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April 2009

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

**FULL PUBLIC REPORT**

**Setal 1406**

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 the Environment, Water, Heritage and the Arts.

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 334-336 Illawarra Road, Marrickville NSW 2204.

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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**FULL PUBLIC REPORT****Setal 1406****1. APPLICANT AND NOTIFICATION DETAILS**

## APPLICANT(S)

Nuplex Industries (Aust) Pty Ltd (ABN 25 000 045 572) of 49-61 Stephen Rd, Botany, NSW, 2019

AND

Akzo Nobel Car Refinishes Australia Pty Ltd (ABN 26 087 571 882), 269 Williamstown Road, Port Melbourne, VIC, 3207

## 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, Other Names, CAS Number, Molecular Formula, Structural Formula, Molecular Weight, Analytical Data, Hazardous Impurities/Residual Monomers, Additives/Adjuvants, Polymer Constituents, Introduction Volume and Details of Use.

## VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows:

Hydrolysis as a Function of pH

Partition Coefficient

Autoignition Temperature

Acute Dermal Toxicity

Repeat Dose Toxicity

Chromosome Aberration Test

Ready Biodegradability

## PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

CEC/753

## NOTIFICATION IN OTHER COUNTRIES

Canada

**2. IDENTITY OF CHEMICAL**

## MARKETING NAME(S)

Setal 1406 (notified polymer)

## MOLECULAR WEIGHT

>500 Da

## ANALYTICAL DATA

Reference IR and GPC spectra were provided.

**3. COMPOSITION**

DEGREE OF PURITY > 99 %

## HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

All hazardous residual monomers and hazardous impurities are present below the relevant cut-offs for classification.

## NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (&gt;1% by weight)

None

## LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES

Any residual monomers would be expected to be available for release until the paint is cured. The residual monomers are only present at low concentrations.

## DEGRADATION PRODUCTS

None under normal conditions of use.

**4. PHYSICAL AND CHEMICAL PROPERTIES**

APPEARANCE AT 20°C AND 101.3 kPa: Almost colourless viscous liquid

Property	Value	Data Source/Justification
Pour Point	< -20 °C	MSDS
Boiling Point	> 300 °C	MSDS
Density	1080 kg/m <sup>3</sup> at 20°C	MSDS
Vapour Pressure	< 0.001 kPa (temperature unknown)	MSDS
Water Solubility	<10 g/L at 20°C (see comments below)	Determined gravimetrically after centrifugation of the aqueous dispersion of the notified polymer.
Hydrolysis as a Function of pH	Not determined	The notified polymer contains hydrolysable groups. However, hydrolysis is not expected to occur throughout the environmental pH range of 4-9.
Partition Coefficient (n-octanol/water)	Not determined	The log P <sub>OW</sub> of the notified polymer is expected to be high based on its largely hydrophobic nature.
Adsorption/Desorption	Not determined	Based on the log P <sub>OW</sub> and the low water solubility, the notified polymer is expected to have a high affinity for organic matter in soils.
Dissociation Constant	Not determined	There are no functional groups within the notified polymer which can undergo dissociation.
Flash Point	> 100 °C (pressure unknown)	MSDS
Flammability	Not a flammable liquid	Based on Flash Point
Autoignition Temperature	Not determined.	Not expected to autoignite under normal conditions of use.
Explosive Properties	Not predicted to be explosive	Estimated. From examination of the structure, there are no chemical groups that would infer explosive properties; therefore the result has been predicted negative.

## DISCUSSION OF PROPERTIES

*Water solubility*

Considering the significant percentage of the low molecular weight fraction of the polymer, and the existing of hydrophilic end groups in the molecule, the dissolved solids detected may be from the low molecular weight portion that was dissolved or possibly dispersed in water. Ecotoxicity study reports indicate that the solubility would be < 50 mg/L, which is more consistent with that is stated (insoluble) in the MSDS provided by the notifier and complying with the mainly hydrophobic structure of the polymer. Therefore, the test result is considered an over estimate for the solubility of the notified polymer in water.

*Reactivity*

The notified polymer is expected to be stable under normal conditions of use.

**5. INTRODUCTION AND USE INFORMATION**

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

The notified polymer will be imported in finished automotive paint at a concentration of < 30%.

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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	< 20	< 20	< 20	< 20	< 20

## PORT OF ENTRY

Melbourne and Sydney

## IDENTITY OF MANUFACTURER/RECIPIENTS

The imported paint products will be transported from the dockside to the Akzo Nobel warehouse. The automotive paints will be supplied to car manufacturers and car refinish shops.

## TRANSPORTATION AND PACKAGING

The automotive paint containing the notified polymer will be packaged in 1 and 5 L steel cans.

## USE

The notified polymer is a component (< 30%) of automotive paint products.

## OPERATION DESCRIPTION

The notified polymer will not be manufactured, reformulated or repackaged in Australia.

The finished paints containing the notified polymer (< 30%) will be transported to the customers (car manufacturers and crash repair shops) in the original packaging.

The paint may be mixed with other additives prior to application. The mixture is then loaded into the spray equipment and applied to the car. The majority of spray applications will occur in a spray booth. The level of ventilation present in the spray booth will vary between workshops. In smaller automotive refinish repair shops spray applications may occur outside of a spray booth.

Once spraying is completed or the paint has been exhausted, the equipment is drained and cleaned using solvents and rags.

## 6. HUMAN HEALTH IMPLICATIONS

### 6.1 Exposure assessment

#### 6.1.1 Occupational exposure

##### NUMBER AND CATEGORY OF WORKERS

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
<b><i>Notifiers Site</i></b>			
Transport & Warehousing	10	1-2 hours	200 days/year
<b><i>At Car manufacturers</i></b>			
<b><i>Paint Application</i></b>			
Unloading and preparation of mixture	1-2	1-2 hours	200 days/year
Spray painting	20	8 hours/day	200 days/year
Cleaning equipment	10	2 hours/day	200 days/year
<b><i>Aftermarket industry e.g. Crash car shop</i></b>			
Unloading and preparation of mixture	1-2	1 hour/day	50 days/year
Spray painting	2	10-45 minutes	200 days/year
Cleaning equipment	2	15-30 minutes	200 days/year

##### EXPOSURE DETAILS

Exposure of transport and storage workers is not expected except in the event of accidental spillage or breach of packaging.

##### *Professional spray painters*

Dermal and ocular exposure to the notified polymer (at up to 30%) may occur during mixing and transfer of the automotive paint. Inhalation exposure is unlikely due the low vapour pressure of the notified polymer. However, exposure should be minimised where PPE consisting of coveralls, gloves, safety boots and eye protection goggles are worn. The level of personal protective equipment (PPE) will vary between workshops.

Dermal and ocular exposure to the notified polymer (at up to 30%) may occur during spray application of the finished paints to automobile parts and when cleaning spray gun equipment. However, exposure should be minimised where PPE consisting of coveralls, gloves, safety boots and eye protection goggles are worn. The level of PPE will vary between workshops.

Due to the formation of aerosols, inhalation exposure is also likely during spray application, particularly where the level of ventilation within the spray booths is insufficient, application occurs outside of a spray booth and/or workers do not wear air respirators.

Workers will likely make dermal contact with the notified polymer after application. However, once the paint is cured, the notified polymer will be reacted into the polymer matrix and will not be bioavailable.

#### 6.1.2. Public exposure

The general public will not use products containing the notified polymer. The public will likely make dermal contact with surfaces containing the notified polymer on automobiles, however once cured the notified polymer is bound within a polymer matrix and will not be bioavailable.

### 6.2. Human health effects assessment

The results from toxicological investigations conducted on the notified polymer are summarised in the table below. Details of these studies can be found in Appendix A.

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Rat, acute oral toxicity	oral LD50 >2000 mg/kg bw low toxicity
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating

Mouse, skin sensitisation – Local lymph node assay  
Mutagenicity – bacterial reverse mutation

no evidence of sensitisation  
non mutagenic

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A polyester with a molecular weight less than or equal to 1000 is a polymer of low concern under *the Act* if it is made from prescribed reactants. The notified polymer is a polyester oligomer constructed from one prescribed reactant and two reactants that are not prescribed but give rise to a structure that is comparable to a structure derived from prescribed reactants. The notified polymer does not contain any high or moderate concern reactive functional groups. Therefore, no additional hazard contribution is expected.

This is supported by toxicological endpoints observed in testing conducted on the notified polymer

Acute toxicity.

The notified polymer is of low acute toxicity by the oral route.

Irritation and Sensitisation.

The notified polymer was very slightly irritating to skin and eyes in a rabbit study. The slight irritation effects fully resolved within 24 hours. The notified polymer did not demonstrate evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation.

Mutagenicity.

The notified polymer was negative in an Ames test.

#### **Health hazard classification**

Based on the available data, the notified polymer is not classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

### **6.3. Human health risk characterisation**

#### **6.3.1. Occupational health and safety**

Although the level of exposure will vary between workshops, given the expected low order of toxicity of the notified polymer, the risk to workers is not considered to be unacceptable.

To minimise exposure to aerosols, spraying should be carried out according to the *National Guidance Material for Spray Painting* (NOHSC, 1999).

#### **6.3.2. Public health**

The notified polymer is not available to the public, except after the product has been applied and cured and the notified polymer becomes bound within a matrix. The notified polymer is not available for exposure, hence the risk to the public is negligible.

## 7. ENVIRONMENTAL IMPLICATIONS

### 7.1.1 Environmental Exposure

#### RELEASE OF CHEMICAL AT SITE

The notified polymer will not be manufactured, reformulated or repackaged in Australia. Release at the notifier's warehouse may occur as a result of accidental spills.

It is estimated that a maximum of 100 kg per year of notified polymer would be lost from accidental spills. Spills are contained and soaked up with inert absorbent material (sand, soil or vermiculite) and placed in a sealable container for appropriate disposal. Waste material is disposed of in accordance with local, state or national EPA regulations.

#### RELEASE OF CHEMICAL FROM USE

The paint may be mixed with other additives prior to application. The mixture is then loaded into the spray equipment and applied to the car. The majority of spray applications will occur in a spray booth. The level of ventilation present in the spray booth will vary between workshops. In smaller automotive refinish repair shops spray applications may occur outside of a spray booth.

The majority of the chemical will be released as overspray during automotive spray painting operations. It is estimated that approximately 30% of the ready for use material will be lost using High Volume Low Pressure (HVLP) spray guns with slightly higher losses from more outdated spray guns. This is expected to result in an overall loss rate of approximately 35%.

The majority of spray painting is expected to be performed in spray booths where the overspray will be collected using filters and water scrubbers. The filters will be disposed of to landfill. The polymer in the scrubber water is likely to cure as a component of the paint and be removed periodically and also be disposed of to landfill. Any residual amount of polymer released to sewer is likely to adsorb to the sewage sludge in the Sewage Treatment Plant (STP) where it will be landfilled or incinerated. In smaller smash repair workshops, which may not have spray booths, the overspray will be collected on newspaper sheet and disposed of as domestic waste to landfill.

Approximately 1% of the notified polymer is likely to be lost from cleaning of equipment. It is expected that this will be collected for disposal to landfill in accordance with local, State and Federal regulations.

Residue in the 1 and 5 L steel containers is expected to be approximately 0.2% of the total amount imported and will be disposed of to landfill.

#### RELEASE OF CHEMICAL FROM DISPOSAL

Residues of the polymer in paint containers will be disposed of either professionally by licensed contractors and most likely to landfill.

If incidental spillage occurs during normal operating procedures, it will be contained and soaked up with inert absorbent material (sand, soil or vermiculite) and placed in a sealable container for appropriate disposal which will most likely be to landfill.

Any overspray of the new material that does occur would be trapped in the spray booth and removed to an approved landfill.

The polymer that is coated on automobile as part of the paint will either be sent to landfill with the associated substrate or be burnt during recycling of the automobile.

### 7.1.2 Environmental fate

No environmental fate data were submitted.

Most of the notified polymer is expected to go to landfill, with some possibly being incinerated in the process of automobile recycling. Degradation, either through incineration or biotic and abiotic processes in landfill, will result in formation of small molecules of water and oxides of carbon. The notified polymer will be cured and bound within a polymer matrix during application and hence will not be bioavailable. Hence, it is not expected to cross biological membranes and to bioaccumulate.



### 7.1.3 Predicted Environmental Concentration (PEC)

The calculation of PEC for the notified polymer is not necessary since no significant release to water is expected given the reported use pattern.

## 7.2. Environmental effects assessment

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

<i>Endpoint</i>	<i>Result</i>	<i>Assessment Conclusion</i>
Fish Toxicity	EC50 >100 mg/L (Cloudy solution)	Not harmful to fish above the solubility
Daphnia Toxicity	EC50=16.3 mg/L 48-h	Harmful to Daphnia
Algal Toxicity	EC50 >100 mg/L	Not toxic to algae

Based on the ecotoxicity studies provided by the notifier, the notified polymer is considered harmful to the aquatic life.

### 7.2.1 Predicted No-Effect Concentration

The calculation of NOEC is not necessary considering no significant release of the notified polymer to aquatic environment is expected.

## 7.3. Environmental risk assessment

No significant release of the notified polymer to the aquatic ecosystem is expected based on the reported use pattern. Therefore, the calculation of the risk quotient (Q) has not been conducted. Further, any release of the notified polymer will be in the inert matrix of the cured paint. Therefore, the notified polymer is not considered to pose an unacceptable risk to the environment.

## 8. CONCLUSIONS AND REGULATORY OBLIGATIONS

### Hazard classification

Based on the available data the notified chemical is not classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

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 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

	<i>Hazard category</i>	<i>Hazard statement</i>
Environment	Acute Category 3 Chronic Category 3	The notified polymer is 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 reported use pattern, the notified polymer is not considered to pose a risk to the environment.

## Recommendations

### CONTROL MEASURES

#### Occupational Health and Safety

- No specific engineering controls or personal protective equipment are required for the safe use of the notified polymer itself, however, these should be selected on the basis of all ingredients in the formulation.

Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- A copy of the MSDS should be easily accessible to employees.
- Employers should implement the following safe work practices to minimise occupational exposure to the notified polymer during spray application:
  - Use of spray paints containing the notified polymer should be in accordance with the NOHSC National Guidance Material for Spray Painting (NOHSC 1999).
- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

#### Disposal

- The notified chemical should be disposed of to landfill.

#### Emergency procedures

- Spills or accidental release of the notified chemical 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(2) of the Act; if
  - the function or use of the chemical has changed from a component of automotive paint products, or is likely to change significantly;
  - the amount of chemical being introduced has increased from 20 tonnes, or is likely to increase, significantly;
  - the chemical has begun to be manufactured in Australia;
  - additional information has become available to the person as to an adverse effect of the chemical 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.

No additional secondary notification conditions are stipulated.

*Material Safety Data Sheet*

The MSDS of the notified polymer and products 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 A: TOXICOLOGICAL INVESTIGATIONS

### A.1. Acute toxicity – oral

TEST SUBSTANCE	Setal 1406
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/Wistar
Vehicle	Test substance administered as supplied.
Remarks – Method	No significant protocol deviations.

#### RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
1	3 females	2000	0
2	3 females	2000	0

LD50	> 2000 mg/kg bw
Signs of Toxicity	Hunched posture observed on Day 1 only in all animals. There were no other clinical signs of toxicity.
Effects in Organs	No abnormalities were observed at necropsy.

CONCLUSION	The notified chemical is of low toxicity via the oral route.
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TEST FACILITY	Notox (2006a)
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### A.2. Irritation – skin

TEST SUBSTANCE	Setal 1406
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 males
Vehicle	Test substance administered as supplied.
Observation Period	72 hours
Type of Dressing	Semi-occlusive
Remarks – Method	No significant protocol deviations.

#### RESULTS

<i>Lesion</i>	<i>Mean Score* Animal No.</i>			<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
	1	2	3			
<i>Erythema/Eschar</i>	0	0	0	1	< 24 hr	0
<i>Oedema</i>	0	0	0	1	< 24hr	0

\*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

Remarks – Results	No symptoms of systemic toxicity were observed in the animals during the test period and no mortality occurred. Sticky remnants of test substance were observed on day one.
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CONCLUSION	The notified chemical is slightly irritating to skin.
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TEST FACILITY	Notox (2006b)
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**A.3. Irritation – eye**

TEST SUBSTANCE	Setal 1406
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 males
Observation Period	1, 24, 48 and 72 hours after instillation
Remarks – Method	No significant protocol deviations

**RESULTS**

<i>Lesion</i>	<i>Mean Score*</i> <i>Animal No.</i>			<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
	1	2	3			
<i>Conjunctiva: redness</i>	0.3	0.3	0.3	2	< 48 h	0
<i>Conjunctiva: chemosis</i>	0	0	0	2	< 24 h	0
<i>Conjunctiva: discharge</i>	0	0	0	1	< 24 h	0
<i>Corneal opacity</i>	0	0	0	0	-	0
<i>Iridial inflammation</i>	0	0	0	0	-	0

\*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

Remarks – Results	No symptoms of systemic toxicity were observed in the animals during the test period and no mortality occurred.
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CONCLUSION	The notified chemical is slightly irritating to the eye.
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TEST FACILITY	Notox (2006c)
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**A.4. Skin sensitisation – mouse local lymph node assay (LLNA)**

TEST SUBSTANCE	Setal 1406
METHOD	OECD 429 Skin Sensitisation: Local Lymph Node Assay
Species/Strain	Mouse/CBA strain/Females
Vehicle	Acetone/olive oil (4:1 v/v)
Remarks – Method	No significant protocol deviations.

**RESULTS**

<i>Concentration</i>	<i>Proliferative response (DPM/lymph node)</i>	<i>Stimulation Index (SI) (Test/Control Ratio)</i>
Test Substance		
25%	483	1.3
50%	852	2.3
100%	814	2.2
Vehicle	374	
Positive Control		
Hexylcinnamic aldehyde 85%		
5%	551	2.1
10%	952	3.6
25%	1969	7.5
Vehicle	262	

Remarks – Results	No irritation was observed. The SI with the test substance did not exceed 3.
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CONCLUSION	There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical.
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TEST FACILITY Notox (2006d)

#### A.5. Genotoxicity – bacteria

TEST SUBSTANCE Setal 1406

METHOD OECD TG 471 Bacterial Reverse Mutation Test.  
Plate incorporation procedure

Species/Strain *S. typhimurium*:  
TA1535, TA1537, TA98, TA100  
*E. coli*: WP2 uvrA

Metabolic Activation System S9 mix from Phenobarbital/β-naphthoflavone induced rat livers

Concentration Range in a) With metabolic activation: 3 - 5000 µg/plate.

Main Test b) Without metabolic activation: 3 - 5000 µg/plate.

Vehicle Dimethyl sulphoxide

Remarks – Method No significant protocol deviations.

#### RESULTS

Metabolic Activation	Test Substance Concentration (µg/plate) Resulting in:			
	Cytotoxicity in Preliminary Test	Cytotoxicity in Main Test	Precipitation	Genotoxic Effect
<i>Present</i>				
Test 1	-	> 5000	5000	negative
Test 2	-	> 5000	5000	negative
<i>Absent</i>				
Test 1	-	> 5000	5000	negative
Test 2	-	> 5000	5000	negative

Remarks – Results All strains showed negative responses over the entire dose range i.e. no dose-related significant increase in the number of revertants was observed. The positive controls demonstrated the validity of the tests performed. The negative controls data was within historical controls.

CONCLUSION The notified chemical was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY Notox (2006e)

## APPENDIX B: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

### B.1. Ecotoxicological Investigations

#### B.1.1. Acute toxicity to fish

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 203 Fish, Acute Toxicity Test -Static. ESA Standard Operation Procedure 117/USEPA Method (1994 and 2002).
Species	<i>Melanotaenia splendida</i>
Exposure Period	96-h
Auxiliary Solvent	HPLC grade methanol
Water Hardness	Not specified
Analytical Monitoring	Not performed
Remarks – Method	<p>The Fish Imbalance Test (FIT) was conducted at concentrations of 100, 50, 25, 12.5, 6.25, 3.13 and 1.56 mg/L at 23±1°C. A range finding test was conducted with the information being used to determine the highest concentration in the definitive test.</p> <p>Dilute Mineral Water (DMW) was used as the diluent for the toxicity test and as the culture medium for the culturing of the test organisms. DMW was prepared 24-48 h prior to use. DMW was prepared by diluting Perrier mineral water to a concentration of 20% (v/v) with deionised water. A vitamin B12 and selenium supplement was added to the DMW to give final concentration of 10 to 2 µg/L, respectively. DMW was prepared in a 20L HDPE carboy and aerated using an aquarium aerator.</p> <p>The stock solution prepared in HPLC grade methanol was prepared at a concentration of 100 g/L. It was noted that the addition of 0.1 mL of this stock solution to DMW diluent resulted in the test solution becoming cloudy, which suggested that the solubility of the notified polymer in DMW diluent was &lt;100 mg/L and not all of the test material had remained dissolve at this concentration.</p> <p>The concentration of methanol in the 100 mg/L test treatment was 0.01%, and a solvent control treatment was prepared with the same concentration of HPLC grade methanol but without the test material. To test the relative sensitivity of the test organisms and the proficiency of the Laboratory Technicians, a separate positive (toxic) control test using copper was conducted in the same manner as with the definitive test with the notified polymer.</p> <p>Four replicates were done with five larval fish being used in each for all of the tests.</p>

#### RESULTS

Concentration mg/L		Number of Fish	Imbalance				
Nominal	Actual		1h	24h	48h	72h	96h
0 control		5×4	0	0	0	0	0
0 solvent control		5×4	0	0	0	0	0
1.56		5×4	0	0	0	0	0
3.13		5×4	0	0	0	0	0
6.25		5×4	0	0	0	0	0
12.5		5×4	0	0	0	0	0
25		5×4	0	0	0	0	0
50		5×4	0	0	0	0	0
100		5×4	0	0	0	0	0

EC50	> 100 mg/L at 96 hours.
NOEC	100 mg/L at 96 hours.
Remarks – Results	All validity criteria were met.

No significant imbalance was observed throughout the whole test concentration range of 1.56 - 100 mg/L. Given the solution being cloudy at 100 mg/L suggesting not all the test material remained dissolved, the notified polymer is considered at worst harmful to fish.

CONCLUSION	The notified polymer is not harmful to fish above its limit of solubility.
TEST FACILITY	Ecotox (2008)

### B.1.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified polymer
METHOD	ESA Standard Operation Procedure 101-Static/USEPA Method (1993 and 2002)
Species	<i>Ceriodaphnia dubia</i>
Exposure Period	48 hours
Auxiliary Solvent	HPLC grade methanol
Water Hardness	Not specified
Analytical Monitoring	Not performed
Remarks - Method	Acute toxicity tests with cladoceran <i>Ceriodaphnia dubia</i> was conducted at concentrations of 20, 10, 5, 2.5 and 1.25 mg/L at 25±1°C. A range finding test was conducted with the information being used to determine the highest concentration in the definitive test. DMW) was used as the diluent for the toxicity test and as the culture medium for the culturing of the test organisms. The preparation of DMW was the same as that for fish, except that the DMW for <i>Ceriodaphnia dubia</i> was prepared in a 5-L Schott bottle. The preparation for the test solutions was in the same way as for the fish. Solvent and positive (toxic) control tests were conducted with the same methods as for fish, except that the concentration for the solvent control was at 20 mg/L and the test material used for the toxic control was potassium chloride. Four replicates were done with five organisms being used for each for all of the tests.

### RESULTS

Concentration mg/L		Number of <i>D. magna</i>	Number Immobilised	
Nominal	Actual		24 h	48 h
0 (Control)		5×4	0	0
Solvent control		5×4	0	0
1		5×4	0	0
2.5		5×4	0	0
5		5×4	0	0
10		5×4	0	17
20		5×4	0	65

EC50	>20 mg/L at 24 hours >16.3 (13.1-20.2) mg/L (with 95% confidence limits) at 48 hours
NOEC and LOEC	10 and 20 mg/L, respectively, at 48 hours
Remarks - Results	All validity criteria were met. No significant mortalities were observed at or below the 20 mg/L treatment after 48-h exposure, and consequently the NOEC and LOEC estimates were 10 and 20 mg/L, respectively.

CONCLUSION	The notified chemical is considered harmful to <i>Ceriodaphnia dubia</i> based on the test results.
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TEST FACILITY Ecotox (2008)

### B.1.3. Algal growth inhibition test

TEST SUBSTANCE

METHOD ESA Standard Operation Procedure 103/USEPA Method (1993 and 2002)

Species *Selenastrum capricornutum*

Exposure Period 72 hours

Concentration Range 6.25, 12.5, 25, 50, 100 mg/L

Auxiliary Solvent HPLC grade acetone

Water Hardness Not specified

Analytical Monitoring Improved Neubauer Haemocytometer was used to enumerate the cell densities.

Remarks - Method Acute toxicity tests with algae *Selenastrum capricornutum* was conducted at concentrations of 100, 50, 25, 12.5 and 6.25 mg/L at 25±1°C. A range finding test was conducted with the information being used to determine the highest concentration in the definitive test.

The stock solution prepared in HPLC grade acetone was prepared at a concentration of 500 mg/L. Similar The test treatments of 100 and 50 mg/L exhibited cloudiness, suggesting that not all of the test material had remained dissolved.

The concentration of acetone in the 100 mg/L test treatment was 0.01%, and a solvent control treatment was prepared with the same concentration of HPLC grade acetone but without the test material. To test the relative sensitivity of the test organisms and the proficiency of the Laboratory Technicians, a separate positive (toxic) control test using potassium chloride was conducted in the same manner as with the definitive test with the notified polymer.

Four replicates were done with initial cell density being 10,000 cells/mL for each of all the tests.

### RESULTS

<i>IC50</i> mg/L at 72 h	<i>NOEC</i> mg/L at 72 h	<i>LOEC</i> mg/L at 72 h
>100	12.5	25

Remarks - Results All validity criteria were met.

Cell density was not affected at concentrations up to 12.5 mg/L inclusive. The NOEC and LOEC were determined to be 12.5 and 25 mg/L, respectively.

CONCLUSION The notified chemical was not toxic to algae, *Selenastrum capricornutum*.

TEST FACILITY Ecotox (2008)

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