File No: LTD/2004

December 2017

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Polymer in Dispex® Ultra FA 4484

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 and Energy.

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

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Director
NICNAS

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SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/2004	BASF Australia Ltd	Polymer in Dispex® Ultra FA 4484	ND*	≤ 30 tonnes per annum	Component of industrial and automotive paints

ND* = Not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on limited available information, the notified polymer cannot be recommended for classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia.

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 reported use pattern and expected limited aquatic exposure, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

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 Dispex Ultra FA 4484:
  - Enclosed, automated processes, where possible

- 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 in the product Dispex Ultra FA 4484:
  - Avoid contact with skin and eyes

- 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 in the product Dispex Ultra FA 4484:
  - Coveralls
  - Impervious gloves
  - Safety glasses or 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 Code of Practice for *Spray Painting and Powder Coating* (SWA, 2015) or relevant State or Territory Code of Practice.

- A copy of the 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.

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 containment, physical collection and subsequent safe disposal.

Regulatory Obligations

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

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

(1) Under Section 64(1) of the Act; if
- the polymer has a number-average molecular weight of less than 1,000;
- the polymer is intended to be available for public use;
- the polymer is intended to be imported in powder form;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the polymer has changed from component of 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.

Safety Data Sheet
The SDS of the products containing the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the 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 g/mol

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, spectral data, degree of purity, use details, polymer constituents, residual monomers, impurities, additives/adjuvants and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: specific gravity/density, hydrolysis as a function of pH, flash point, flammability, autoignition temperature, explosive properties, oxidising properties, and reactivity.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
China (2017)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Dispex® Ultra FA 4484 (product containing the notified polymer at < 30% concentration)

MOLECULAR WEIGHT
Number Average Molecular Weight (Mn) is > 1,000 g/mol.

ANALYTICAL DATA
Reference NMR, FTIR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 95%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: White fine powder

Property	Value	Data Source/Justification
Melting Range	25 – 37 °C	Measured
Boiling Point	96 °C at 10 kPa	Calculated
Density	1,030 kg/m^3 at 20 °C	SDS
Vapour Pressure	0.32 kPa at 20 °C	Measured
Water Solubility	≥ 30 wt % at 20 °C	Estimated using a visual method, as it was not possible to achieve a liquid phase at the saturation concentration. Therefore, the notified polymer is soluble to the limit of practical testing.

Property	Value	Data Source/Justification
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionalities. However, stability tests showed that the notified polymer was stable under the environmental pH range of 4-9.
Partition Coefficient (n-octanol/water)	log Pow = 0.1 at 20 °C	Estimated from the single solubilities in n-octanol and in water. It is not feasible to measure the log Pow of the notified polymer using either the shake flask or HPLC methods as the notified polymer has both hydrophilic and hydrophobic properties. The notified polymer is surface active and is therefore likely to be present at the water-octanol interface.
Adsorption/Desorption	Not determined	It was not possible to measure the Koc experimentally by HPLC as the notified polymer cannot by chromatographed under the prescribed. Based on the log Kow the notified polymer is not expected to adsorb to organic carbon.
Dissociation Constant	$pKa_2 = 6.6$	Measured. The notified polymer has multiple ionisation constants. Based on the pKa_2 value it is expected to be ionised in the environmentally relevant pH range of 4 – 9.
Particle Size	Not determined	Powder form of the notified polymer will not be imported.
Flash Point	Not determined	SDS
Flammability	Not flammable	SDS
Autoignition Temperature	Not expected to autoignite	SDS
Explosive Properties	Not expected to be explosive	SDS
Oxidising Properties	Not expected to oxidise	SDS

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 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. It will be imported into Australia in the product Dispex Ultra FA 4484 at concentrations < 30%, which will be reformulated into industrial and automotive paints.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	30	30	30	30	30

PORT OF ENTRY
Various ports throughout Australia

TRANSPORTATION AND PACKAGING
The product Dispex® Ultra FA 4484 containing the notified polymer will be imported in 1,000 kg bulk containers or 150 kg plastic drums. These containers will be transported from the wharf to warehouses for storage. The finished paint products will be transported in lined steel drums of 1 L, 4 L, 10 L and 210 kg sizes.

USE
The notified polymer will be used as a pigment dispersant introduced in the product Dispex Ultra FA 4484 at < 30% concentration. Dispex Ultra FA 4484 will be blended with other paint components to formulate various finished industrial and automotive paints. These paint products will contain the notified polymer at < 0.5% concentration.

OPERATION DESCRIPTION

Reformulation
Dispex® Ultra FA 4484 will be added into blending tanks using gravity or low pressure pumps as a dispersant in combination with other ingredients including solvents and resins to formulate water-based paints. After the addition of Dispex Ultra FA 4484, dry pigments will be added and the paint mixture will be mixed with high speed. After the pigments are dispersed, quality control (QC) workers will transfer small samples of the paint product to the laboratory for testing. The finished paint will be filled into lined steel containers by gravity feed or low pressure pumps, sealed, loaded and transported to warehouses. The paint products will then be distributed to the end-users. The mixing and filling processes of the paints containing the notified polymer are expected to be automated.

End Use
The finished paint products containing the notified polymer at concentration of < 0.5 % will be applied by spray, brush or roller in an industrial setting, such as vehicle repair shops and vehicle manufacturing facilities. Any equipment used to apply the paint products will be cleaned with water. The rinse-off waste water will be collected and either recycled for paint manufacturing or be disposed of in accordance to the environmental regulations.

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
Warehouse	1	4
Process operator	2.5	40
Quality control	0.5	40
Packaging	2	40
End use	1	60

EXPOSURE DETAILS

Transport and Storage
Transport and storage workers may come into contact with the notified polymer in the unlikely event of accidental breaching of the drum containers. Appropriate personal protective equipment (PPE) is expected to be used by the workers to reduce the potential for exposure.

Reformulation
For coating and paint product reformulations, dermal and ocular exposure of workers to the notified polymer at < 30% concentration may occur when weighing, metering, mixing and transferring materials containing the polymer or during QC laboratory testing, equipment cleaning and maintenance. Given that the notified polymer will be imported in water dispersions, inhalation exposure is not expected, unless aerosols are formed during the mixing processes. Exposure to the notified polymer is expected to be minimised through the use of enclosed and automated systems, local exhaust ventilation and suitable personal protective equipment (PPE) capable of protecting workers from exposure to the notified polymer, including impervious rubber gloves, safety glasses with side protection or goggles, protective clothing and respiratory protection (if aerosols are expected).

End use
Professional workers will apply the paint products containing the notified polymer at < 0.5 % in a controlled industrial setting, and may be exposed (dermal, ocular and inhalation) to the notified polymer during application of finished paints by brush, roller or spray. Exposure should be minimised through the recommended use of PPE (as described on the product SDS), including coveralls, gloves and goggles, as well as respiratory protection when applied by spray.

Once the paints are dried, the notified polymer will be bound within a polymer matrix and will not be available for exposure.

6.1.2. Public Exposure
The products containing the notified polymer will not be available to the general public. The finished paints will require a high level of equipment and expertise to be applied successfully and will be used exclusively by professional workers. Members of the public may come into contact with coated articles; however, once the coatings are cured, the notified polymer is expected to be bound into the inert matrix and will not be bioavailable for exposure.

6.2. Human Health Effects Assessment
The results from toxicological investigations conducted on the notified polymer are summarised in the following table. For full details of the studies, refer to Appendix B.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 > 2,000 mg/kg bw; low toxicity
Mutagenicity – bacterial reverse mutation	non mutagenic

Toxicokinetics, metabolism and distribution
No information on the toxicokinetics, metabolism and distribution of the notified polymer was provided. Based on the relatively high molecular weight (> 1,000 Da), absorption of the notified polymer across the skin or biological membranes is expected to be limited.

Acute toxicity
The notified polymer was found to have low acute oral toxicity in rats.

Irritation and sensitisation
No irritation or sensitisation studies were provided for the notified polymer.

The notified polymer contains a terminal phosphonium salt functional group, indicating that it may have potential to cause serious skin or eye irritation. However, as there is no skin or eye irritation study data submitted for the notified polymer, the polymer cannot be classified under the GHS for skin or eye corrosion/irritation.

Mutagenicity/Genotoxicity
The notified polymer was not mutagenic in a bacterial reverse mutation study.

Health hazard classification
Based on limited available information, the notified polymer cannot be recommended for classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

Reformulation
Reformulation workers may come into contact with to the notified polymer in an aqueous solution at concentration < 30%. Workers may mainly have potential for risk of skin or eye irritation effects. However, the use of engineering controls, such as enclosed/automated processes and local exhaust ventilation, and suitable PPE, is expected to minimise the exposure and hence reduce the risk.

End Use
During end-use, professional workers may come into contact with the notified polymer at up to < 0.5 % concentration. Similar to reformulation workers, these workers may mainly be at risk of irritation effects caused by the notified polymer. However, at this low final use concentration, the potential for the polymer to cause irritation effects is expected to be limited. The use of PPE is further expected to minimise the exposure and hence reduce the risk.

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

6.3.2. Public Health
Products containing the notified polymer will not be available to the public. Members of the public may come into contact with articles coated with finished paint products containing the notified polymer. However, the notified polymer in cured coatings is expected to be bound with the inert matrix and will not be bioavailable for exposure.

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

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 a pigment dispersant, and hence will not be manufactured in Australia. The paint pigment dispersant containing the notified polymer will be mixed with solvents, water and resins at sites in Australia. There may be release of the notified polymer when formulating paints, but this release is expected to be insignificant because paint formulation is likely to occur within a closed system and waste washings will be disposed of by accredited third party facilities.

Leaks and spills of dispersant, or paints containing the notified polymer are expected to be minimal, as paint manufacturing activities will occur in a closed system and the dispersant will be stored in bunded concrete warehouses. Spills will be contained on site, absorbed onto inert material and disposed of to landfill.

Empty containers of dispersant containing the notified polymer will be disposed of as trade waste in accordance with local regulations.

RELEASE OF CHEMICAL FROM USE
Paints containing the notified polymer are expected to be applied by spray (~50% of applications), roller and brush. The paints will predominantly be used at vehicle collision repair shops, in purpose built industrial and protective paint spray application facilities, and in coating large fibreglass mouldings (e.g., boats and pools). Engineering controls and operating procedures are such that significant release of the notified polymer to air, soil or water is unlikely.

The notifier has indicated that paint application equipment will be cleaned with water. Wastes containing the notified polymer generated during painting will be disposed of according to local regulations. There is not expected to be any discharge of wastes containing the notified polymer to the sewer or waterways. Therefore, release of the notified polymer to the environment is likely to be minimal.

Paints will be cured on end use products, thus likely preventing the release of notified polymer during the lifetime of the painted metal product.

RELEASE OF CHEMICAL FROM DISPOSAL
Empty containers from paint formulation are likely to be disposed of as trade waste to landfill. These containers are expected to be flushed with solvent prior to disposal, and hence are unlikely to contain much residual product.

The majority of the notified polymer is expected to share the fate of the product to which it has been applied and be disposed of to landfill or recycled at the end of its useful life.

7.1.2. Environmental Fate

No environmental fate studies were submitted for the notified polymer. However, it is unlikely that significant amounts of the notified polymer will enter the environment during paint formulation, use and disposal. Once cured, most of the notified polymer should be irreversibly bound into the inert paint matrix and in this form, is not expected to be bioavailable nor biodegradable. The notified polymer will share the same fate as the substrates to which it has been applied. The majority of notified polymer will be disposed of to landfill bound to the substrates, and is therefore not expected to be mobile in this form, or it will enter metal recycling. It will eventually degrade in landfill via biotic or abiotic processes or be thermally degraded during metal recycling to form oxides of carbon and phosphorus.

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 is dissociated in the aquatic environment under environmental conditions. The dissociated anionic polymer is expected to be practically non-toxic to fish and invertebrates. Anionic polymers are known to be moderately toxic to algae when there are acid groups on alternating carbons of the polymer backbone, however, this does not apply to the notified polymer (Boethling,& Nabholz, 1997).

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 paints for metal structures. The majority of the environmental release of the notified polymer will be by disposal of the cured paints to landfill and by thermal decomposition during metal reclamation processes. In its cured state the notified polymer is expected to be irreversibly bound into the inert paint matrix and is unlikely to leach or be bioavailable. Therefore, based on its use pattern, likely limited release to the environment, and expected low exposure of aquatic organisms the notified polymer is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Range 25 – 37 °C

Method	OECD TG 102 Melting Point/Melting Range
Remarks	Measured by Differential Scanning Calorimetry (DSC); pronounced peak at 36 °C
Test Facility	BASF (2016a)

Boiling Point 96 °C at 10 kPa

Method	Calculated from OECD TG 104 Vapour Pressure
Remarks	Normal boiling point was unable to be determined.
Test Facility	BASF (2016a)

Vapour Pressure 0.32 kPa at 20 °C

Method	OECD TG 104 Vapour Pressure EC Council Regulation No 440/2008 A.4 Vapour Pressure
Remarks	Static method
Test Facility	BASF (2016a)

Water Solubility ≥ 30 wt %) at 20 °C

Method	OECD TG 105 Water Solubility EC Council Regulation No 440/2008 A.6 Water Solubility
Remarks	Modified Flask Method – water solubility tested to its practical limits for the notified polymer
Test Facility	BASF (2016b)

Dissociation Constant $pKa_2 = 6.6 \pm 0.1$ at 20 °C

Method	OECD TG 112 Dissociation Constants in Water
Remarks	Titration method was used. Only one of the two dissociation constants was measured. However, the other dissociation constant is not expected to be environmentally relevant ($pKa < 4$).
Test Facility	BASF (2016a)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method EC Council Regulation No 440/2008 B.1 tris Acute Oral Toxicity – Acute Toxic Class Method
Species/Strain	Rat/Crl: WI Wistar
Vehicle	Corn oil
Remarks - Method	GLP Certificate No significant protocol deviations

RESULTS

Group	*Number and Sex of Animals*	*Dose (mg/kg bw)*	*Mortality*
1	3F	2,000	0/3
2	3F	2,000	0/3

LD50	> 2,000 mg/kg bw
Signs of Toxicity	No signs of toxicity were noted.
Effects in Organs	No abnormalities were noted at necropsy.
Remarks - Results	All but two animals showed expected gains in bodyweight over the study period. Two females from the second test group showed only a slight increase in bodyweight which was not considered by the study authors to be treatment-related.

CONCLUSION	The notified polymer is of low toxicity via the oral route.
TEST FACILITY	Bioassay (2016)

B.2. Genotoxicity – bacteria

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 471 Bacterial Reverse Mutation Test EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria Plate incorporation and Pre-incubation procedures
Species/Strain	*Salmonella typhimurium*: TA1535, TA1537, TA98, TA100 *Escherichia coli*: WP2uvrA
Metabolic Activation System	S9 mix from phenobarbitone (PB)/5,6-benzoflavone (BF) induced rat liver
Concentration Range in Main Test	a) With metabolic activation: 10 – 5,000 µg/plate b) Without metabolic activation: 3.3 – 5,000 µg/plate
Vehicle	Acetone
Remarks - Method	GLP certificate No significant protocol deviations

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in*		
	Cytotoxicity	*Precipitation*	*Genotoxic Effect*
Absent			
Test 1 (Plate incorporation)	≥ 1,000	> 5,000	Negative
Test 2 (Plate incorporation)	≥ 1,000	> 5,000	Negative
Test 3 (Pre-incubation)	≥ 333	> 5,000	Negative
Present			
Test 1 (Plate incorporation)	≥ 1,000	> 5,000	Negative
Test 2 (Plate incorporation)	Not tested	> 5,000	Negative

Test 3 (Pre-incubation)	1,000	> 5,000	Negative

Remarks - Results	The notified polymer did not increase the number of revertant colonies more than 2-fold in the presence or absence of metabolic activation in all strains tested.
CONCLUSION	The notified polymer was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	BASF (2016c)

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BASF (2016b) Water Solubility of [notified polymer] (Study No. 16L00157, April 2016), Ludwigshafen Germany, BASF SE Kompetenzzentrum Analytik (Unpublished report submitted by the notifier)

BASF (2016c) [notified polymer] Salmonella Typhimurium/Escherichia Coli Reverse Mutation Assasy (Project No. 40M0091/16M072, November 2016), Ludwigshafen Germany, BASF SE Kompetenzzentrum Analytik (Unpublished report submitted by the notifier)

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