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August 2007

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

PMP

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 and Water Resources.

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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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT
Akzo Nobel Pty Ltd (ABN: 59 000 119 424)
51 McIntyre Road
Sunshine North 3020 VIC

NOTIFICATION CATEGORY
Standard: Chemical other than polymer (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, Spectral data, Methods of detection and determination, Purity, Hazardous impurities, Non-hazardous impurities, Additives, Import volume and use details

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Chronic toxicity to aquatic invertebrates

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
UK (2006)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
PMP

ANALYTICAL DATA
Reference ^{1}H-NMR, IR, GC-MS and UV spectra were provided.

MOLECULAR WEIGHT
< 500 g/mol

3. COMPOSITION

DEGREE OF PURITY
> 99%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa
Clear colourless liquid (PMP)

Property	Value	Data Source/Justification
Freezing Point	< -20°C	Measured
Boiling Point	161°C at 99.13 to 100.8 kPa	Measured
Density	948 kg/m^3 at 19.8 ± 0.5°C	Measured
Vapour Pressure	0.232 kPa at 25°C	Measured

Water Solubility	53.2 g/L at 20ºC	Measured
Hydrolysis as a Function of pH	pH 4, 25ºC > 1 year pH 7, 25ºC > 1 year pH 9, 25ºC 9.67 days	Measured
Partition Coefficient (n-octanol/water)	log P_{ow} = 1.43.at 20ºC	Measured
Adsorption/Desorption	log K_{oc} = 1.04 at 30°C	Measured
Dissociation Constant	Not determined	No modes of dissociation.
Particle Size	Not applicable	The test material is a liquid.
Flash Point	54 ± 2ºC at 101.62 kPa	Measured
Flammability	Flammable	Estimated/MSDS
Autoignition Temperature	340 ± 5ºC	Measured
Explosive Properties	Not explosive	Estimated
Oxidising Properties	Not oxidising	Estimated

DISCUSSION OF PROPERTIES
For full details of tests on physical and chemical properties, please refer to Appendix A.

Reactivity
The notified chemical is not predicted to be reactive under normal use conditions, based on its structure.

Dangerous Goods classification
Based on the available Property data the notified chemical is classified as a Class 3 flammable liquid according to the Australian Dangerous Goods Code (FORS, 1998).

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will not be manufactured in Australia. It will be imported as a component of 2-pack coatings or thinners (at concentrations of < 50%) for professional application to yachts.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	1-3	3-10	3-10	3-10	3-10

PORT OF ENTRY
Brisbane

IDENTITY OF MANUFACTURER/RECIPIENTS
Akzo Nobel Pty Ltd.

TRANSPORTATION AND PACKAGING
The product will be transported in unlined 3.8 L and 0.95 L cans with triple tight and level lid. All cans will be cartoned for shipping.

The imported products will be transported mainly by road to the notifier's warehouse before distribution for reformulation or end use.

USE
The notified chemical will be used as a component of coating products (paints/lacquers/varnishes) or thinners (for diluting coatings prior to applications) for application to yachts.

OPERATION DESCRIPTION

The majority of the imported products are finished products which will be supplied to end users without repackaging or reformulation. Only some colour-based imported products will be reformulated before the end use.

Reformulation (colour blending)
Some colour-based imported products will be mixed with other colours to enable a wider range of colours to be available to customers. The mixing process will be carried out using a gravimetric Fillon-Pichon mixing system or equivalent which uses 4-litre cans of paint. To blend a specific colour, the original lid will be removed and replaced by a lid with an integrated stirrer and trigger valve. The can will then be put on the machine which automatically stirs it. Once cans are loaded on the mixing machine the system will be sealed. An empty 4-litre can will be placed on a balance and filled from the range of 4-litre cans loaded on the machine with the special lids. The empty can will be filled from two or more of the other cans in a pre-defined ratio. Only one can is open to the atmosphere at any one time. Mixing a can takes approximately 5 minutes. The concentration of PMP in the end product is < 50%. The can will then be lidded and sealed manually before another can is mixed. A normal mixing operation will be of 1 to 20 cans, with 1 to 4 being the usual scenario.

End use
The paint and/or thinner will be used in two main types of operation: building of new yachts and maintenance/repair of existing yachts.

Yacht coatings are normally applied by spray. The applicator crew normally consists of a sprayer and a "potman". The latter is responsible for ensuring that the spray equipment is fed with a continual supply of mixed paints. The potman therefore mixes the two parts of the products, adds any necessary thinner and supplies this to the spray equipment in the original packaging. The packing is designed so that the curing agent can be added to the base can for mixing. Depending on the size of the yacht, a cherry picker may be used to lift the sprayer to the work area.

Some smaller jobs may be carried out by brushes and/or rollers. A single applicator will mix the two parts of paint and apply using a brush and/or roller. The paint may be applied directly from the can, from a paint kettle or a roller tray. In some cases thinners may be added to reduce the viscosity of the paint prior to applications.

At the end of the spraying operation, the applicator crew will clean out the spray equipment (usually by hand) using solvents.

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 storage workers	< 400	1-2	10-15
Reformulation operators	2	1-2	136-260
End users	200-400	1-3	100

EXPOSURE DETAILS
The main routes of occupational exposure are *via* dermal, ocular and inhalation.

Exposure of transportation and storage workers to the imported product (containing < 50% notified chemical) is unlikely unless in an event of accident.

During reformulation, workers' exposure is likely when removing and replacing lids and when operating the paint mixing system, especially if spills and leakages occur. However, the exposure will be limited due to the use of a sealed mixing system, one open can at any one time, short operation duration, and operation by trained personnel only. This will be further reduced by use of engineering controls such as local exhaust ventilation (LEV) and personal protective equipment (PPE), such as gloves, boiler suit, eye protection, and respiratory and

breathing protective equipment.

During end uses, the frequency of use, duration, and number of workers involved (ranging from 1 to 20 operators at a site) will differ significantly. Dermal, ocular and inhalation exposure may occur during preparation of the paint, application of paint by spraying/brushes/rollers, and during manual equipment cleaning. Spray operations will be usually carried out in paint sheds (with extraction and LEV) and occasionally in open air. Applications using brushes and rollers will be mostly carried out in open air. However, workers' exposure *via* inhalation would be potentially significant given its volatility and spray application. All operators will be required to wear full PPE (gloves, boiler suit, eye protection, and respiratory and breathing protective equipment) due to the isocyanate content of the paint. This equipment is also likely to protect against significant exposure to the notified chemical.

The cherry-picker driver will operate from inside an enclosed cab; therefore, their potential exposure will be minimal.

6.1.2. Public exposure

The imported product containing < 50% of the notified chemical is intended for industrial or professional use only. After application to boats, the notified chemical will evaporate from the paint film as it cures/dries.

Public exposure to the notified chemical (in products) as a result of transportation within Australia is unlikely unless there is an accident.

6.2. Human health effects assessment

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

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 > 2500 mg/kg bw, low toxicity
Rat, acute dermal toxicity	LD50 > 2000 mg/kg bw, low toxicity
Rat, acute inhalation toxicity	LC50 > 5.55 mg/L/4.hours, low toxicity
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Mouse, skin sensitisation – LLNA*	no evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days.	NOAEL = 150 mg/kg bw/day
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro Mammalian Chromosome Aberration	non genotoxic

*Local lymph node assay

Toxicokinetics

Given the low molecular weight of the notified chemical and its log P_{ow} of 1.43, it is likely to be significantly absorbed following oral, dermal or inhalation exposure. The octanol-buffer partition coefficient suggests that distribution of parent substance is unlikely to be bioaccumulate. Hydrolysis is likely to minimise the amount of parent substance available for distribution. Metabolism is likely to be extensive.

Acute toxicity

The notified chemical is of low acute toxicity *via* the oral and dermal routes and by inhalation. The notified chemical has a vapour pressure of 0.232 kPa and hence will be volatile.

Irritation

Based on the studies provided, the notified chemical is considered to be slightly irritating to eyes and skin.

Sensitisation

There was no evidence of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical in a mouse LLNA.

Repeated Dose Toxicity

The No Observed (Adverse) Effect Level (NO(A)EL) was established as 1000 mg/kg bw/day for female rats and 150 mg/kg bw/day for male rats. However, the investigators added for the purpose of hazard evaluation the

NOAEL for males should be regarded as 1000 mg/kg/day, because: "the microscopic kidney changes detected in male rats treated with 1000 mg/kg/day were consistent with well documented changes that are peculiar to the male rat in response to treatment with some hydrocarbons. This effect is, therefore, not indicative of a hazard to human health." This statement is in agreement with published literature on rat renal toxicology, where xenobiotic-induced α_2-microglobulin nephropathy is exclusively found in male experimental rats (reference/s). Nonetheless, some kidney effects were also observed in female rats, suggesting that some renal toxicity may have occurred by another mechanism. It should be noted that human occupational exposure to various volatile solvents has been known to result in chronic renal failure and glomerulonephritis (Mutti, 1996).

Genotoxicity
The notified chemical tested was not mutagenic in a bacterial reverse mutation study and not genotoxic in an *in vitro* mammalian chromosome aberration study.

Based on the available data the notified chemical 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
The notified chemical, a Class 3 flammable liquid, and finished products containing notified chemical should be handled and stored accordingly.

Formulation
The notified chemical will be transported to paint manufacturing facilities as a neat raw material and formulated into paint products which will be applied by spraying/brushes/rollers for industrial or professional use only. The final concentration of notified chemical in the paint product is < 50%.

Typical exposure scenarios for paint formulation involve transfer of the raw material to a mixing system and finally the product is automatically packed off into consumer-sized containers. Other operations involve sampling and testing of paint, and the cleaning and maintenance of equipment and vessels.

Dermal exposure to the notified chemical can be estimated using the EASE model using reasonable worst case defaults for a particular activity (European Commission, 2003) as follows:

Activity	*Estimated exposure for activity (mg/day)*	*Estimated exposure for notified chemical (mg/kg bw/day)**
Manual addition of liquids	420	6
Coupling and decoupling of transfer line	42	0.6
Quality control sampling	21	0.3

*for a 70 kg worker and a 100% dermal absorption factor

Based on a NOAEL of 150 mg/kg bw/day for notified chemical derived from a 28-day rat oral repeat dose study the margins of exposure (MOE) for various activities are as follows:

Activity	*Estimated exposure for notified chemical (mg/kg bw/day)*	*Margin of Exposure*
Manual addition of liquid form	6	25
Coupling and decoupling of transfer line	0.6	250
Quality control sampling	0.3	500

MOE greater than or equal to 100 are considered acceptable to account for intra- and inter-species differences. Therefore, the risk of systemic effects using modelled worker data may not be acceptable for workers involved in addition of the notified chemical to mixing system if any manual addition occurs. The notifier has stated that the exposure will be limited due to the use of a sealed mixing system, one open can at any one time, short

operation duration, and operation by trained personnel only. Therefore, maximum exposure should be about 0.6 mg/kg bw/day, with an acceptable MOE, provided LEV and PPE are employed.

End Use
The risk to workers handling formulated products containing the notified chemical is acceptable given that workers will use PPE.

Exposure to the notified chemical during end application will be limited by the use of PPE. As the notified chemical is slightly irritating to eyes and skin, the workers should avoid skin and eye contact with the product containing notified chemical at < 50%. Inhalation exposure is possible due to spray application of formulations containing the notified chemical and because of its significant vapour pressure; however, this is expected to be limited by the application of appropriate ventilation and use of PPE, such as a respirator. Inhalation exposure to the notified chemical in spray painting is considered to be low if spraying occurs in spraying booths.

6.3.2. Public health
Once the paint containing the notified chemical is applied to the boats, the notified chemical will evaporate from the paint film as it cures/dries. Therefore negligible exposure to the public is expected.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE
There will be no release during manufacture of the notified chemical, as it is not produced in Australia.

The majority of the imported products will be finished products which will be supplied to end users without repackaging or reformulation. However, some colour-based imported products will be reformulated before the end use to enable a wider range of colours to be available to customers. The mixing process will be carried out with a gravimetric Fillon-Pichon mixing system or equivalent which uses 4-litre cans of paint, during which there is a short period when release to the atmosphere may occur before cans are sealed/resealed.

Spillage of the notified chemical during transport, storage and processing is expected to be minimal and largely due to accidents. In the event of spillage, the notifier indicates that spillage should be contained and absorbed with non-combustible material, placed in closed containers outside buildings and disposed of in accordance with local regulations. Surfaces may then be cleaned with detergent, but minimal amounts of the notified chemical would be expected to remain on surfaces by that time and the notifier indicates that spills should not be allowed to enter drains or watercourses.

Until spilt material is collected and enclosed, and where it is again exposed to the atmosphere (eg in landfill), the notified chemical is expected to volatilise, with at most small amounts entering water.

RELEASE OF CHEMICAL FROM USE
The paint and/or thinner will be used in two main types of operation: building of new yachts and maintenance/repair of existing yachts.

Yacht coatings are normally applied by spray, but some smaller jobs may be carried out by brushes and/or rollers. Applications will normally take place in paint sheds with extraction facilities and local exhaust ventilation. Occasionally paint may be applied in the open air, particularly if applied by brush/roller. The notified chemical is expected to volatilise during and after application, with negligible residues in dry paint particles generated by overspray or the removal of paint systems from the vessel. Any residues in paint waste will be prevented from reaching surface waters by controls in place at commercial ship and boat yards.

RELEASE OF CHEMICAL FROM DISPOSAL
The waste generated is expected to be mainly in the form of dry overspray and dried paint left in tins. In both

cases, levels of any notified chemical left in the dried paint will be minimal due to its high volatility, with any residue trapped within the dried paint. Waste paint will generally be allowed to cure, trapping any residual notified chemical within the paint film. Depending on the amount of paint left in tins they may be recycled or disposed of to landfill.

Wastes from filters at facilities such as spray booths would be expected to be disposed of to landfill, as such facilities use various types of fibre-based filters, which are normally disposed of to landfill, in accordance with applicable local regulations.

Any notified chemical reaching landfill would ultimately be expected to be volatilised if it becomes exposed to the atmosphere, or degraded if it enters water or as the paint in which it is trapped degrades.

7.1.2 Environmental fate

The notified chemical is highly volatile and highly soluble in water, with the calculated Henry's Law Constant of 0.64 Pa m^3/mole, indicating moderate volatility from water or moist surfaces. In the minor amount of reformulation occurring in Australia and with use as a component of coating products or thinners for application to yachts, it is expected that almost all the notified chemical imported would be released to the atmosphere.

While not hydrolysed at acid to neutral pH, the notified chemical is hydrolysed at a moderate rate at pH 9 and hence may hydrolyse at a slow to moderate rate at the slightly lower pH of seawater (pH ~ 8.2), as is likely to be present near to areas where the notified chemical would be used in painting yachts. While not meeting the criteria for classification as readily biodegradable, it exhibited potential for biodegradation in a Ready Biodegradability Closed Bottle Test. The notified chemical is not surface active and has a log Pow value of below 3. Hence any notified chemical partitioning to water or soil would not be expected to persist, and the notified chemical is not expected to bioaccumulate.

The notified chemical is expected to be almost completely released to the atmosphere, mainly during paint application and drying. Assessment of the fate of the notified chemical in the atmosphere was conducted using the Atmospheric Oxidation Programv1.90 (AOPWIN) module in the EPISuite™ program. This modeling indicates that the notified chemical is not expected to persist in the atmosphere, with a relatively short estimated atmospheric half life of 10.5 hours (0.87 × 12 hour days) for gas-phase reaction with hydroxyl radicals. A very small fraction (10^{-6} to 10^{-7}) is predicted to adsorb to atmospheric particulates. A small amount of the notified chemical may be deposited in rain drops, but the potential for deposition is low due to the rapidity of photolytic oxidative degradation.

For the details of the environmental fate studies please refer to Appendix C.

7.1.3 Predicted Environmental Concentration (PEC)

As it is not expected that the notified chemical will be deliberately released to the aquatic compartment, a PEC could not be determined.

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 C.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	LC50 19 mg/L	Harmful to fish.
Daphnia Toxicity	EC50 > 100 mg/L	Not harmful to *Daphnia*.
Algal Toxicity	EC50 > 35 mg/L	At most harmful to algae.

7.2.1 Predicted No-Effect Concentration

Aquatic ecotoxicity data were provided for three trophic levels. The most sensitive endpoint was the 96 h LC50 of 19 mg/L for fish, with no toxic effects evident to daphnids or algae at the maximum concentrations tested. The following Predicted No-Effect Concentration has been calculated using an assessment factor of 100 and based on the LC50 value for fish.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
LC50 for fish	19	mg/L
Assessment Factor	100	
PNEC:	190	µg/L

7.3. Environmental risk assessment

Under normal usage there will be no release into the aquatic or soil environments. A risk quotient (PEC/PNEC) for aquatic organisms cannot be calculated as minimal release to water is expected and an accurate PEC cannot be estimated. However, the notified chemical is not expected to pose any significant hazard to the aquatic or terrestrial environments.

The notified chemical is not expected to pose any significant hazard to the environment through its release to the atmosphere due to the relatively small volume of use and short estimated atmospheric half-life. It is not expected to have ozone depleting potential.

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)].

and

As a comparison only, the classification of the notified chemical 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.

	Hazard category	***Hazard statement***
Flammable liquids	Category 3	Flammable liquid and vapour
Environment - aquatic toxicity	Acute Category 3	Harmful to aquatic life

Human health risk assessment

Under the conditions of the occupational settings described, the risk to workers is considered to be acceptable.

When used in the proposed manner the risk to the public is considered to be acceptable.

Environmental risk assessment

The chemical is not considered to pose a risk to the environment based on its reported use pattern.

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- The notified chemical should be classified as follows under the ADG Code:
  - Class 3 (Flammable liquids)

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced in coating product:
  - Avoid contact with skin and eyes
  - Avoid splashes and spills
  - Wash eye promptly if exposed
  - Do not breathe spray
  - Use local exhaust ventilation

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced in coating product:
  - Suitable protective clothing
  - Eye/face protection
  - Suitable gloves
  - Suitable respirators wherever inhalation exposure to spray or vapours is possible

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

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical as introduced and in the formulated paint product:
  - Avoid generation of aerosols during paint formulation and preparation
  - Use adequate general and local exhaust ventilation

- A copy of the MSDS should be easily accessible to employees.

- 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.

Environment

Disposal

- The notified chemical should be disposed of to landfill. Do not allow material or contaminated packaging to enter drains, sewers or watercourses.

Storage

- The notified chemical as introduced should be stored consistent with provisions of State and Territory legislation regarding the Storage of Flammable Liquids.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by containment and absorption using non-combustible material. Material should be collected and placed in closed containers for disposal to landfill.

Transport and Packaging

- The notified chemical as introduced should be transported and packaged consistent with provisions of State and Territory legislation regarding the Storage of Flammable Liquids.

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 coating products (paints/lacquers/varnishes) or thinners (for diluting coatings prior to applications) for application to yachts, or is likely to change significantly;
- the amount of chemical being introduced has increased to more than 10 tonnes per annum, or is likely to increase, significantly;
- if 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 products containing the notified chemical provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Freezing Point < -20 ± 0.5°C

METHOD EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks The test substance did not change state during cooling in a dry ice/acetone bath.
TEST FACILITY SafePharm Laboratories Ltd. (2006a)

Boiling Point 161°C at 99.13 and 100.8 kPa

METHOD EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks Determined by differential Scanning Calorimetry (DSC)
TEST FACILITY SafePharm Laboratories Ltd. (2006a)

Density 948 kg/m^3 at 19.8 ± 0.5°C

METHOD EC Directive 92/69/EEC A.3 Relative Density.
Remarks Pycnometer method.
TEST FACILITY SafePharm Laboratories Ltd. (2006b)

Vapour Pressure 0.232 kPa at 25°C

METHOD EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks An isoteniscope system was used, in which the sample's vapour pressure is measured using a mercury in glass manometer.
The notified chemical is highly volatile.
TEST FACILITY SafePharm Laboratories Ltd. (2006c)

Water Solubility 53.2 g/L at 20°C ± 0.5°C (highly water soluble)

METHOD EC Directive 92/69/EEC A.6 Water Solubility.
Remarks Flask Method Analytical Method: Gas Chromatography
It is evident from the information obtained in the hydrolysis test and data relating to the pH of the test material in water that negligible hydrolysis of the sample solution would have occurred during the course of the water solubility test, and presumably loss by volatilisation was minimised by the use of stoppered flasks. However, there was an additional peak evident in the example chromatogram provided that was present at only a low level in the chromatogram for the standard.
TEST FACILITY SafePharm Laboratories Ltd. (2006a)

Hydrolysis as a Function of pH

METHOD EC Directive 92/69/EEC C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH.

pH	*T (°C)*	*$t_{½}$ <hours or days>*
4	25	> 1 year
7	25	> 1 year
9	25	9.67 days

Remarks Stoppered flasks were used, which would have minimised losses by volatility. The notified chemical is stable to hydrolysis at pH 4 and 7, but is moderately hydrolysing at pH 9.
TEST FACILITY SafePharm Laboratories Ltd. (2006b)

Partition Coefficient (n-octanol/water) log P_{ow} at 20°C = 1.43

METHOD EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks Analytical Method: HPLC.
A preliminary estimation (log P_{ow} = 1.14) was based on the solubilities of the

notified chemical in octanol and water. Six reference substances with log P_{ow} ranging from 0.3 for 2-butanone to 3.6 for naphthalene were used to establish the calibration range. The retention time of the notified chemical was within this range. The notified chemical prefers the water phase and is unlikely to bioaccumulate.

TEST FACILITY SafePharm Laboratories Ltd. (2006a)

Surface Tension 65.5 mN/m at 21.4 ± 0.5°C

METHOD EC Directive 92/69/EEC A.5 Surface Tension.
Remarks A tension balance was used based on the ring method.
Concentration: 1.07 g/L
The test material is considered not to be a surface-active material.
TEST FACILITY SafePharm Laboratories Ltd. (2006b)

Adsorption/Desorption log K_{oc} = 1.04 at 30°C
– screening test

METHOD EC Directive 2001/59/EC C.19 Estimation of the Adsorption Coefficient (Koc) on Soil and on Sewage Sludge using High Performance Liquid Chromatography
Remarks HPLC screening method. Twelve reference substances with log Koc ranging from 1.25 for acetanilide to 5.63 for DDT were used to establish the calibration range. The retention time of the notified chemical was slightly below that for acetanilide.
TEST FACILITY SafePharm Laboratories Ltd. (2006b)

Flash Point 54 ± 2°C at 101.62 kPa

METHOD EC Directive 92/69/EEC A.9 Flash Point.
Remarks Closed cup equilibrium method.
TEST FACILITY SafePharm Laboratories Ltd. (2006d)

Autoignition Temperature 340 ± 5°C

METHOD 92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases).
Remarks Flask method.
TEST FACILITY SafePharm Laboratories Ltd. (2006c)

Explosive Properties Not explosive

Remarks Estimated based on the chemical structure according to EC Directive 92/69/EEC A14

Oxidising Properties Not oxidising

Remarks Estimated based on the chemical structure according to EC Directive 2004/73/EC A.21

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method. EC Directive 2004/73/EC B.1tris Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/ Sprague-Dawley Crl:CD® (SD) IGS BR
Vehicle	None (undiluted)
Remarks - Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	6 F	2000	0

LD50	> 2500 mg/kg bw
Signs of Toxicity	Signs of systemic toxicity noted during the study were hunched posture, ataxia and pilo-erection. All animals appeared normal one day after dosing. All animals showed expected gains in bodyweight over the study period.
Effects in Organs	No abnormalities were noted at necropsy.
CONCLUSION	The notified chemical is of low toxicity *via* the oral route.
TEST FACILITY	SafePharm Laboratories Ltd. (2006e)

B.2. Acute toxicity – dermal

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 402 Acute Dermal Toxicity. EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal).
Species/Strain	Rat/ Sprague-Dawley Crl:CD® (SD) IGS BR
Vehicle	None (undiluted)
Type of dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 per sex	2000	0

LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	There were no signs of dermal irritation.
Signs of Toxicity - Systemic	There were no signs of systemic toxicity. All animals showed expected gains in bodyweight over the study period.
Effects in Organs	No abnormalities were noted at necropsy.
CONCLUSION	The notified chemical is of low toxicity *via* the dermal route.
TEST FACILITY	SafePharm Laboratories Ltd. (2007)

B.3. Acute toxicity – inhalation

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 403 Acute Inhalation Toxicity. EC Directive 92/69/EEC, 93/21/EEC B.2 Acute Toxicity (Inhalation).
Species/Strain	Rat/ Sprague-Dawley Crl:CD® (SD) IGS BR
Vehicle	None (undiluted)
Method of Exposure	Nose only exposure.
Exposure Period	4 hours
Physical Form	Aerosol
Particle Size	Mean mass median aerodynamic diameter = 3.78 μm Inhalable fraction (< 4μm, as defined by the investigators) = 53.0%
Remarks - Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Mean atmospheric concentration (mg/L)*		*Mortality*
		Nominal	*Actual*	
1	5 per sex	33.2*	5.55	0

*The nominal concentration is calculated from "Total test material"/"Total air flow", it does not take into account that the test material will tend to adhere to pipe work and walls of the exposure chamber or that dense particles may not become airborne and simply drop to the floor of the exposure chamber.

LC50	> 5.55 mg/L/4 hours
Signs of Toxicity	Common abnormalities noted during the study included increased respiratory rate, hunched posture, pilo-erection and wet fur. The latter three observations are considered to be associated with the restraint procedure and, in isolation, are not indicative of toxicity. Animals recovered quickly to appear normal from days 4 to 5 post-exposure. Normal bodyweight development was noted for all animals during the study.
Effects in Organs	No macroscopic abnormalities were detected amongst animals at necropsy.
CONCLUSION	The notified chemical is of low toxicity *via* inhalation.
TEST FACILITY	SafePharm Laboratories Ltd. (2006f)

B.4. Irritation – skin

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion. EC Directive 2004/73/EC B.4 Acute Toxicity (Skin Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 M
Vehicle	None (undiluted)
Observation Period	7 days
Type of Dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0.67	1	1.33	2	72 hours	0
Oedema	0.33	0.33	1	1	72 hours	0

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

Remarks - Results

Very slight to well-defined erythema was noted at all treated skin sites at the 24-hour observation with very slight erythema noted at all treated skin sites at the 48-hour observation and at two treated skin sites at the 72-hour observation.
Very slight oedema was noted at all treated skin sites at the 24-hour observation and at one treated skin site at the 48 and 72-hour observations.
Treated skin sites appeared normal 72 hours after treatment in one animal, and after 7 days in the second. Slight desquamation was noted in the third animal, 7 days post-treatment.

CONCLUSION

The notified chemical is slightly irritating to the skin.

TEST FACILITY

SafePharm Laboratories Ltd. (2006g)

B.5. Irritation – eye

TEST SUBSTANCE

Notified chemical

METHOD

OECD TG 405 Acute Eye Irritation/Corrosion.
EC Directive 2004/73/EC B.5 Acute Toxicity (Eye Irritation).

Species/Strain: Rabbit/New Zealand White
Number of Animals: 3 M
Observation Period: 72 h

Remarks - Method

Initially a single rabbit was treated. Instillation of the test substance resulted in a moderate initial pain response. After consideration of the ocular responses produced in the first treated animal, two additional animals were treated. In order to minimise pain on application of the test material, one drop of local anaesthetic (Amethocaine hydrochloride 0.5 %) was instilled into both eyes of these animals 1 to 2 minutes before treatment.

RESULTS

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

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

Remarks - Results

Minimal conjunctival irritation was noted in two treated eyes one hour after treatment.
One treated eye appeared normal throughout the study and the remaining two treated eyes appeared normal at the 24-hour observation.

CONCLUSION

The notified chemical is slightly irritating to the eye.

TEST FACILITY

SafePharm Laboratories Ltd. (2006h)

B.6. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE

Notified chemical

METHOD

OECD 429 Skin Sensitisation: Local Lymph Node Assay.
EC Directive 2004/73/EC B.42 Skin Sensitisation (Local Lymph Node Assay).

Species/Strain	Female Mouse/CBA/Ca CruBR
Vehicle	Acetone/olive oil 4:1
Remarks - Method	No signs of systemic toxicity were noted during preliminary screening test. Based on this information the dose levels selected for the main test were 25% and 50% v/v in acetone/olive oil 4:1 and 100%.

RESULTS

Concentration (% v/v)	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance		
0 (vehicle control)	1697.72 ± 648.50	1.0
25	1236.38 ± 257.88	0.73
50	1364.62 ± 465.06	0.80
100	885.36 ± 223.93	0.52
*Positive Control**		
5		2.50**
10		4.03**
25		9.13**

*α-Hexylcinnamaldehyde, Tech, 85% in 4:1 (v/v) acetone/olive oil
**Most recent historical data for the positive control substance.

Remarks - Results	A stimulation index of less than 3 was recorded for the three concentrations of the test material (25% and 50% v/v in acetone/olive oil 4:1 and 100%). There were no deaths. No signs of systemic toxicity were noted in the test or control animals during the test. Bodyweight changes of the test animals between Day 1 and Day 6 were comparable to those observed in the corresponding control group animals over the same period.
CONCLUSION	There was no evidence of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical.
TEST FACILITY	SafePharm Laboratories Ltd. (2006i)

B.7. Repeat dose toxicity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents. EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral).
Species/Strain	Rat/Sprague-Dawley Crl:CD® (SD) IGS BR
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 7 days per week
Vehicle	Arachis oil BP
Remarks - Method	No significant protocol deviations.

RESULTS

Dose mg/kg bw/day	*Number and Sex of Animals*	*Mortality*
0	5 per sex	0/10
15	5 per sex	0/10
150	5 per sex	0/10
1000	5 per sex	0/10

Mortality and Time to Death
There were no unscheduled deaths.

Clinical Observations

No clinically observable signs of toxicity were detected in test or control animals throughout the study period. There were no treatment-related changes in measured behavioural parameters. Instances of transient increased salivation were noted in all treatment groups, but particularly in animals treated with 1000 mg/kg bw/day, from Day 2 (females) and from Day 7 (males). This was considered to be due to oral administration of an unpalatable or irritant test material. Males from all treatment groups showed a statistically significant reduction in the second test of mean hind limb grip strength. Females treated with 150 or 1000 mg/kg bw/day showed a significant reduction in the asymptotic period of activity and mobile activity. These findings were considered by the investigators to be of no toxicological significance in the absence of any other observations that might suggest neurotoxicity.

There were no treatment-related changes in sensory reactivity. No adverse effects on bodyweight development or on food or water consumption were detected.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

No toxicologically significant changes were detected in blood chemistry or haematology.

Males treated with 1000 mg/kg bw/day showed a reduction in eosinophil count, increased plasma creatinine, and reduced plasma albumin/globulin ratio. Females treated at all dose levels showed significantly reduced plasma potassium concentrations These findings were considered by the investigators to have arisen fortuitously or to be due to higher than average control values.

Effects in Organs

Treated females showed statistically significant changes in organ weights, both absolute and bodyweight-relative: increases in kidney (1000 mg/kg bw/day) and reductions in liver (15 or 150 mg/kg bw/day).

No macroscopic abnormalities were detected at necropsy. Upon microscopic investigation, globular accumulations of eosinophilic material were observed in the tubular epithelium of the kidney in males treated with 1000 mg/kg bw/day, but not at any other treatment level. This finding is consistent the presence of hydrocarbon nephropathy, which results from the excessive accumulation of α_2-microglobulin in renal proximal tubular epithelial cells. Sections of kidney from all affected high dose male animals stained positively with Mallory-Heidenhain stain. α_2-microglobulin is found only in the proximal tubular epithelium of adult male rats.

Remarks – Results

There might be correlations between in the toxicological effects that were dismissed as being of no relevance by the investigators and possible effects on kidney, eg, the changes in renal blood parameters (effects in males: reduced eosinophils, increase in increases in serum creatinine, reduced albumin/globumin; effects in females: plasma electrolyte changes, increased kidney weights). The effects in the males might result from eosinophilic α_2-microglobulin deposition in renal proximal tubules.

CONCLUSION

The No Observed (Adverse) Effect Level (NOAEL) was established as 1000 mg/kg bw/day for females and 150 mg/kg bw/day for males in this study, based on the results of this study.

TEST FACILITY SafePharm Laboratories Ltd. (2006j)

B.8. Genotoxicity – bacteria

TEST SUBSTANCE	Notified chemical
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
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100, TA102
Metabolic Activation System	Liver fraction (S9 mix) from rats pretreated with phenobarbitone/β-naphthoflavone
Concentration Range in Main Test	a) With metabolic activation: 0, 50, 150, 500, 1500, 5000 µg/plate b) Without metabolic activation: 0, 50, 150, 500, 1500, 5000 µg/plate
Vehicle	Sterile distilled water
Physical Form	Gas/vapour

Remarks - Method	No significant protocol deviations.

RESULTS

Remarks - Results	The test material caused no visible reduction in the growth of the bacterial background lawn at any dose level. The test material was, therefore, tested up to the maximum recommended dose level of 5000 µg/plate. No test material precipitate was observed on the plates at any of the doses tested in either the presence or absence of S9-mix. No significant increases in the frequency of revertant colonies were recorded for any of the strains of *Salmonella*, at any dose level either with or without metabolic activation. All the positive control chemicals used in the test induced marked increases in the frequency of revertant colonies thus confirming the activity of the S9-mix and the sensitivity of the bacterial strains.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	SafePharm Laboratories Ltd. (2006k)

B.9. Genotoxicity – *in vitro*

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 473 In vitro Mammalian Chromosome Aberration Test. EC Directive 2000/32/EC B.10 Mutagenicity - In vitro Mammalian Chromosome Aberration Test.
Species/Strain	Human
Cell Type/Cell Line	Lymphocyte cells
Metabolic Activation System	Liver fraction (S9 mix) from rats pretreated with phenobarbitone/β-naphthoflavone
Vehicle	Minimal Essential Medium (MEM)
Remarks - Method	No significant protocol deviations. The dose level was set based on a preliminary toxicity test using concentrations of 5.70 to 1460 µg/mL. No cytotoxicity or precipitation was observed, so the maximum concentration was set as 1460 µg/mL (equivalent of 10 mM notified chemical).

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0*, 45.63, 91.25, 182.5, 365*, 730*, 1460*	4 hr	24 hr
Test 2	0*, 91.25, 182.5, 365, 730*, 1095*, 1460*	24 hr	24 hr
Present			
Test 1	0*, 45.63, 91.25, 182.5, 365*, 730*, 1460*	4 hr	24 hr
Test 2	0*, 45.63, 91.25, 182.5, 365*, 730*, 1460*	4 hr	24 hr

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent	> 1460			
Test 1		> 1460	> 1460	negative
Test 2		> 1460	> 1460	negative
Present	> 1460			
Test 1		> 1460	> 1460	negative
Test 2		> 1460	> 1460	negative

Remarks - Results	All vehicle (solvent) controls had frequencies of cells with aberrations within the range expected for normal human lymphocytes. All the positive control materials induced statistically significant increases in the frequency of cells with aberrations indicating the satisfactory performance of the test and of the activity of the metabolising system.
CONCLUSION	The notified chemical was not clastogenic to human lymphocytes treated *in vitro* under the conditions of the test.
TEST FACILITY	SafePharm Laboratories Ltd. (2006l)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 D Ready Biodegradability: Closed Bottle Test.
Inoculum	Sewage sludge microorganisms from the final effluent stage of a domestic treatment plant (Loughborough, Leicestershire UK).
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	BOD
Remarks - Method	No significant protocol deviations. A closed bottle test was used due to the volatility of the notified chemical. Test concentration: 2.0 mg/L Reference material: sodium benzoate Test conducted in duplicate, with determination of dissolved oxygen content at each sampling occasion to indicate oxygen depletion relative to the theoretical oxygen demand (ThOD - calculated to be 1.97 mg O_2/mg).

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
3	27	3	59
5	26	5	58
7	25	7	60
11	33	11	61
14	36	14	63
18	60	18	63
21	58	21	67
24	62	24	68
28	64	28	72

Remarks - Results	10% biodegradation was achieved after 3 days, 60% after 18 days and 64% after 28 days. While not meeting the strict 10-day window validation criterion for ready biodegradation this indicates that the notified chemical will biodegrade in the environment. The reference substance reached 60% degradation by day 10 and 72% after 28 days, confirming the suitability of the test method and culture conditions, and testing of the notified chemical together with the reference substance confirmed it was not toxic to sewage sludge organisms.
CONCLUSION	The notified chemical cannot be considered readily biodegradable under OECD Guideline No 301B, but has exhibited potential for biodegradation.
TEST FACILITY	SafePharm Laboratories Ltd. (2006m)

C.1.2. Bioaccumulation

The notified chemical is not expected to bioaccumulate based upon its potential for degradation and low log Pow.

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test – semi-static conditions. EC Directive 92/69/EEC C.1 Acute Toxicity for Fish – 96 h, semi-static.
Species	Rainbow trout (*Oncorhynchus mykiss*)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	ca. 100 mg $CaCO_3$/L
Analytical Monitoring	GC
Remarks – Method	No significant protocol deviations. Single replicate; 20 L glass test vessels completely filled and sealed, with no aeration. Solutions renewed at 24 h intervals. Temperature 14.0 - 16.3ºC and pH 7.0 - 7.6 throughout the test, and oxygen concentration 10.8 -11.3 mg O_2/L in new solutions and 4.9 -8.6 mg O_2/L in 24 h old media, with no treatment related differences.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*3 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control	<LOQ	7	0	0	0	0	0
10	5.6	7	0	0	0	0	0
18	13	7	0	0	0	1	3
32	28	7	0	0	0	1	4
56	53	7	0	0	3	7	7
100	10	7	0	7	7	7	7

LC50	Time-weighted mean measured test concentrations: 73 mg/L at 24 hours. 55 mg/L at 48 hours. 30 mg/L at 72 hours. 19 mg/L at 96 hours (95% confidence limits 11 - 28 mg/L using probit analysis).
NOEC	5.6 mg/L at 96 hours.
Remarks – Results	A large decline in concentration over each 24 h period before renewal was not expected, due to the notified chemical's claimed stability and precautions to minimise loss by volatility by sealing. Sub-lethal effects were evident at a nominal concentration of 18 mg/L (1/4 remaining fish with increased pigmentation at 96 h), with other effects (swimming at bottom, moribund, swimming at surface) evident at higher concentrations, as early as 6 h at 100 mg/L.
CONCLUSION	The notified chemical is harmful to rainbow trout, with a 96 h LC50 = 19 mg/L (measured concentrations)
TEST FACILITY	SafePharm Laboratories Ltd. (2006n)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test– 48 h static. EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia - 48 h static.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None

Water Hardness	ca. 250 mg $CaCO_3$/L
Analytical Monitoring	GC
Remarks – Method	No significant protocol deviations. Four replicates; minimal headspace and sealing of the conical flask test vessels were used to prevent losses of the test material due to volatility. Measured concentrations were only obtained for the 100 mg/L treatment. Temperature 19.9 - 21.2ºC, pH 7.7 - 7.9 and oxygen concentration 8.5-8.7 mg O_2/L throughout the test. Test was also conducted with potassium dichromate as a positive control.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
Control	<LOQ	20	0	0
0.10		20	0	0
1.0		20	0	0
10		20	0	0
100	Mean 88.4	20	0	0

LC50	Nominal concentration > 100 mg/L at 24 hours > 100 mg/L at 48 hours
NOEC	100 mg/L at 48 hours
Remarks - Results	Results were consistent with a range-finding test, where no mortalities occurred over the same range. Results for the positive control were within the normal range.

CONCLUSION The notified chemical is not harmful to the waterflea *Daphnia magna* based on nominal concentrations.

TEST FACILITY SafePharm Laboratories Ltd. (2006o)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified chemical

METHOD OECD TG 201 Alga, Growth Inhibition Test.
EC Directive 92/69/EEC C.3 Algal Inhibition Test.

Species	*Scenedesmus subspicatus*
Exposure Period	72 hours
Concentration Range	Nominal: Limit test at 100 mg/L Actual: Mean measured concentrations = 35 mg/L
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	GC
Remarks - Method	The conical flask test vessels were completely filled and sealed, with bicarbonate added as a source of CO_2. The mean measured concentration at 0 h was 81.6 mg/L and at 72 h was 14.8 mg/L in test vessels, but was 49.5 mg/L in extra vessels which had not been opened for daily sampling for algal cell density, hence loss was presumably exacerbated by volatilisation during daily opening. Temperature 24 ± 1ºC throughout the test, pH 7.8 at 0 h increasing to 9.8 at 72 h, exceeding the guideline limit of 1.5 pH units after 72 h, but not considered to have adversely affected the results of the study given that the increase in cell concentration in the cultures exceeded the guideline validation criterion.

RESULTS

Biomass	*Growth*

EbC50 *mg/L at 72 h*	*NOEC* *mg/L*	*ErC50* *mg/L at 72 h*	*NOEC* *mg/L*
> 35	35	> 35	35

Remarks - Results	Geometric mean of initial and final measured concentrations: EbC50, ErC50 (0 – 72 h) > 35 mg/L NOEC (0 – 72 h) = 35 mg/L
CONCLUSION	The notified chemical is not harmful to algae based on nominal concentrations, but based on measured concentrations is classified as at most harmful to algae.
TEST FACILITY	SafePharm Laboratories Ltd. (2006p)

C.2.4. Inhibition of microbial activity

This test was not conducted due to the volatility of the notified chemical. A toxicity control was run as part of the ready biodegradation test, and showed no toxic effects. Therefore it is reasonable to assume that the notified chemical would not be toxic to sewage treatment plant micro-organisms.

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