File No: LTD/1659

August 2013

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Nuosperse 2008

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

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:

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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/1659	Tradechem Pty Ltd	Nuosperse 2008	ND*	≤ 1 tonne per annum	Additive for coatings and plastics

*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 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).

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
REGULATORY CONTROLS
Health Surveillance

- As the notified polymer is a potential skin sensitiser, employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of sensitisation.

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:
  - Use of enclosed, automated processes, where possible
  - Local exhaust ventilation if aerosols are generated.

- 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:
  - Avoid contact with eyes and skin
  - Avoid inhalation
  - Clean up any spills or soiled personal protective equipment promptly

- 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:
  - impervious gloves
  - goggles
  - protective clothing
  - respiratory protection if inhalation exposure may occur

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 for the 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

- 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 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 importation volume exceeds one tonne per annum notified chemical;
- the notified polymer is used as an additive for coatings and plastics at > 1% concentration;
- additional information becomes available on the irritation or sensitisation potential of the notified polymer.

or

(2) Under Section 64(2) of the Act; if
- the function or use of the polymer has changed from an additive for coatings and plastics, or is likely to change 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)
Tradechem Pty Ltd (ABN: 50 052 234 438)
14 Mount Street
HUNTERS HILL NSW 2110

NOTIFICATION CATEGORY
Limited-small volume: Synthetic polymer with Mn < 1000 Da (1 tonne or less per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: chemical name, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, polymer constituents, residual monomers and identity of manufacturer.

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

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Nuosperse 2008

MOLECULAR WEIGHT
> 500 Da

ANALYTICAL DATA
Reference IR spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 98%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS Below classification cut-off levels.

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: Liquid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	12 – 15 °C	(M)SDS
Boiling Point	> 250 °C at 101.3 kPa	(M)SDS
Density	1,042 kg/m^3	(M)SDS
Viscosity	745 cSt at 40 °C	(M)SDS
Vapour Pressure	Not determined	Expected to be low due to the polymer being an ionic salt with a molecular

		weight > 500 Da.
Water Solubility	Not determined	The notified polymer is expected to be at least water dispersible based on its hydrophilic functionalities, data in the MSDS and its use pattern in aqueous products.
Hydrolysis as a Function of pH	Not determined	The notified polymer contains functional groups that are expected to very slowly hydrolyse under ambient environmental conditions
Partition Coefficient (n-octanol/water)	Not determined	The notified polymer is surface active and expected to partition to phase boundaries
Adsorption/Desorption	Not determined	The notified polymer is expected to partition from water to surfaces in the environment based on its surface activity
Dissociation Constant	Not determined	The notified polymer will be ionised in the environmental pH range (4 – 9)
Flash Point	> 100 °C	(M)SDS
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.
Oxidising Properties	Not expected to be oxidising	Contains no functional groups that would infer oxidising properties

DISCUSSION OF PROPERTIES

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 for the 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 in pigment at a concentration of < 1%.

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

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

PORT OF ENTRY

Sydney, Melbourne, Brisbane, Adelaide and Perth.

TRANSPORTATION AND PACKAGING

The dry powder pigments containing the notified polymer will be imported in 15 kg bags and transported by road to the reformulation sites. Bags may also be held in storage at DG approved warehouses.

USE

Additive in pigment preparations that will be used in coatings (paints) and plastics for industrial and consumer applications.

OPERATION DESCRIPTION

Reformulation

At the reformulation sites, the pigment powder containing the notified polymer at < 1% will be added to paints or tint concentrates. Similar processes are expected to be used when the pigment containing the notified polymer is added to plastics. A second reformulation step may occur where the tint concentrate is added to paints or plastics.

End use

Paints containing the notified polymer at < 1% will be applied by workers and consumers through a variety of methods, including spray.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

EXPOSURE DETAILS

Reformulation

During weighing, transfer and mixing in reformulation processes for coatings or plastics, workers may have dermal, occupational or inhalation exposure to the notified polymer at < 1%. The potential for exposure is likely to be highest during the weighing of powder pigment. At this stage of processing, workers are expected to wear personal protective equipment such as dust masks, coveralls, gloves and eye protection, in order to reduce exposure.

Plastic moulding

The potential for worker exposure during plastic moulding is likely to be low, as the notified polymer will already be incorporated in the plastic mixture.

End use

Workers applying coatings containing the notified polymer at < 1% may have incidental dermal or ocular exposure to the coatings. Inhalation exposure may also occur if the coatings are applied by spray. The exposure would be limited by the very low concentration of the polymer in the coatings.

Once the coatings are cured, the notified polymer is expected to be trapped within the coating matrix, and not be bioavailable. Similarly, the notified polymer within finished plastic articles is not expected to be bioavailable.

6.1.2. Public Exposure

The public may have incidental exposure to the notified polymer at < 1% (likely to be < 0.5%) while applying coatings. The exposure would be limited by the very low concentration of the polymer in the coatings and their infrequent application.

Incidental contact of the public to cured coatings or plastic articles containing the notified polymer may occur, however the polymer is expected to be trapped within the coating matrix, and not to be bioavailable.

6.2. Human Health Effects Assessment

No toxicity data were submitted for the notified polymer.

Toxicokinetics, metabolism and distribution.

The notified polymer is ionised with the combined molecular weight of the two components being > 1,000 Da and contains negligible amounts of molecular weight species < 500 Da. These factors are likely to limit dermal absorption; however, the surface active nature of the notified polymer may facilitate its dermal absorption or that of other substances.

Irritation and sensitisation.

The notified polymer contains a structural alert for corrosion and sensitisation (Barratt et al. 1994; Hulzebos et al. 2005; Tsakovska et al. 2007). Given the notified polymer has a low percentage of low molecular weight species, any irritant and sensitisation effects are expected to be limited, and it is not expected to be corrosive,

based on its molecular weight. The manufacturer has classified the polymer as a skin and eye irritant based on 'a similar product'; however, as no information on this similar product was provided, its suitability as an analogue cannot be confirmed.

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).

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
While the potential for irritation and sensitisation effects associated with exposure to the notified polymer cannot be ruled out, this is expected to be limited given the low percentage of low molecular weight species and the low concentration to which workers will be exposed (less than 1%). The risk would be further reduced by the appropriate use of engineering controls, safe work practices and PPE to minimise exposure.

Workers may come into contact with cured coatings or plastic articles containing the notified polymer; however, the polymer is expected to be trapped within the coating matrix, and not be bioavailable.

Overall, given the proposed concentration of the notified polymer in products and with control measures in place to minimise exposure, the risk to workers from use of the notified polymer is not considered unreasonable.

6.3.2. Public Health
The public may encounter incidental exposure to the notified polymer at up to 1% (likely up to 0.5%) concentration during application of coatings containing it. The risk to the public from the notified polymer would be less than that for workers, since the frequency and magnitude of exposure is expected to be significantly reduced. Therefore, given the proposed concentration of the notified polymer in products, and the incidental nature of exposure, the risk to the public from use of the notified polymer is not considered unreasonable.

The public may also come into contact with surfaces coated with paints containing the notified polymer; however, once the paint is cured and dried the notified polymer will be trapped within a polymer matrix and will not be bioavailable. Similarly the polymer in plastic articles is not expected to be bioavailable.

Therefore, the risk to the public associated with the use of the notified polymer at < 1% concentration in paint products 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 be imported into Australia as a component of pigment preparations. The pigment preparations will be reformulated locally into paints and plastic formulations. Waste notified polymer (up to 5 kg per year) produced during reformulation processes is expected to be contained by plant waste treatment processes and subsequently disposed of by a licensed waste treatment company. Effluent from the waste treatment plants may contain small amount of the notified polymer, which is expected to be ultimately released to sewers.

RELEASE OF CHEMICAL FROM USE
During its use in paints and coatings (90%), it is estimated by the notifier that up to 5 kg per year of the notified polymer may be released to the environment from splashes and cleaning of residues on brushes and rollers. Given that the paint products containing the notified polymer are likely to be used by Do-It-Yourself (DIY) customers, there is the potential for notified polymer wastes to be discarded into sewers. The conservative release for water-based paints is estimated to be 5% (50 kg/year) due to the DIY use.

The notified polymer will be also used in plastic formulations (10%). The formulation activities are expected to take place at the industrial settings with proper engineering controls to limit the release of the notified polymer to the environment. Therefore, significant release of the notified polymer is not expected due to these activities.

RELEASE OF CHEMICAL FROM DISPOSAL

The majority of the notified polymer is expected to be discarded to landfill along with coated articles to which the paint products containing the notified polymer have been applied. Notified polymer applied in plastic formulations is expected to share the fate of the plastic articles in which it is encapsulated and be disposed of to landfill at the end of the useful life of the plastic articles. Small amounts of the residual notified polymer contained in empty containers are expected to be either washed to sewers or disposed of to landfill.

7.1.2. Environmental Fate

No environmental fate data were submitted. The notified polymer has a potential to degrade under environmental conditions as it contains a high percentage of degradable components.

The majority of the notified polymer is expected to be cured after application and be trapped within the coating matrix or within finished plastic articles. In this form, the notified polymer is immobile and is not expected to be bioavailable or bioaccumulative. Uncured waste notified polymer discarded to landfill is not expected to be mobile based on its surface activity and ionic character. When introduced into sewers, notified polymer is expected to be efficiently removed from the aquatic compartment at wastewater treatment plants (STPs) by sorption in sludge (Boethling and Nabholz, 1997) or degradation. The sludge containing the notified polymer is expected to be sent to landfill or applied to agricultural soils. Small amounts of the notified polymer remaining in the effluent from STPs may be released to surface waters. Notified polymer that is released to surface waters is expected to partition to suspended solids and disperse.

The notified polymer has surface activity and therefore, is not expected to bioaccumulate. In landfill, soil and water, the notified polymer is expected to degrade through biotic and abiotic processes to water, oxides of carbon and nitrogen, and inorganic salts.

7.1.3. Predicted Environmental Concentration (PEC)

Notified polymer is expected to be released to sewers during its use as paint by DIY users. Therefore, under a worst case scenario, it is assumed that 100% of the total import volume of the notified polymer will be used as component in paint products and 5% of the entire volume will be discharged into sewers over 365 days per year. Assuming no removal of the notified polymer in the sewage treatment processes, the resultant Predicted Environmental Concentration (PEC) in sewage effluent on a nationwide basis is estimated as follows:

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	1,000	kg/year
Proportion expected to be released to sewer	5 %	
Annual quantity of chemical released to sewer	50	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	0.14	kg/day
Water use	200	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	0%	
Daily effluent production:	4,523	ML
Dilution Factor - River	1	
Dilution Factor - Ocean	10	
PEC - River:	0.03	µg/L
PEC - Ocean:	0.003	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m^2/year (10 ML/ha/year). The notified polymer in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m^3). Using these assumptions, irrigation with a concentration of 0.03 µg/L may potentially result in a soil concentration of approximately 0.201 µg/kg. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated irrigation, the concentration of notified polymer in the applied soil in 5 and 10 years may be approximately 1.010 µg/kg and

2.01 µg/kg, respectively.

7.2. Environmental Effects Assessment

No ecotoxicity data were submitted for the notified polymer. The notified polymer is a surfactant containing a cationic polymeric component.

Cationic polymers are toxic to a wide array of species in the environment. Ecotoxicological endpoints for the cationic component of the notified polymer were calculated based on Structure Activity Relationships (SARs) equations assuming a worst case cationic charge density for the polymer (Boethling and Nabholz, 1997). The toxicity endpoints were predicted based on endpoints derived from tests conducted in standard aquatic toxicity testing media. The results are summarised in the table below.

Endpoint	*Results*	*Assessment Conclusion*
Acute		
Fish Toxicity	LC50 (96 h) = 3.2 mg/L	Predicted to be toxic to fish
Daphnia Toxicity	LC50 (48 h) = 11.2 mg/L	Predicted to be harmful to aquatic invertebrates
Algal Toxicity	EC50 (96 h) = 1.3 mg/L	Predicted to be toxic to algae
Chronic		
Fish Toxicity	ChV* = 0.18 mg/L	Potentially toxic to fish with long lasting effects
Daphnia Toxicity	ChV* = 0.80 mg/L	Potentially toxic to aquatic invertebrates with long lasting effects
Algal Toxicity	ChV* = 0.36 mg/L	Potentially toxic to algae with long lasting effects

* ChV = Chronic value = $(NOEC \times LOEC)^{1/2}$

The SAR estimation endpoints indicate that the cationic component of the notified polymer is potentially toxic to aquatic organisms. However, the actual toxicity of this component to aquatic life may be overestimated by SAR estimation used here as surface waters tend to have higher total organic content (TOC) and dissolved organic content (DOC) than what is used in standard aquatic toxicity testing media. Furthermore, these endpoints are not entirely representative of the ecotoxicity of the whole notified polymer, which may be further reduced by dilution. Classification should be based on actual toxicity endpoints for the whole polymer and, therefore, the notified polymer cannot be formally classified under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009).

7.2.1. Predicted No-Effect Concentration

The Predicted No-Effect Concentration (PNEC) has been calculated from the most conservative endpoint (fish, ChV) for the cationic component of the notified polymer and an assessment factor of 50. A conservative assessment factor is appropriate, in this case, as although chronic endpoints ($ChV = (LOEC \times NOEC)^{½}$) for three trophic levels are available, these chronic endpoints are greater than no-observed effect concentrations (NOECs).

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
NOEC (fish).	0.18	mg/L
Assessment Factor	50	
PNEC:	3.6	µg/L

7.3. Environmental Risk Assessment

Risk Assessment	***PEC µg/L***	***PNEC µg/L***	***Q***
Q - River:	0.03	3.6	0.008
Q - Ocean:	0.003	3.6	0.001

The worst case risk quotients (Q = PEC/PNEC) have been calculated to be < 1 for both the riverine and marine compartments, indicating significant ecotoxicological concentrations will not be reached from the use of the notified polymer at the maximum import volume. The notified polymer is not expected to bioaccumulate and has potential to degrade under environmental conditions. Based on the calculated risk quotients and the assessed use pattern, the notified polymer is not expected to pose an unreasonable risk to the aquatic environment from the proposed application at the maximum introduction volume of 1000 kg per annum.

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