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January 2011

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Maphos 24T

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:

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Director
NICNAS

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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
Standard: Synthetic Polymer with Mn < 1000 Da (more than 1 tonne 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, polymer constituents, residual monomers/impurities, use details and import volume

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: melting point, boiling point, density, vapour pressure, water solubility, hydrolysis as a function of pH, partition coefficient, adsorption/desorption, dissociation constant, particle size, flash point, flammability limits, autoignition temperature, explosive properties, toxicological data and ecotoxicological data.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Maphos 24T

OTHER NAME(S)
Phosphate ester of C10 ethoxylated alcohol
Phosphate ester of C10 alcohol ethoxylate

MOLECULAR WEIGHT
< 500 Da

ANALYTICAL DATA
Reference GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 70%

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
No degradation, decomposition or depolymerisation of the notified polymer is expected to occur under normal conditions of use.

No losses by volatilisation, exudation or leaching are expected from the notified polymer.

DEGRADATION PRODUCTS
Thermal decomposition may release toxic fumes containing products of combustion such as carbon monoxide and carbon dioxide together with traces of oxides of phosphorus.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: a clear colourless liquid

Property	Value	Data Source/Justification
Boiling Point	> 100°C at 101.3 kPa	MSDS
Density	1020 kg/m^3 at 20°C	MSDS
Vapour Pressure	8.08 × 10^{-9} Pa	Estimated by HENRYWIN (v.3.20). The notified polymer is considered to be very slightly volatile based on both the estimated data and the structure.
Water Solubility	Not determined	Based on structural considerations, the notified polymer is expected to be dispersible in water. It is also expected to be soluble in water under basic conditions.
Hydrolysis as a Function of pH	Not determined	The notified polymer has no functional groups that are likely to hydrolyse within the environmental pH range of 4 – 9.
Partition Coefficient (n-octanol/water)	Not determined	LogP_{OW} is predicted to be 3.03 by KOWWIN v1.67. It is difficult to determine the logP_{OW} of the notified polymer due to its surface active characteristics. Despite the presence of hydrophobic chain segments, the notified polymer is not expected to have a high logP_{OW} due to the presence of a significant fraction of hydrophilic and water soluble moieties in the molecule.
Adsorption/Desorption	Not determined	The notified polymer contains a significant amount of hydrophilic moieties. Therefore, it is conservatively expected not to be strongly adsorbed to soil or sediments from water.
Dissociation Constant	Not determined	The notified polymer is expected to be ionised with anionic functional groups in the environmental pH range of 4 – 9.
Flash Point	> 100°C	MSDS
Autoignition Temperature	> 200°C	Estimated by the notifier
Explosive Properties	Not determined	The notified polymer contains no functional groups that would imply explosive properties.

DISCUSSION OF PROPERTIES

Reactivity

Stable under normal conditions.

Dangerous Goods classification

Based on the submitted physical-chemical data in the above table the notified polymer is not classified according to the Australian Dangerous Goods Code (NTC, 2007). However the polymer is considered to be Class 8 (Corrosive) based on the results of an *in vitro* irritation study.

5. INTRODUCTION AND USE INFORMATION

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

The notified polymer will be imported into Australia by sea at 100% concentration.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	20-50	20-60	20-70	20-80	20-100

PORT OF ENTRY
Melbourne, Sydney and Brisbane

IDENTITY OF RECIPIENTS
BASF Australia Ltd

TRANSPORTATION AND PACKAGING
The notified polymer will be imported in 20 or 200 L plastic (PE) open head drums or 1000 L Intermediate Bulk Containers (Shutz Tank). Following reformulation processes, the latex polymer product containing the notified polymer will be packaged into 1000 L Intermediate Bulk Containers (Shutz Tank) and bulk tankers and delivered to paint manufacturers. The paint manufacturers may sell their product in 200 mL, 500 mL, 1 L, 10 L, 20 L and 200 L containers.

USE
The notified polymer will be used as a wetting agent (< 0.5%) in the production of water based polymers in the paint industry.

OPERATION DESCRIPTION
The notified polymer will be transferred/pumped into blending vessels and mixed with other materials automatically and in enclosed tanks which are situated in a well ventilated area to produce the water based latex polymer (containing approximately 0.5% notified polymer). At the end of mixing, laboratory technicians will perform testing and adjustment to the formulation specifications if necessary.

The water based latex polymer will be delivered to paint formulators to blend with other materials to manufacture paint containing < 0.5% notified polymer. The polymer is neutralised during this process. The paint will be sold to a variety of end users, both industrial and domestic, and these paints will be applied undiluted by end users using brush, roller and spray equipment.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

Category of Worker	*Number*	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and Warehouse workers	2-3	1.5	2-3
Store persons	1	0.5-10 h/week	240
Blenders	1	0.5-10 h/week	240
Laboratory technicians	2	0.5-10 h/week	240
Drum recyclers	1	10 min/week	240
Paint manufacturers	10	8	240
End users (painters)	> 100	8	365

EXPOSURE DETAILS
During transport and storage, workers are unlikely to be exposed to the notified polymer except when packaging is accidentally breached.

Manufacturing staff and laboratory technicians at the latex manufacturing site may be potentially exposed to the notified polymer at 100% when blending, sampling and testing. Dermal and ocular exposure to splashes and spillages can occur during weighing, mixing, packing and equipment cleaning. Workers will wear appropriate personal protective equipment (PPE) and engineering controls to further minimise the exposure are

in place, such as automated processes, enclosed systems and local exhaust ventilation where natural ventilation is considered inadequate.

The paint formulators using the water based latex to manufacture paint may be exposed to the notified polymer at approximately 0.5%. However, they are expected to wear appropriate PPE during the formulation process.

The end users (professional painters) of the formulated paint containing the neutralised version of the notified polymer (< 0.5%) are expected to wear only limited PPE (overalls) when paint is applied by brush, roller or spray. Inhalation exposure may occur during spray painting and additional controls are expected to be used in this method of application.

The workers may also have contact with dried paint films containing the notified polymer. However in this case the polymer is trapped within the film and is not bioavailable.

6.1.2. Public exposure

The potential for exposure of the public to the notified polymer during normal industrial storage, handling and transportation is negligible, except in the case of an accident.

However, there will be widespread exposure of DIY painters to paints that contain the neutralised version of the notified polymer at < 0.5%. Incidental dermal or ocular contact may occur during application by brush or roller. It is not expected that the public would apply the paints by spray methods.

The public may also have contact with dried paint films containing the notified polymer. However in this case the polymer is trapped within the film and is not bioavailable.

6.2. Human health effects assessment

No toxicological information was provided on the notified polymer, however, analogue data are provided. The analogues of the notified polymer used for toxicological testing are alkyl alcohol ethoxylate phosphate derivatives and contain similar functional groups to the notified polymer, though with a varying side chain and degree of ethoxylation.

The results from toxicological investigations conducted on analogue chemical 1 are summarised in the table below. Details of these studies can be found in Appendix B.

Endpoint	*Test substance*	*Result*
Rat, acute oral toxicity	Analogue 1	LD50 > 2000 mg/kg bw; low toxicity
EpiDerm corrosivity-test *in vitro* (summary)	Analogue 1	corrosive
Mutagenicity – bacterial reverse mutation	Analogue 1	non mutagenic

No information was available on the toxicokinetics of the notified polymer or its analogues. The notified polymer may be absorbed dermally following skin contact due to its surfactant properties and relatively low molecular weight.

Similar chemicals to the notified polymer are proposed to initially be metabolisd to generate the corresponding alkyl alcohol and the polyoxyalkylene phosphate glycol which is then acted upon by phosphatases to generate phosphate and a dephosphorylated polyalkoxylate glycol. The dephosphorylated polyalkoxylate glycols should be conjugated and excreted or hydrolysd and oxidisd to various degraded metabolites before being conjugated and excreted. The alkyl alcohols would be oxidisd and degraded by fatty acid oxidation metabolic pathways (US EPA 2009).

Acute toxicity

The acute oral toxicity of an analogue of the notified polymer was determined to be of low toxicity. By analogy, the notified polymer is also considered to be of low acute oral toxicity.

Acute dermal and inhalation toxicity studies were not available for the notified polymer or analogue chemicals.

Irritation
A summary report only of an EpiDerm Corrosivity-Test *in vitro* for skin irritation was provided for analogue chemical 1. The test substance showed corrosive effects on the tissues similar to the positive control after 1 hour exposure. On the basis of this information, the notified polymer is considered to be corrosive.

No eye irritation study was provided. Based on the *in vitro* skin study, the notified polymer is considered to be corrosive.

Sensitisation
No skin sensitisation study was provided for the notified polymer or analogue chemicals. However, similar surfactants may be skin sensitisers (US EPA 2009).

Repeated dose toxicity
No repeat dose toxicity study was submitted for the notified polymer.

A 13-week repeated dose oral feeding study in rats using a mixture of analogue chemicals 2 and 3 (ratio unknown) in the diet at concentrations of 0.5, 1.0 and 2.0% (254, 530 and 1080 mg/kg bw/day) showed no adverse effects in haematopoietic function or clinical parameters. Growth rate was depressed in high dose animals, however absolute and relative increases in organ weight had no supportive histopathological abnormalities. The NOEL for the mixture used in the diet was 530 mg/kg bw/day (Food and Drug Research Laboratories 1967).

Based on the results of a 90-day feeding study, a NOAEL of 125 mg/kg/day in rats was derived for analogue chemical 2 (Reference 2004).

Analogues 4 and 5 were tested in combined repeated dose toxicity studies with reproductive/developmental toxicity test (OECD TG422). Parental NOAEL for each of the two analogues was 200 mg/kg bw/day in these studies. The reproductive/developmental NOAEL for analogue 4 was 800 mg/kg bw/day, the highest dose tested and was 200 mg/kg bw day for analogue 5, based on developmental effects at 800 mg/kg bw/day.

Based on the information available on analogues, a definite NOAEL cannot be established for the notified polymer. The lowest NOAEL reported for analogues was 125 mg/kg bw/day.

Mutagenicity
Analogue chemical 1 was non-mutagenic in bacterial reverse mutation assays. As no other genotoxicity data on the notified polymer or acceptable analogue chemicals were provided, the genotoxicity potential of the notified polymer cannot be determined.

Carcinogenicity
US EPA (2009) noted that there is no evidence that surfactants similar to the notified polymer are carcinogenic.

Health hazard classification
Based on the results of the EpiDerm Corrosivity-Test *in vitro* for the analogue polymer, the notified polymer is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phrase:

C; R34 Causes burns

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

An *in vitro* study on an analogue of the notified polymer indicated that the notified polymer is likely to be corrosive to skin.

Dermal, ocular and inhalation (aerosol) exposure of workers to the notified polymer at 100% may occur during handling of the notified polymer, particularly during charging of the mixer in latex manufacture. At such concentrations, workers involved in these operations could potentially be at risk of corrosive effects to the skin and eyes. However, the use of engineering controls, safe work practices and PPE is expected to minimise exposure and reduce the risk of such effects.

Incidental dermal and ocular exposure of professional painters to the notified polymer at concentrations up to 0.5% may occur, mainly during application of the coating products containing the notified polymer. The concentration used in end-use products (< 0.5%) is very low and therefore irritation effects are not expected when using end-use products. The polymer is neutralised in end-use products, and this may further reduce the potential for irritation. The use of PPE (overalls) by workers during application is also expected to minimise exposure.

The potential for skin sensitisation cannot be ruled out, but would be limited by the low concentration of the notified polymer in paint products.

When paint is applied by spray, a higher potential for exposure exists, including inhalation exposure. No inhalation toxicity data are provided for the notified polymer. Controls such as spray booth and/or PPE (including respirators) would be needed to reduce exposure during spray application.

While a NOAEL for the notified polymer has not been identified from analogue data, the risk of systemic effects from repeated exposure is considered to be low because of the very low concentration of the notified polymer in the paint.

Overall, the occupational health and safety risk associated with the notified polymer is not considered to be unacceptable when appropriate controls are used during formulation of paints and due to very low concentration of the notified polymer in end-use products.

6.3.2. Public health

The public may come into contact with the notified polymer in end-use products, however exposure to the paint is likely to be low and the notified polymer is present at a very low concentration (< 0.5%) or in a cured form where the notified polymer is not bioavailable. It is not expected that the public would apply the paints by spray methods. Thus the risks of adverse health effects are not expected.

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 raw material for further reformulation for use in paint products. At the manufacturing site for preparation of water based latex polymers, the main base of a paint formulation, the transferring/pumping of the notified polymer into blending vessels and the packing of the mixture into the final industrial products will be automated. It is expected that < 0.5% of the notified polymer would be discharged to effluent through the washout procedures of the transfer hose and dip pipes. It is estimated that the maximum residue in the empty import containers will amount to approximately 0.5% and will be discharged to effluent via registered drum recyclers. The water based latex polymer containing the notified polymer will be further blended with other ingredients to manufacture final paint products. It is expected that < 0.5% of waste is occurred from residues in blending equipment and containers and is expected to be either reused in the following blending process or for the worst case to be released to sewer system. If any incidental spillage or wastes occur during the above normal operating procedures, it will be contained and soaked up with absorbent material before being transported off-site to an approved industrial facility for disposal to landfill.

RELEASE OF CHEMICAL FROM USE

The paint products will be used undiluted by both industrial and domestic end users (DIYs). The paints containing the notified polymer will be applied by spray, roller and brush. Residual paint containing the notified polymer may be released to the environment from disposal of excess paint or from cleaning of equipment. Residue from professional spray painting applications results in losses of up to 30% overspray which is captured in filters and disposed to landfill. Professional painters are expected to brush out excess paint onto newspaper or rags etc before rinsing brushes and rollers and capturing the rinse in a container. The waste paint/adhesive in the container is expected to be allowed to cure before disposal as solid waste (2%). The excess paint in containers is expected to be stored for later use or disposed of to authority landfill.

DIY painters may follow the same practice as professional painters with rollers and brushes, however, it has been estimated that between 10 and 15% of paint remains unused by householders at the end of a job. Much of this may be used for subsequent jobs but it is estimated that residue in used paint containers will account for approximately 5% of the paint containing the notified polymer which is expected to be disposed of to landfill. Incorrectly disposed paints (containing the notified polymer) from waste and washing of equipment may be released to sewer, drains or ground (1%).

The fate of the paint cured on the substrate will be shared with the fate of the coated article, which ultimately is expected to be the majority to landfill and the remainder, if applicable, will be thermally decomposed during reclamation of metals.

RELEASE OF CHEMICAL FROM DISPOSAL

It is expected that up to 2.5% of waste of the notified polymer may be generated from cleaning of reformulation and DIYs painting equipment and reformulation stage containers and be released to sewage. Most of the loss from final use of paint products containing the notified polymer is expected to be collected for disposal to landfill.

7.1.2 Environmental fate

A ready biodegradability study on an acceptable analogue indicates that the analogue chemical, and by inference the notified polymer, is not readily biodegradable. However, they are expected to have potential to biodegrade moderately rapidly. Bioaccumulation of the notified polymer in organisms is not expected due to the expected water solubility and hydrophilicity of the notified polymer. For the details of the environmental fate studies refer to Appendix C.

Due to the expected dispersibility and solubility of the notified polymer in water, there is a potential of leaching in landfill. However, most of the notified polymer is expected to be disposed of to landfill after being dried or cured into solids and trapped in the paint matrix, in which case leaching is unlikely to occur. In landfill, the notified polymer is expected to undergo biotic or abiotic degradation, forming water and oxides of carbon and phosphorus.

7.1.3 Predicted Environmental Concentration (PEC)

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	100,000	kg/year
Proportion expected to be released to sewer	2.5%	
Annual quantity of chemical released to sewer	2,500	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	6.85	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:	1.62	µg/L
PEC - Ocean:	0.16	µg/L

The PEC has been calculated based on an assumption of 2.5% release of the notified polymer to sewage and no removal of the polymer from STPs for the most conservative consideration.

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 1.618 µg/L may potentially result in a soil concentration of approximately 0.01079 mg/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 0.05395 mg/kg and 0.1079 mg/kg, respectively. However, this is a worst case scenario and it is expected some of the notified polymer will be adsorbed to sludge given its surface active characteristics.

7.2. Environmental effects assessment

The results from ecotoxicological investigations conducted on the analogue chemical of the notified polymer are summarised in the table below. Details of these studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Daphnia Toxicity	EC50 = 15.4 mg/L	Harmful to *Daphnia magna*
Inhibition of Bacterial Respiration	30 min. IC50 > 1000 mg/L	Not inhibitory to microbe respiration

Under the Globally Harmonised System of Classification and Labeling of Chemicals (United Nations, 2009) the notified polymer, based on its similarity to the analogue chemical, is not inhibitory to microbe respiration, but is harmful to aquatic invertebrates. The notified polymer, based on its similarity to the analogue chemical, was predicted to be not readily biodegradable, and based on its harmful toxicity to aquatic invertebrates it was classified as harmful to aquatic life with long lasting effects.

7.2.1 Predicted No-Effect Concentration

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (Invertebrates).	15.40	mg/L
Assessment Factor	1,000	
PNEC:	15.40	µg/L

The PNEC for the notified polymer from the proposed use pattern has been calculated based on the EC50 of daphnids for the analogue chemical using a safety factor of 1000 due to the limited number of available endpoints.

7.3. Environmental risk assessment

Risk Assessment	*PEC µg/L*	*PNEC µg/L*	*Q*
Q - River:	1.62	15.4	0.105
Q - Ocean:	0.16	15.4	0.011

The Risk Quotient (Q = PEC/PNEC) has been calculated to be < 1. However, the Q value is expected to be lower since it is expected that some of the notified polymer will adsorb to sludge given its surface active characteristics. Therefore, no unacceptable risk is expected from the proposed use of the notified polymer.

The notified polymer is not expected to pose an unacceptable risk to the aquatic environment from the reported use pattern.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the data provided the notified polymer is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)]. The following risk phrase applies to the notified polymer:

C; R34 Causes burns

and

As a comparison only, the classification of the notified polymer using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2009) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

	Hazard category	*Hazard statement*
Corrosive	1C	Causes severe skin burns and eye damage
Aquatic Environment	Acute Category 3 Chronic Category 3	Harmful to aquatic life Harmful to aquatic life with long lasting effects

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

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

Environmental risk assessment
On the basis of the PEC/PNEC ratio and the reported use pattern, the notified polymer is not expected to pose a risk to the environment.

Recommendations

REGULATORY CONTROLS
Hazard Classification and Labelling

- Safe Work Australia should consider the following health hazard classification for the notified polymer:
  - C; R34 Causes burns

- Use the following risk phrases for products/mixtures containing the notified polymer:
  - ≥10%: R34
  - ≥ 5%; < 10%: R36/38

- The imported product containing the notified polymer should be classified as Class 8 (Corrosive) under the Australian Dangerous Goods Code (NTC, 2007).

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer as introduced:
  - Local exhaust ventilation during reformulation operations
  - Enclosed mixing vessels for reformulation

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer as introduced and when using the end-use products:
  - Avoid contact with skin and eyes
  - Avoid inhaling aerosols or spray mists
  - Ready access to emergency shower and eye wash facilities when handling 100% notified polymer

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced:
  - Impervious gloves and overalls
  - Eye protection e.g. safety glasses/face mask
  - Respiratory protection if aerosols or mists are generated

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer in end-use products (< 0.5% concentration):
  - Coveralls
  - Eye and respiratory protection during spray application

  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.

Public Health

- Products marketed to the public containing the notified polymer should not recommend application by spraying.

Disposal

- The notified polymer should be disposed of to landfill.

Emergency procedures

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

Regulatory Obligations

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

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

(1) Under Section 64(1) of the Act; if
  - the polymer is to be introduced at concentration > 0.5% in end-use products. In the case that secondary notification is required, provision of further toxicological data may be required.

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the polymer has changed from a component used in the production of water based polymers in the paint industry < 0.5%, or is likely to change significantly;
  - the amount of polymer being introduced has increased from 100 tonne per year, or is likely to increase, significantly;
  - the polymer has begun to be manufactured in Australia;
  - additional information has become available to the person as to an adverse effect of the polymer on occupational health and safety, public health, or the environment.

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

Material Safety Data Sheet

The MSDS of the product containing the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE: Analogue chemical 1

METHOD: OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
EC Directive 96/54/EC B.1tris Acute Oral Toxicity – Acute Toxic Class Method.

Species/Strain: Rat/Wistar
Vehicle: Doubly distilled water
Remarks - Method: No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3 M	2000	0
2	3 F	2000	0

LD50: > 2000 mg/kg bw
Signs of Toxicity: Signs of toxicity comprised impaired general state, dyspnoea, staggering, salivation and piloerection and were observed until 5 hours after administration for male and female animals.
Effects in Organs: No macroscopic pathologic abnormalities were noted in animals at termination of the study.
Remarks - Results: The mean body weights of the dose group increased throughout the study period.

CONCLUSION: The test substance is of low toxicity via the oral route.

TEST FACILITY: BASF (2001a)

B.2. Irritation – skin irritancy potential by *in vitro* EpiDerm corrosivity test

TEST SUBSTANCE: Analogue chemical 1

METHOD: Internal method (summary only supplied)
Remarks – Method: A negative control and positive control (identities unknown) were performed for the 3 min and 4 hour exposure times.

RESULTS

Viability (%)	3 min	1 hour
Negative control	100	100
Test substance	78	9
Positive control	15	11

CONCLUSION: The test substance is corrosive to the skin.

TEST FACILITY: BASF (2001b)

B.3. Genotoxicity – bacteria

TEST SUBSTANCE: Analogue chemical 1

METHOD: OECD TG 471 Bacterial Reverse Mutation Test.
EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test

	using Bacteria. Plate incorporation procedure (Tests 1 and 2)/Pre incubation procedure (Test 3)
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA
Metabolic Activation System	Aroclor-induced rat liver S-9 mix
Concentration Range in Main Test	Test 1 with and without metabolic activation: 0, 20, 100, 500, 2500 and 5000 µg/plate Test 2 with and without metabolic activation: 0, 4, 20, 100, 500 and 1000 µg/plate Test 3 with and without metabolic activation: Salmonella strains: 0, 0.8, 4, 20, 100 and 500 µg/plate E. Coli: 0, 4, 20, 100, 500 and 2500 µg/plate
Vehicle	DMSO
Remarks - Method	No significant protocol deviations. No preliminary test was carried out.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*		
	Cytotoxicity in Main Test	*Precipitation*	*Genotoxic Effect*
Absent			
Test 1	> 500	> 5000	negative
Test 2	> 500	> 1000	negative
Test 3	> 20	> 500	negative
Present			
Test 1	> 100	> 5000	negative
Test 2	> 500	> 1000	negative
Test 3	> 100	> 500	negative

Remarks - Results	A bacteriotoxic effect (reduced his^- background growth, decrease in the number his^+ revetants, reduction in the titer) was observed in the standard plate test depending on the strain and test conditions from about 500 – 1,000 µg/plate onward. Using *E. coli* bacteriotoxicity was found only with S-9 mix at doses ≥ 2,500 µg/plate. In the preincubation assay bacteriotoxicity was observed depending on the strain and test conditions at doses ≥ 100 µg/plate. No test substance precipitation was observed. There was no increase in the number of revertants in any of the tests. Results of the concurrent positive controls confirmed the sensitivity of test system.
CONCLUSION	The test substance was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	BASF (2001c)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE: Analogue chemical 1

METHOD: OECD TG 301 A Ready Biodegradability: DOC Die-Away Test

Inoculum	Activated sludge from laboratory waste water plants fed with municipal sewage (no pre-adapted inoculum used)
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	DOC (dissolved organic carbon) analysis for determination of the biodegradation degree.
Remarks - Method	The test substance was considered to be an acceptable analogue of the notified polymer. The study was conducted at 22 ± 2°C and a nominal concentration of 40 mg/L (20 mg DOC/L) for the analogue chemical. Aniline was used as a reference substance at 20 mg DOC/L in the reference and the inhibition controls. A blank control, an abiotic control and an adsorption control (for 3 days) were also performed. All the tests were conducted in duplicates except the inhibition and the reference controls.

RESULTS

Test substance		*Aniline*	
Day	*% Degradation*	*Day*	*% Degradation*
1	1	3	7
3	26	5	83
10	62	14	91
14	68	21	96
28	93	28	97

Remarks - Results: No water solubility of the test substance was available, however, it is considered to be dispersible in water as a surfactant. Therefore, it can be deemed to meet the criterion of > 100 mg/L for the TG regarding the water solubility. The test substance did not pass the 10-day window criterion (> 70% DOC) of the TG. Therefore, the analogue, and by inference the notified polymer, is not considered to be readily biodegradable. However, they are considered to have potential for moderately rapid biodegradation due to the significant degree of biodegradation detected.

CONCLUSION: The notified polymer is not readily biodegradable.

TEST FACILITY: BASF (2001d)

C.1.2. Bioaccumulation

CONCLUSION: No study has been conducted on the bioaccumulation potential of the notified polymer (and the analogue chemical). Based on the significant fraction of hydrophilic moieties, and the expected anionic functional group present in the molecule, the notified polymer is not considered to have high potential for bioaccumulation in aquatic species.

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Analogue chemical 1
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test - Static. EEC Directive 92/32/EEC C.2 Acute Toxicity for Daphnia - Static.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	2.20 – 3.20 mmol/L
Analytical Monitoring	The actual concentrations for the highest and lowest tested levels were determined at start and end of the study.
Remarks - Method	Daphids were exposed to the test substance of six test levels at 18 - 22˚C, pH 7.5 – 8.1 and oxygen content of 8.4-8.7 mg/L. A blank control was also organised. All were conducted in four replicates using 5 animals in each vessel. Immobilised numbers of daphnids were recorded after 24 and 48 hours. A reference control with potassium dichromate was performed about half a year before the study. The EC50 was determined from a dose-response graph.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
Control	< 2	20	0	0
3.13	N/A	20	0	0
6.25	N/A	20	0	1
12.5	9.8	20	2	7
25	N/A	20	7	16
50	N/A	20	11	20
100	83.5	20	20	20

EC50	15.4 (95% confidence limits of 12.5 – 18.9) mg/L at 48 hours
NOEC	3.13 mg/L at 48 hours
Remarks - Results	All the test criteria reported were met. The measurement of actual concentrations showed about 80% recovery. No decrease in the concentration was indicated throughout the test period. The EC50 of 15.4 mg/L indicates the analogue chemical, and by inference the notified polymer, is harmful to daphnids.
CONCLUSION	The notified polymer is harmful to *Daphnia magna*
TEST FACILITY	BASF (2001e)

C.2.2. Inhibition of microbial activity

TEST SUBSTANCE	Analogue chemical 1
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test. EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test.
Inoculum	Activated sludge from laboratory waste water plants fed with municipal sewage
Exposure Period	30 min
Concentration Range	Nominal: 9.6, 100, 248, 496,1000 mg/L
Remarks – Method	Micro-organisms in active sludge were exposed for 30 minutes to the test substance at nominal levels up to 1000 mg/L at 20±2˚C, pH 6.9 – 7.2 and

	oxygen levels of > 6.5 mg/L. 3,5-Dichlorophenol was used for reference control at concentrations of 1, 10 and 100 mg/L.
RESULTS	
IC50 (30 min.)	> 1000 mg/L
NOEC (30 min.)	100 mg/L
Remarks – Results	The IC50 for the reference control was detected to be 17 mg/L, falling in the range of 5 – 30 mg/L required in the TG. The oxygen consumption rate reached 41% of that for the blank control at the highest test level of 1000 mg/L. This indicates that the 30 min. IC50 is > 1000 mg/L for the analogue chemical. Considering the high value of IC50 (30 min.), the analogue chemical, and by inference the notified polymer, is not considered harmful to the sludge bacteria.
CONCLUSION	The notified polymer is not inhibitory to microbe respiration.
TEST FACILITY	BASF (2001f)

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