤ 30	≤ 40

PORT OF ENTRY
Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
BASF Australia Ltd (and coating formulators throughout Australia)

TRANSPORTATION AND PACKAGING
The product containing the notified polymer will be imported by sea in 18 kg plastic Jerri cans and 180 kg lined steel closed head drums. These containers will be packed on wooden pallets and bound with plastic shrink wrap and will be transported by road to a storage warehouse before distribution to reformulation sites. The paints containing the notified polymer at < 15% concentration will be stored and transported in lined steel 1 L, 4 L and 10 L paint cans and 210 kg drums.

USE
The notified polymer functions as a pigment dispersant and will be used at < 15% concentration in water dilutable industrial and automotive paints.

OPERATION DESCRIPTION

Formulation of paints
Reformulation of the notified polymer will occur in paint manufacturing facilities in Australia and will likely involve the process described below.

The imported product containing the notified polymer (≤ 75%) will be transferred to mixing tank via gravity or low pressure pump. The pH of the notified polymer will then be adjusted under a slow mixing speed, followed by the addition of other paint components under high speed mixing. Following quality assurance testing, the paints containing the notified polymer will be transferred to lined steel containers for sale.

The paint manufacturing equipment will be cleaned by flushing with water or solvents. Liquid waste will be either recycled for reuse in the paint manufacturing facility or disposed of.

End Use
The finished paints containing the notified polymer at < 15% concentration will predominantly be applied by spray (estimated to be > 95% of use; brush or roller may also be used, e.g. in touch-up instances). Typical substrates on which paint containing the notified polymer will be applied are metal and plastic car parts, and in the case of heavy duty and protective paints, the substrate would be predominantly steel parts and structures.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and storage	1	4 - 8
Process operator	2 - 3	40 - 50
Quality control	0.5	40 - 50
Packaging	2 - 3	40 - 50
End use	1	60 - 80

EXPOSURE DETAILS
Transport and storage workers may come into contact with the notified polymer at ≤ 75% concentration, only in the unlikely event of an accident.

Dermal, ocular or perhaps inhalation exposure to the notified polymer at concentrations up to ≤ 75% may occur during reformulation processes. Exposure is expected to be minimised through the use of automated processes (where possible), ventilation and the use of personal protective equipment (PPE).

At end-use sites, dermal, ocular and inhalation exposure to the paint containing the notified polymer at < 15% concentration may occur during paint application process. Paint application will be primarily by spray, but potentially with brush and roller. Application by spray is expected to occur in purposely built spray facilities, and the notifier has indicated that ~ 70% of the sprayed paint will be transferred to the substrate, with the remainder caught in the industrial and automotive spray booths. Exposure during application is expected to be minimised with the use of PPE (including, gloves, protective clothing and respiratory protection). Once the paint has hardened, the notified polymer will be unavailable for exposure.

6.1.2. Public Exposure
Paints containing the notified polymer at < 15% concentration are primarily intended for industrial use. The notifier has indicated that < 1% of paint sales will be to the general public (with the products not expected to be sold in general retail/hardware stores). Dermal and ocular exposure to the notified polymer at concentrations < 15% may occur during the end use. Inhalation exposure to the notified polymer in the paints is also possible if spray method is used. However, the exposure is expected to be of low frequency and small scale.

Once the paint has hardened, the notified polymer is expected to be incorporated into the matrix and will not be available for further exposure.

6.2. Human Health Effects Assessment
No toxicity data were submitted for the notified polymer.

Based on the high molecular weight (> 1,000 Da) of the notified polymer and its low percentage of low molecular weight species (2.7%), the potential for the notified polymer to be absorbed across biological membranes is expected to be limited.

The notified polymer contains tertiary amines and phenyl ester groups which are structural alerts for corrosion/irritation. Phenyl ester is also a structural alert for skin sensitisation. Therefore the potential for skin irritation and sensitisation effects associated with reformulation and applications of the paints containing the notified polymer cannot be ruled out.

The notified polymer also contains aromatic hydrocarbon (arenes) for which the breakdown metabolites are known to have DNA-binding potential via a Michael addition mechanism (QSAR Toolbox V3.2). Therefore, if the notified polymer is absorbed through skin, the possibility for its breakdown products to cause genotoxicity cannot be ruled out.

However, due to the high molecular weight of the notified polymer, the potential for the polymer to cause the above effects may be limited by its estimated low dermal absorption. The proposed use of engineering controls and PPE for other hazardous ingredients in the paints would further reduce the potential for adverse health effects to occur.

Health hazard classification
As no toxicity data were provided, the notified polymer cannot be classified according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

Although not considered in this risk assessment, NICNAS notes that the notified polymer contains impurities / residual monomers that are classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004). One of the impurities / residual monomers, classified as R43 – may cause sensitisation by skin contact, is present in the notified polymer above the cut off concentration for classifications. Benzene is also an impurity, classified as R45 – may cause cancer and R46 – may cause inheritable genetic damage, and is present in the notified polymer above the cut off concentrations for classifications. However, in the final paint products, benzene is not present above the cut-off concentration for classification.

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
The notified polymer may have the potential to cause skin/eye irritation and skin sensitisation due to the presence of relevant structural alerts. However, the risk of the adverse effects from exposure to the notified polymer is expected to be limited by its high molecular weight (Mn > 1000 Da) with low percentage (2.7%) of low molecular weight species.

The notified polymer contains benzene as an impurity which is classed as R45 and R46 under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004). In consideration of control measures for protection, users of the notified polymer should be aware that Australian exposure standard for benzene in occupational settings is 3.2 milligrams per cubic metre of air at 25 °C and one atmosphere pressure (time weighted average)(SWA, 2013).

During reformulation workers will be handling the notified polymer at concentrations up to 75%. During the end use workers may come into contact with the notified polymer at concentrations < 15%. However, in industrial settings significant exposure of workers to the notified polymer is not expected given the control measures in place (e.g. PPE, enclosed and automated processes, and spray facilities) to minimise exposure.

Provided that the recommended control measures are in place to minimise exposure, the risk to workers to the notified polymer is not considered to be unreasonable.

6.3.2. Public Health
Paints containing the notified polymer at < 15% concentration are primarily intended for industrial use. The notifier has indicated that < 1% of the paint products may be used by the general public. As frequency and scale of the exposure are expected to be much reduced compared to those of workers, the risk to do-it-yourself (DIY)

users is expected to be of a lesser extent than that experienced by workers using the same products containing the notified polymer.

The paint products containing the notified polymer also contain benzene as an impurity. Preparations containing > 15 mL/L benzene are scheduled in the Poisons Standard (the SUSMP, 2015) under Schedule 7, indicating a high potential for causing harm at low exposure. However, based on the proposed final use concentrations of the notifier polymer in the paint products, the concentration of benzene in the end use products is << 15 mL/L.

Once the paint is hardened, further exposure to the notified polymer is not expected as the polymer will be bound within the matrix and unavailable for exposure.

Overall, based on the assessed use patterns, 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

The notified polymer will not be manufactured in Australia; therefore, there will be no release from this activity. Environmental release during importation, transport and distribution may occur as a result of accidental spills. In the event of a spill, the notified polymer is expected to be contained and collected with an inert absorbent material and disposed of in accordance with local regulations.

Reformulation of the notified polymer occurs in a closed system and release to atmosphere is expected to be negligible. Solvent used for equipment washing containing residues of the notified polymer are expected to be recycled for reuse on site or disposed of via accredited waste disposal contractors. Wastes and spills (1% of annual import volume) during reformulation activities are expected to be contained on-site and disposed of in accordance with local regulations. Residues in import containers are expected to be disposed of via the trade waste stream of the formulator in accordance with local regulations.

RELEASE OF CHEMICAL FROM USE

Paint products containing the notified polymer are expected to only be used in industrial facilities for metal coating. Therefore, any losses from overspray (estimated at 30% of annual import volume) during industrial use are expected to be collected using standard engineering controls such as spray booths. These losses, together with other wastes generated during use, including residues in application equipment washings and empty paint containers (estimated at up to 5% and 2.5%, respectively, of the annual import volume), are expected to be disposed of in accordance with local regulations, namely to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

The notified polymer in paints is expected to share the fate of metal structures to which it has been applied. The notified polymer is likely to be either thermally decomposed during metal reclamation processes or disposed of to landfill at the end of the useful life of the article to which is has been applied

7.1.2. Environmental Fate

No environmental fate data were submitted. The majority of the notified polymer is expected to be bound within an inert matrix of cured paints as part of its normal use pattern as a component in industrial paints. The majority of notified polymer in wastes disposed of to landfill is expected to be in solid cured paint and it is not expected to be bioavailable, biodegradable nor mobile in this form. Based on the high molecular weight of the notified polymer, it is not likely to cross biological membranes, hence bioaccumulation is not expected. Furthermore, bioaccumulation of the notified polymer is unlikely due to limited bioavailability in its solid form in landfill and its limited release to surface waters during use. The notified polymer will eventually degrade in landfill, or by thermal decomposition during metal reclamation processes, to form water and oxides of carbon and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has not been calculated for the notified polymer as, based on its reported use pattern, ecotoxicologically significant quantities are not expected to be released to the aquatic environment.

7.2. Environmental Effects Assessment

No ecotoxicity data were submitted. The notified polymer contains basic functionality which has the potential to become cationic under environmental conditions (pH 4-9). The cationic charge density is < 5000 Da and thus the notified polymer has the potential to be toxic to aquatic life. However, significant exposure of the notified polymer to aquatic organisms is unlikely based on the reported use pattern. Furthermore, the majority of the notified polymer will be bound within the inert matrix of cured paints and is not expected to be bioavailable.

7.2.1. Predicted No-Effect Concentration

A predicted no-effect concentration (PNEC) has not been calculated for the notified polymer as, based on its reported use pattern, ecotoxicologically significant quantities are not expected to be released to the aquatic environment.

7.3. Environmental Risk Assessment

The risk quotient (Q = PEC/PNEC) for the notified polymer has not been calculated as release to the aquatic environment in ecotoxicologically significant quantities is not expected based on its reported use pattern as a component in industrial paints for use on metal substrates. The majority of the environmental release of the notified polymer will be disposal of the cured paints to landfill and by thermal decomposition during metal reclamation processes. In cured paints the notified polymer is bound within the inert paint matrix and is unlikely to leach or be bioavailable. On the basis of its limited aquatic exposure and assessed use pattern, the notified polymer is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Water Solubility	0.046 g/L (loading rate 1 g/L) and 0.377 g/L (loading rate 10 g/L) at 20 °C, pH 6
Method	OECD TG 105 Water Solubility.
Remarks	Flask method with determination by total organic carbon content. The water solubility was conducted on an analogue.
Test Facility	BASF (2012)
Partition Coefficient (n-octanol/water)	log Pow ≥ 3.4 at 20 °C
Method	In-house. [The partition coefficient was determined for an analogue].
Remarks	Estimated from the water solubility (0.377 g/L) and solubility in n-octanol (≥ 900 g/L). The test substance (solvent free notified polymer) was determined to be completely miscible in n-octanol in ratios ranging 1:9 to 9:1. The solubility of the test substance in n-octanol was ≥ 900 g/L.
Test Facility	BASF (2012)

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