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February 2010

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

1,3-Benzenedicarboxamide, N1,N3-bis(2,2,6,6-tetramethyl-4-piperidinyl)-

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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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Clariant (Australia) Pty Ltd (ABN 30 069 435 552)
Brandon Office Park, Building 5, L2
530-540 Springvale Road
Glen Waverley, VIC 3150

Godfrey Hirst Australia Pty Ltd (ABN 58 000 849 758)
7 Factories Road
South Geelong, VIC 3220

NOTIFICATION CATEGORY
Standard: Chemical other than polymer (more than 1 tonne per year)

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
No details are claimed exempt from publication.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: Adsorption/desorption and acute inhalation toxicity.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Canada (2003)
Korea (2001)
USA (1998)
France (1996)

2. IDENTITY OF CHEMICAL

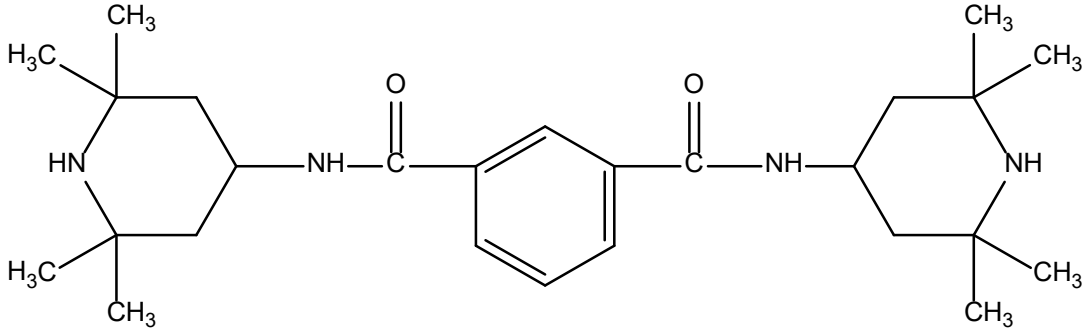
MARKETING NAME(S)
Nylostab S-EED

CAS NUMBER
42774-15-2

CHEMICAL NAME
1,3-Benzenedicarboxamide, N1,N3-bis(2,2,6,6-tetramethyl-4-piperidinyl)-

MOLECULAR FORMULA
$C_{26}H_{42}N_4O_2$

STRUCTURAL FORMULA



MOLECULAR WEIGHT
442.6 g.mol^{-1}

METHOD	Infrared Spectroscopy
Remarks	Major bands observed at: 3261, 3078, 2961, 1655, 1632, 1596, 1557, 1453, 1376, 1365, 1323, 1265, 1238, 1201 and 702 cm^{-1}. The IR spectrum is consistent with the structure of the notified chemical.
TEST FACILITY	Sandoz Pharma Ltd (1995)

METHOD	Nuclear Magnetic Resonance Spectroscopy
Remarks	Major ^{1}H NMR (DMSO) peaks not specified. Major ^{13}C NMR (DMSO) peaks: 29.16, 35.09, 42.91, 44.69, 50.92, 99.19, 126.72, 128.46, 129.96, 135.58 and 165.62 ppm. The NMR spectra are consistent with the structure of the notified chemical.
TEST FACILITY	Sandoz Pharma Ltd (1995)

METHOD	Ultraviolet / Visible Spectroscopy
Remarks	λ_{max} = 241 nm, ε = 10.7 cm^{-1} g^{-1} L. The UV-Vis spectrum is consistent with the structure of the notified chemical.
TEST FACILITY	Sandoz Pharma Ltd (1995)

METHOD	High-performance liquid chromatography
Remarks	Column: Knauer cartridge filled with RP (Hypersil) (10 cm length by 5 µm diameter). Solvent: 95% 4 g.L^{-1} ammonium acetate in water and 5% tetrahydrofuran. Temperature: 30 °C. Detector: UV detection at 230 nm. There were only two peaks observed corresponding to the solvent at 1.155 minutes and the notified chemical at 3.184 minutes.
TEST FACILITY	Clariant (1995)

3. COMPOSITION

DEGREE OF PURITY 99.3% (98.2 – 99.9%)

HAZARDOUS IMPURITIES

Chemical Name	4-Piperidinamine, 2,2,6,6-tetramethyl-		
CAS No.	36768-62-4	*Weight %*	≤ 0.2%
Hazardous Properties	R22 Harmful if swallowed		

Chemical Name	1,3-Benzenedicarbonyl dichloride		
CAS No.	99-63-8	*Weight %*	≤ 0.2%
Hazardous Properties	R21 Harmful in contact with skin R22 Harmful if swallowed R36 Irritating to eyes R38 Irritating to skin		

NON HAZARDOUS IMPURITIES

Chemical Name	Sodium chloride		
CAS No.	7647-14-5	*Weight %*	≤ 0.7%
Chemical Name	Water		
CAS No.	7732-18-5	*Weight %*	≤ 0.7%

ADDITIVES/ADJUVANTS None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: White to pale yellow powder

Property	Value	Data Source/Justification
Melting Point	275-276°C	Measured
Boiling Point	644°C	Calculated
Density	1119 kg/m^3 at 20.2°C	Measured
Vapour Pressure	1.19 × 10^{-9} kPa at 25°C	Calculated
Water Solubility	0.139 g/L at 30°C	Measured
Hydrolysis as a Function of pH	t½ > 1 year	Measured. Although the notified chemical contains hydrolysable functionalities, it does not contain any functional groups that are readily hydrolysable in the environmental pH range of 4-9.
Partition Coefficient (n-octanol/water)	log P_{OW} = 1.12 at 20°C	Measured
Adsorption/Desorption	Not determined	Despite the low log P_{OW}, the notified chemical is expected to adsorb strongly to soils and sludge sediments due to the presence of the potential cationic secondary amine groups.
Dissociation Constant	pKa = 10	Calculated. The notified chemical is expected to be ionised in the environmental pH range of 4-9.
Particle Size	Inhalable fraction (<100 μm): 99% Respirable fraction (<10 μm): 42% Median = 7 μm	MSDS
Flash Point	Not determined	The notified chemical is a solid with a melting point > 200°C
Flammability	Solids – not highly flammable Water – no evolution of gas Air – no pyrophoric properties	Measured
Autoignition Temperature	> 420°C	Measured
Explosive Properties	Not explosive	Measured
Oxidising Properties	Not oxidising	Measured

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

Reactivity
Stable under normal conditions of use. The notifier mentions that it may react with strong oxidising agents.

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.
The notified chemical will be imported either as an additive (30%) of polyamide (nylon 6) masterbatch

formulations (pellets) or as the technical grade (99.3%) product Nylostab S-EED (powder) for use in production of polyamide fibres or articles.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 50	< 50	< 50	< 50	< 50

PORT OF ENTRY
Sydney, Melbourne and Brisbane via air or sea ports.

IDENTITY OF MANUFACTURER/RECIPIENTS
Clariant (Australia) Pty Ltd
Brandon Office Park, Building 5, L2
530-540 Springvale Road
Glen Waverley, Vic 3150

Godfrey Hirst Australia Pty Ltd (Head Office)
7 Factories Road, South
Geelong, Vic 3220

Godfrey Hirst Australia Pty Ltd
(Manufacturing Plant – site of end use of 30% masterbatch formulation)
254 Canterbury Road
Bayswater, Vic 3153

TRANSPORTATION AND PACKAGING
The notified chemical will be imported as the technical grade product in either fibreboard boxes (12 kg) with 2 polyethylene bags of 6 kg net weight or in fibreboard boxes (200 kg) with 10 PE bags of 20 kg net weight. Formulated masterbatch concentrate material will be imported in 100 kg fibreboard drums with a plastic liner containing 30% notified substance in nylon 6 carrier. It is also possible that the masterbatch material will be imported in 500 kg bulk bags. Up to 10 tonnes of the introduced volume per annum will be technical grade substance and up to 40 tonnes per annum will be imported as the 30% masterbatch material.

The notified chemical will be transported by road from the port of entry to Clariant (Australia) Pty Ltd.

USE
The notified chemical will be used as a multi-functional additive for processing of polyamides (nylon). The notified chemical will be used to improve the melt processing operations of polyamides, enhance long-term heat and photo-stability as well as increasing the polyamides affinity for acid dyes. Polyamide materials containing the notified chemical are expected to be used in the moulding of nylon articles and for production of nylon 6 and nylon 66 fibres for carpet manufacture. The notified chemical will be bound in articles at a level of up to 2% by weight of the article or bound in carpet fibres at a level up to 0.6%.

OPERATION DESCRIPTION
Reformulation
The imported technical grade product Nylostab S-EED containing the notified chemical at 99.3% will be reformulated by incorporation into masterbatch formulations with nylon 6 or nylon 66 polyamide carriers. Production operators will either weigh the batch quantity of the technical grade product Nylostab S-EED or the product will be added to a loss-in-weight feeder. Weighing batches or addition to a loss-in-weight feeder will require the personnel to slit open PE bags that contain the new substance and scoop or pour the product into weighing containers or feeders under exhaust ventilation. The product will then be added to a hopper for blending with other batch additives prior to blending with polyamide in a masterbatch extruder. The resultant polyamide mixture incorporating the notified chemical at concentrations up to 40% will then be extruded and pelletised. The pelletised polyamide grades will be packaged into 25 kg bags or into 500 kg bulk bags or boxes via an automated process. Quality control personnel will be required to sample batches of additives and of the finished masterbatch grades.

Use
Production operators will either control a suction wand to take up pellets from import packaging into a feed

hopper or manually scoop the masterbatch pellets into the feed hopper. Near-emptied liner bags from the fibreboard drums will be manually shaken empty into the feed hopper.

Once the masterbatch pellets containing notified substance are enclosed in hoppers mounted above extruder machines, all further processes take place automatically under computer control. Natural nylon 6 pellets are added and the extrusion of the blended nylon 6 undergoes processes of hot melt and spinning to produce fibres. The fibres containing the notified substance at up to 0.6% undergo further automated texturising processes of cooling, freezing, distortion, crimping and rolling to produce fibres for carpet production. All extrusion and processing operations will take place under local exhaust ventilation for removal of any fumes generated during hot processing. Quality control personnel will be required to sample batches of masterbatch pellets and of the finished fibre products.

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)*
Use of technical grade			
Warehouse/ Stores personnel	8	1 hour per day	100 days per year
Production operators	20	4 hours per day	100 days per year
Production supervisors	4	4 hours per day	100 days per year
Quality control personnel	4	4 hours per day	100 days per year
Use of 30% masterbatch grade			
Warehouse/ Stores personnel	6	1 hour per day	100 days per year
Production operators	12	4 hours per day	220 days per year
Quality control personnel	4	2 hours per day	220 days per year

EXPOSURE DETAILS
It is anticipated that transport and warehouse/stores personnel would only be exposed to the notified chemical in the event of an accident.

Reformulation
Dermal, ocular and inhalation exposure to the technical grade notified chemical (99.3%) will occur during weighing of batches or addition to a loss-in-weight feeder. Exposure will be limited by the use of PPE (including dust masks, gloves and protective clothing) and the presence of local exhaust ventilation. Exposure to the notified chemical at concentrations up to 40% will also occur during the extrusion, pelletising and packaging processes; however the notified chemical will be incorporated into a polymer matrix and hence will not be bioavailable.

Use
Dermal and ocular exposure to the masterbatch pellets containing the notified chemical (at concentrations up to 40%) is possible during the transfer of them into the hoppers. Exposure to the notified chemical is expected to be limited by its incorporation into a polymer matrix where it will not be bioavailable.

6.1.2. Public exposure
The notified chemical will only be present in articles at concentrations of 2% or less and will be bound within a polymer matrix and hence will not be bioavailable. Therefore, the potential for dermal exposure to the public from the notified chemical during contact with articles containing it is expected to be low.

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	oral LD50 = 1258 mg/kg bw harmful
Rat, acute dermal toxicity	LD50 > 2000 mg/kg bw low toxicity
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	irritating
Guinea pig, skin sensitisation – adjuvant test	limited evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days.	NOAEL > 500 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro mammalian chromosome aberration test.	non genotoxic

Toxicokinetics, metabolism and distribution.
The notified chemical is expected to be absorbed across biological membranes, based on the relatively low molecular weight (442.6 Da) and the favourable physical-chemical properties (log Pow at 20ºC = 1.12, water solubility of 0.139 g/L at 30ºC). Absorption of the notified chemical across the gastrointestinal tract was confirmed by the observation of toxic effects after acute oral exposure. While no evidence for acute toxic effects was observed in the acute dermal toxicity study the possibility of dermal absorption cannot be ruled out.

The vast majority of the notified chemical (99%) is of inhalable (< 100 µm) particle size and could be inhaled into the upper respiratory tract. A significant portion (42%) is also of small enough particle size (<10 µm) to reach the lower respiratory tract (tracheobronchial and pulmonary regions). Larger particles of inhalable size are expected to deposit in the nasopharyngeal region and be cleared by coughing/sneezing or be swallowed. Due to the moderate water solubility of the notified chemical inhaled respirable particulates lodging in the tracheobronchial and pulmonary regions are expected to be cleared from the lungs, although inhalation of high airborne concentrations, may present some risk of lung overloading effects. Absorption of the notified chemical across the respiratory tract epithelium may occur due to the favourable physical-chemical properties.

Acute toxicity.
The notified chemical was found to be harmful to rats after acute dosing via the oral route. Adverse effects after oral exposure included hunched posture, lethargy, prostration, subdued behaviour and tremors. The notified chemical is of low toxicity after dermal exposure based on a study conducted in rats. No signs of local or systemic toxicity were observed during the study.

The acute and chronic inhalation hazard of the notified chemical or of the analogue has not been determined. Given the expected absorption across the respiratory tract epithelium and the signs of toxicity exhibited in the acute oral toxicity study the notified chemical may be at least harmful via inhalation.

Irritation and Sensitisation.
Based on a test conducted in rabbits the notified chemical is considered to be slightly irritating to the skin and irritating to the eye. The notified chemical was considered not to be a skin sensitiser based on tests conducted in guinea pigs.

Repeated Dose Toxicity (sub acute, sub chronic, chronic).
Oral administration of the test material to rats for a period of 28 consecutive days at dose levels of 50, 150 and 500 mg/kg/day resulted in no adverse treatment related effects at any dose level. Therefore, the NOAEL was established as > 500 mg/kg bw/day in this study.

Mutagenicity.
The notified chemical was not mutagenic in a bacterial reverse mutation test, and is not clastogenic to human peripheral lymphocytes *in vitro*.

Health hazard classification
Based on the acute oral toxicity and the eye irritation studies the notified chemical is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004), with the following risk phrases:
Xn: R22 Harmful if swallowed
Xi: R36 Irritating to eyes

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

Dermal, ocular and inhalation exposure to the notified chemical (up to 99.3% concentration) by workers is expected to be greatest during the weighing and transfer of the technical grade product into the hoppers prior to reformulation into the masterbatch pellets. Once the notified chemical is reformulated into the masterbatch pellets the notified chemical will be incorporated into a polymer matrix and hence will not be bioavailable.

Respiratory effects

The acute and chronic effects after inhalation exposure to the notified chemical were not investigated, and therefore an inhalation NOAEL can not be determined. Based on the expected absorption across the respiratory tract epithelium and the signs of toxicity exhibited in the acute oral toxicity study, the notified chemical may pose both an acute and a chronic respiratory hazard. Repeated inhalation of airborne dusts of the notified chemical, or inhalation of high airborne concentrations, may also present some risk of lung overloading effects.

The technical grade product (99.3% notified chemical) will be introduced as a powder with an inhalable fraction (< 100 μm) of 99% and a respirable fraction (< 10 μm) of 42%. Based on the potential for respiratory effects after acute or chronic exposure the inhalation risk to workers handling the powder may be significant. The notifier has specified that dust masks will be worn by workers and local exhaust ventilation will be in place during the handling of the technical grade product. If particle filter masks capable of filtering out particles of respirable size are worn by workers, the exposure to the airborne notified chemical, and therefore the risk to workers, will be significantly reduced.

Local effects

The notified chemical is an eye irritant and a slight skin irritant. Dermal and ocular exposure is expected to be minimised due to the use of personal protective equipment by workers. Therefore the risk of irritation from exposure to the notified chemical by workers is not considered to be unacceptable.

Systemic effects

The NOAEL value for the notified chemical in a 28 day oral repeat dose toxicity study was determined to be greater than or equal to the highest tested dose (500 mg/kg bw/day). The notified chemical was also of low toxicity in an acute dermal toxicity study and was determined to have a LD50 of 1258 mg/kg bw in an acute oral toxicity study. Although the notified chemical is classified as harmful if swallowed, with the PPE and engineering controls in place combined with good hygiene practices oral exposure to the notified chemical is expected to be negligible. Therefore, the risk of repeated exposure is not considered unacceptable, considering the expected use of PPE and engineering controls and the toxicological profile of the notified chemical.

6.3.2. Public health

The notified chemical will only be present in articles at concentrations of 2% or less and will be bound within a polymer matrix and hence will not be bioavailable. Therefore the risk to the public is not considered to be unacceptable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical will be imported as either the technical grade product (20% of the import volume) or 30% formulation masterbatch material (80% of the import volume), for use in production of polyamide (nylon) articles mainly for carpet manufacture.

The imported technical grade product containing the notified chemical at 99.3% will be reformulated by incorporation into masterbatch formulations at concentrations up to 40% with polyamide carriers and will be extruded and pelletised for further application. Release from this stage will occur from the residues in the emptied packaging, spillage of powder during the extrusion process, and the waste purged polymer containing the notified chemical. All of these wastes are estimated to be < 0.5% of the import volume and will be collected and sent to landfill.

RELEASE OF CHEMICAL FROM USE
The masterbatch formulations containing the notified chemical will be used in extrusion processes to produce polyamide articles or carpet fibres. After emptying of bags into feed hoppers, no residues of notified substance will remain in bags. No quantities of the masterbatch material will be released to the environment. These bags will be consigned to landfill. Fibreboard drums will be retained on site and reused on-site to store other coloured nylon masterbatch grades that have been prepared.

Waste material from the extrusion process will be reworked and included in later batches of production. Any wastes residual finished products will contain the notified chemical bound in the polyamide carrier. These wastes will be consigned to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL
It is expected that almost all of the notified chemical will be incorporated into polyamide products. Releases of the notified chemical will be limited and would be sent to landfill if they occurred. The waste product containing the notified chemical is expected to be sent to an approved landfill site.

7.1.2 Environmental fate

The notified chemical is not readily biodegradable. Its potential for bioaccumulation is expected to be low due to its low P_{OW} and its potential to be ionised in the environment. In addition, no significant release of the notified chemical to the water compartment is expected based on the reported use pattern. Therefore, the notified chemical is not considered to be bioavailable to aquatic life. For the details of the environmental fate studies refer to Appendix C.

Most of the notified chemical will be incorporated into the polyamide finished articles and will be immobilized, sharing the fate of the polyamide matrix. At the end of the polyamide articles' life, the notified chemical will most likely be sent to landfill, undergo slow biotic and abiotic degradation to form water and oxides of nitrogen and carbon.

7.1.3 Predicted Environmental Concentration (PEC)

A PEC has not been calculated since no significant release of the notified chemical to the environment is expected from 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 C.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	96 h LC50 > 250 mg/L	Not harmful
Daphnia Toxicity	48 h EC50 > 250mg/L	Not harmful
Algal Toxicity	72 h EC50 > 250 mg/L	Not harmful
Inhibition of Bacterial Respiration	IC50 > 1000 mg/L	Not harmful
Daphnia 21 day reproduction	NOEC = 100 mg/L	Not harmful

The notified chemical is not harmful to aquatic organisms.

7.2.1 Predicted No-Effect Concentration

The calculation of PNEC has not been conducted since no significant release of the notified chemical to the environment is expected based on the reported use pattern.

7.3. Environmental risk assessment
A Risk Quotient (Q = PEC/PNEC) has not been calculated due to the low exposure expected based on the proposed use pattern. The notified chemical is not expected to pose an unacceptable risk to the environment based on the reported use pattern and the low ecotoxicity to aquatic life.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available data the notified chemical is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)], with the following risk phrases:

- Xn: R22 Harmful if swallowed
- Xi: R36 Irritating to eyes

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***
Acute toxicity	Category 4	Harmful if swallowed
Eye irritation	Category 2A	Causes serious eye irritation

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

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

Environmental risk assessment
On the basis of the reported use pattern, the notified chemical 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, environmental and physico-chemical] hazard classification for the notified chemical:
  - Xn: R22 Harmful if swallowed
  - Xi: R36 Irritating to eyes

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - Conc ≥ 25%: R22; R36
  - ≥ 20% Conc < 25%: R36

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical when introduced in the powdered technical grade product:
  - Local exhaust ventilation wherever weighing and transfer of the powdered product occurs

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical when introduced in the powdered technical grade product:
  - Avoid the formation of airborne dusts
  - Avoid skin and eye contact
  - Regularly clean up any spills of the powdered technical grade product

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical when introduced in the powdered technical grade product:
  - Respiratory protection sufficient for respirable particulates during processes where exposure to dust is likely
  - Safety glasses

  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.

- 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 an additive for processing of polyamides or is likely to change significantly;
  - the amount of chemical being introduced has increased from 50 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 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

Melting Point/Freezing Point 275-276ºC

Method OECD TG 102 Melting Point/Melting Range.
EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks Determined using the capillary method.
No significant protocol deviations.
Test Facility Pharmakon (1996a)

Boiling Point 644ºC

Method Adapted Stein and Brown Method
Test Facility Chrysalis (1997)

Density 1119 kg/m^3 at 20.2ºC

Method OECD TG 109 Density of Liquids and Solids.
EC Directive 92/69/EEC A.3 Relative Density.
Remarks The relative density was determined using the pycnometer method.
No significant protocol deviations.
Test Facility RCC (1999a)

Vapour Pressure 1.19×10^{-12} Pa at 25ºC

Method Modified Grain method
Remarks The vapour pressure was also calculated to be;
9.15×10^{-18} Pa at 25ºC (Antoine method)
4.77×10^{-10} Pa at 25ºC (Mackay method)
Test Facility Chrysalis (1997)

Water Solubility 0.139 g/L at 30ºC and pH 10

Method OECD TG 105 Water Solubility.
EC Directive 92/69/EEC A.6 Water Solubility.
Remarks Flask Method. Following a range-finding test, the notified chemical (~50 mg) was mixed with water (~50 mL). After one day of agitation at 30ºC, the mixtures were further re-equilibrated for 24, 48 and 72 hours at the same temperature. A solubility of 0.139 g/L was determined by HPLC analyses of the supernatant fractions of the centrifuged samples. The notified chemical is considered to be moderately soluble in water.
Test Facility Pharmakon (1996a)

Hydrolysis as a Function of pH

Method OECD TG 111 Hydrolysis as a Function of pH.
EC Directive 92/69/EEC C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH.

pH	*T (ºC)*	*t½ (hours)*
4	50	> 120
7	50	> 120
9	50	> 120

Remarks The test was performed in 100 mL volumetric flasks in duplicates for each pH, at 50ºC under continuous magnetic stirring. Samplings at different time intervals were analysed by HPLC. Less than 10% hydrolysis was observed after 5 days for each of the pH value, which is considered to be equivalent to a half life of > 1 year at 25ºC. The notified chemical is considered to be hydrolytically stable.
Test Facility Pharmakon (1997a)

Partition Coefficient (n-octanol/water) log P_{OW} = 1.12 at 20ºC

Method OECD TG 107 Partition Coefficient (n-octanol/water).
EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks Shake Flask Method. A preliminary estimate of the P_{OW} value was estimated to be 79.14 from solubility of the notified chemical in water and n-octanol. Three samples were prepared in duplicates for the test: sample at the calculated volume ratio, sample with twice the n-octanol volume and sample with half the n-octanol volume. Test samples were prepared by agitation followed by centrifuge at 20ºC, and were analysed by HPLC.
Test Facility Pharmakon (1996a)

Dissociation Constant pKa = 10

Method Calculated by using Taft & Hammett correlations based on the presence of secondary amine groups in the notified chemical.
Remarks Nylostab S-EED can be protonated at the secondary amino group in aqueous solutions. The notified chemical is expected to be ionised at the environmental pH range of 4-9.
Test Facility RCC Ltd (1999b)

Flammability Solids – not highly flammable
Water – no evolution of gas
Air – no pyrophoric properties

Method EC Directive 92/69/EEC A.10 Flammability (Solids)[1]
EC Directive 92/69/EEC A.11 Flammability (Gases)[2]
EC Directive 92/69/EEC A.12 Flammability (Contact with Water)[2]
Remarks All three of the above methods were used.
No significant protocol deviations.
Test Facility Pharmakon (1996b)[1]
Pharmakon (1997b)[2]

Autoignition Temperature > 420ºC

Method EC Directive 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Remarks No significant protocol deviations.
Test Facility Pharmakon (1997b)

Explosive Properties Not explosive

Method EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks Tested for thermal, shock and friction sensitivity.
No significant protocol deviations.
Test Facility Pharmakon (1997b)

Oxidizing Properties Not oxidising

Method EC Directive 92/69/EEC A.17 Oxidizing Properties (Solids).
Remarks Mixtures of the test article with cellulose were measured with barium nitrate used as a control reference.
No significant protocol deviations.
Test Facility Pharmakon (1997b)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 401 Acute Oral Toxicity. EC Directive 92/69/EEC B.1 Acute Toxicity (Oral).
Species/Strain	Rat/Sprague-Dawley
Vehicle	1% Aqueous dispersion of carboxymethylcellulose
Remarks - Method	No significant protocol deviations. All animals were dosed by gavage. The study was performed in comparison with a control group of 5 males and 5 females treated with the vehicle under the same conditions. The preliminary study was conducted using 2 animals per sex at each of 3 dose levels (500, 1000 and 2000 mg/kg). In the preliminary study one female animal died in the 1000 mg/kg dose group as well as all the animals in the 2000 mg/kg dose group.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
Control	5 per sex	0	0/10
I	5 per sex	1000	3/10
II	5 per sex	1260	4/10
III	5 per sex	1590	8/10

LD50	1258 (95% CI 1069 - 1480) mg/kg bw
Signs of Toxicity	All deaths occurred within 1 to 4 hours of the animals being dosed. Abnormal clinical signs in the treated animals appeared 1 hour after administration of the test article. Lethargy, prostration, subdued behaviour and tremors were observed until 4 hours after treatment.
Effects in Organs	No abnormalities were noted at necroscopy
Remarks - Results	Body weight gains were as expected.
CONCLUSION	The notified chemical is harmful via the oral route.
TEST FACILITY	Pharmakon (1996c)

B.2. Acute toxicity – dermal

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 402 Acute Dermal Toxicity – Limit Test. EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal) – Limit Test.
Species/Strain	Rat/Sprague-Dawley
Vehicle	Water
Type of dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5 per sex	2000	1/10

LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	There were no test substance-related dermal reactions.

Signs of Toxicity - Systemic	One male rat was found dead on day 2. There were no other signs of systemic toxicity.
Effects in Organs	No abnormalities were noted at necroscopy.
Remarks - Results	Body weight gains were as expected.

CONCLUSION The notified chemical is of low toxicity via the dermal route.

TEST FACILITY Pharmakon (1996d)

B.3. Irritation – skin

TEST SUBSTANCE Notified chemical

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.
EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).

Species/Strain	Rabbit/New Zealand White
Number of Animals	3 male
Vehicle	Water
Observation Period	72 Hours
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	0.33	0	1	< 48 hours	0
Oedema	0	0	0	0	0	0

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

Remarks - Results	A single 4-hour, semi-occluded application of the test material to the intact skin of the three rabbits produced very slight erythema on one animal at the 24 hour observation. No further irritation effects were noted.

CONCLUSION The notified chemical is slightly irritating to the skin.

TEST FACILITY Pharmakon (1996e)

B.4. Irritation – eye

TEST SUBSTANCE Notified chemical

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).

Species/Strain	Rabbit/New Zealand White
Number of Animals	3 Male
Observation Period	14 Days
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			
Conjunctiva: redness	1.7	1.3	1.7	2	< 14 days	0
Conjunctiva: chemosis	1.3	1.3	1.7	3	< 7 days	0
Conjunctiva: discharge						
Corneal opacity	2	2	2	2	< 7 days	0
Iridial inflammation	1	1	1	1	< 14 days	0

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

Remarks - Results

Conjunctival discharge was not recorded.

All effects were reversible within the 14 day observation period.

CONCLUSION

The notified chemical is irritating to the eye.

TEST FACILITY

Pharmakon (1996f)

B.5. Skin sensitisation

TEST SUBSTANCE

Notified chemical

METHOD

OECD TG 406 Skin Sensitisation – Guinea Pig Maximisation Test
EC Directive 96/54/EC B.6 Skin Sensitisation - Guinea Pig Maximisation Test

Species/Strain

Guinea pig/albino Hartley

PRELIMINARY STUDY

Maximum Non-irritating Concentration:
intradermal: < 1%
topical: 60%

MAIN STUDY

Number of Animals

Test Group: 20 Control Group: 10

INDUCTION PHASE

Induction Concentration:
intradermal: 10% (w/w) with ethanol used as the vehicle.
topical: 60% (w/w) in a paste with ethanol as the vehicle.

Signs of Irritation

Signs of irritation in the induction phase were not recorded however injection of the test article in a 10% solution provoked a moderate irritation with burnt appearance to the injection sites during the preliminary study.

CHALLENGE PHASE

1st challenge

topical: 60%

Remarks - Method

In the preliminary study a topical application using an 8 cm^2 patch applied for 48 hours produced mild irritation while an 4 cm^2 patch applied for 24 hours at the same concentrations did not.

As the topical application at 60% only provoked a weak irritation during the preliminary study, a skin painting was performed during the induction phase, with 0.5 ml of sodium lauryl sulphate at 10% (w/w) in Codex paraffin to create irritation.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*			
		1st challenge		*2nd challenge*	
		24 h	*48 h*	*24 h*	*48 h*
Test Group	60%	1/20	1/20	-	-
Vehicle Control Group		0/10	0/10	-	-

Remarks - Results	There were no deaths or substance-related signs of toxicity during the study. On first challenge 1/20 (5%) animal showed scores of 2 and 1 at the 24 and 48 hour observations respectively. This was below the 30% cut-off for evidence of positive responses to meet the classification criteria. Histopathological examinations on one further animal at 24 hours revealed slight to minimal dermal and epidermal effects. The positive control confirmed the sensitivity of the test system.
CONCLUSION	There was only limited evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test. Therefore, the notified chemical was not considered a skin sensitiser.
TEST FACILITY	Pharmakon (1996g)

B.6. 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: Ico: OFA.SD. (IOPS Caw)
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 7 days per week Post-exposure observation period: none
Vehicle	1% Caboxymethylcellulose in water
Remarks - Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
control	5 per sex	0	0/10
low dose	5 per sex	50	0/10
mid dose	5 per sex	150	0/10
high dose	5 per sex	500	0/10

Mortality and Time to Death

There were no unscheduled deaths during the study.

Clinical Observations

There were no treatment related clinical signs noted during the study. There were no significant differences in the bodyweight gain and food consumption between the control and treated groups.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Male rats in the high dose group had slight but statistically significant high mean corpuscular haemoglobin levels and low red blood cell counts compared to the control group. Male rats in the mid dose group also showed a significant increase in aspartate aminotransferase levels. All three of the above effects were within the normal historical range and therefore there were no changes in the haematology, blood clinical chemistry and urinalysis parameters which could be attributed to treatment.

Effects in Organs

There was a reduction in absolute and relative mean kidney and liver weights in low dose males and a reduction of only the relative mean liver weight in high dose males. These findings were not seen in the other dose groups and hence are considered incidental.

A range of macro- and microscopic findings were noted in individual animals including in the control group, however there was no dose response relationship seen and the findings were considered to be part of the normal background pathology of rats of this age and strain.

Remarks – Results

No adverse treatment related effects were seen at any dose level and hence the NOAEL can be regarded as the highest dose level tested.

CONCLUSION

The No Observed Adverse Effect Level (NOAEL) was established as > 500 mg/kg bw/day in this study, based on the absence of any adverse effects at any of the dose rates tested.

TEST FACILITY Pharmakon (1996h)

B.7. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
EC Directive 92/69/EEC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria.
Plate incorporation procedure

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100, TA102
Metabolic Activation System	Rat S9 fraction from aroclor 1254 induced rat liver
Concentration Range in Main Test	a) With metabolic activation: 52 – 5000 µg/plate b) Without metabolic activation: 52 – 5000 µg/plate
Vehicle	Ethanol
Remarks - Method	Two main tests were conducted. 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*
Absent				
Test 1	> 5000	> 5000	> 5000	negative
Test 2		> 5000	> 5000	negative
Present				
Test 1	> 5000	> 5000	> 5000	negative
Test 2		> 5000	> 5000	negative

Remarks - Results

No precipitation was observed. Slight toxicity was observed in the absence of metabolic activation at a dose of 5000 µg/plate. A slight but statistically significant increase in the number of revertants (1.31 times the negative control) was observed in strain TA100 in the presence of metabolic activation at a dose rate of 878 µg/plate. The increase was below the 2 fold increase that is set as the criteria for a positive response in TA100 and combined with the lack of a dose response suggest it is of no biological relevance.
The test substance did not cause a marked increase in the number of revertants per plate of any of the tester strains either in the presence or absence of microsomal enzymes prepared from Aroclor 1254 induced rat liver (S9). Negative controls were within historical limits. Positive controls confirmed the sensitivity of the test system.

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

TEST FACILITY Pharmakon (1996i)

B.8. Genotoxicity – in vitro

TEST SUBSTANCE Notified chemical

METHOD: OECD TG 473 In vitro Mammalian Chromosome Aberration Test.
EC Directive 92/96/EEC B.10 Mutagenicity - In vitro Mammalian Chromosome Aberration Test.

Species/Strain	Human
Cell Type/Cell Line	Peripheral lymphocytes
Metabolic Activation System	Rat S9 fraction from aroclor 1254 induced rat liver
Vehicle	20% Ethanol in water
Remarks - Method	No preliminary study (dose-range finding assay) was performed. This study was replaced by the use of a larger range of test article concentrations in the first experiment. The notified chemical could only be tested at concentrations up to 1500 µg/mL due to it being insoluble at higher concentrations.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1a	0*, 0.5, 1.6, 5, 15.7, 49, 154*, 480*, 1500*	24 hours	24 hours
Test 1b	0*, 0.5, 1.6, 5, 15.7, 49, 154, 480, 1500*	48 hours	48 hours
Test 2a	0*, 200, 267, 356, 475, 633, 844*, 1125*, 1500*	24 hours	24 hours
Test 2b	0*, 200, 267, 356, 475, 633, 844, 1125, 1500*	48 hours	48 hours
Present			
Test 1a	0*, 0.5, 1.6, 5, 15.7, 49, 154*, 480*, 1500*	3 hours	24 hours
Test 1b	0*, 0.5, 1.6, 5, 15.7, 49, 154, 480, 1500*	3 hours	48 hours
Test 2a	0*, 200, 267, 356, 475, 633, 844*, 1125*, 1500*	3 hours	24 hours
Test 2b	0*, 200, 267, 356, 475, 633, 844, 1125, 1500*	3 hours	48 hours

*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				
Test 1a	-	> 1500	> 1500	negative
Test 1b	-	> 1500	> 1500	positive
Test 2a	-	> 1500	> 1500	negative
Test 2b	-	> 1500	> 1500	negative
Present				
Test 1a	-	> 1500	> 1500	negative
Test 1b	-	> 1500	> 1500	negative
Test 2a	-	> 1500	> 1500	negative
Test 2b	-	> 1500	> 1500	negative

Remarks - Results: A slight statistically significant increase in the number of cells with structural chromosome aberrations was observed in the absence of S9 in the first experiment at the 48 hour harvest time. Based on the absence of abnormal values and reproducibility, the change was considered to be of no biological relevance. The positive and vehicle controls gave satisfactory responses, confirming the validity of the test system.

CONCLUSION: The notified chemical was not clastogenic to human peripheral lymphocytes treated in vitro under the conditions of the test.

TEST FACILITY: Pharmakon (1996j)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test. EC Directive 92/69/EEC C.4-C Biodegradation: Determination of the "Ready" Biodegradability: Carbon Dioxide Evolution Test.
Inoculum	Sewage micro-organisms (concentration : 65 x 10^3 colony forming units/ml) from Station de Traitement des eaux usées, Saint Fons, France
Exposure Period	28 days
Auxiliary Solvent	Not applicable
Analytical Monitoring	Biotic degradation was determined by measurement of CO_2 release, trapped as $BaCO_3$ during the test. A titration method was used.
Remarks - Method	Sewage micro-organisms were exposed to the notified chemical (15 mg TOC/L for 28 days, in comparison with the blank control and the reference substance sodium acetate (12.355 mg TOC/L) at 21.2 – 22.2˚C and pH 7.3 – 7.7. Two flasks were arranged for each of the treatment levels. The degradation was followed by CO_2 analysis every 2 or 3 days over a 10-day period and every four to six days until the 28th day. After subtraction of CO_2 production of the blank control, the total amount of CO_2 produced by the notified chemical was determined for the test period and calculated as a percentage of the theoretical CO_2 ($ThCO_2$) that could have been produced based on the carbon content of the test substance.

RESULTS

Notified chemical		*Sodium acetate*	
Day	*% degradation*	*Day*	*% degradation*
3	2	3	20
7	2	10	57
14	2	14	65
24	3	24	77
28	3	28	80

Remarks - Results	It is unclear if the criterion of ≥ 60% degradation in the 10 day window has been met for the reference substance. It may be narrowly missed for the worst case, since degradations of 57% and 65% were detected at Day 10 and Day14, respectively. However, this is not considered to alter the test outcome of the notified chemical due to the very low degradation detected. The notified chemical reached a plateau of 3% degradation by Day 28 of the test. Therefore, it is not considered to be readily biodegradable.
CONCLUSION	The notified chemical is not readily biodegradable.
TEST FACILITY	Pharmakon (1996k)

C.1.2. Bioaccumulation

No bioaccumulation studies have been conducted.

The notified chemical has a low partition coefficient (log Pow 1.12). Also, it is likely to present in ionised form in water. Both these factors indicate the notified chemical may have low potential to partition into lipids and hence is not bioaccumulative.

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified Chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test - Static. EC Directive 92/69/EEC C.1 Acute Toxicity for Fish - Static.
Species	Freshwater fish (*Brachydanio rerio*)
Exposure Period	96 h
Auxiliary Solvent	None
Water Hardness	80 mg $CaCO_3$/L
Analytical Monitoring	HPLC for monitoring of the test concentrations
Remarks – Method	Freshwater fish were exposed to the notified chemical at nominal concentrations of 1, 10, 50, 100 and 250 mg/L and 21.8±1˚C. Ten fish were used per treated group, in comparison with an untreated control group. Dilution water with a pH of 7 was used, the test media for higher concentrations showed higher pH values: a top pH of 9.5 was reached at the start of the 250 mg/L test and it decreased gradually to 7.4 at the end of the test. Measurement of pH, dissolved oxygen and temperature were performed at the start of the study for each test medium then approximately 24, 48, 72 and 96 hours later.

RESULTS

Concentration mg/L	*Number of Fish*	*Mortality*				
Nominal		*2-4h*	*24 h*	*48 h*	*72 h*	*96 h*
0	10	0	0	0	0	0
1	10	0	0	0	0	0
10	10	0	0	0	0	0
50	10	0	0	0	0	0
100	10	0	0	0	0	0
250	10	2	2	2	2	2

LC50	> 250 mg/L at 96 hours.
NOEC	10 mg/L at 96 hours.
Remarks – Results	No significant deviations to the protocol occurred. Mortality Mortality (2/10 fish) was noted about 2 hours 30 minutes after the start of the test at the 250 mg/L concentration. Clinical observations Rapid breathing was observed throughout the study at the 50, 100 and 250 mg/L concentrations. Slow swimming was noted at the 250 mg/L concentration during the first 48 hours. No abnormality was noted throughout the study at the other concentrations. Observations of test media Some white particles were noted in the 250 mg/L test medium about 2 hours 30 minutes after the start of the test. They disappeared thereafter. Analysis of actual concentrations No significant loss in concentration of notified chemical over the test period was observed.

CONCLUSION The notified chemical is not harmful to *Brachydanio rerio*.

TEST FACILITY Pharmakon (1997c)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified chemical

METHOD OECD TG 202 *Daphnia* sp. Acute Immobilisation Test - Static system.
EC Directive 92/69/EEC C.2 Acute Toxicity for *Daphnia* - Static system.

Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	About 180 mg $CaCO_3$/L
Analytical Monitoring	HPLC for monitoring of the test concentrations
Remarks - Method	*Daphnia magna* were exposed to the notified chemical at the nominal concentrations of 1, 10, 50, 100 and 250 mg /L, and at 20.3 – 20.6˚C. Dilution water with a pH of 7.6 was used. However, a top pH of 9.2 was reached at the start of the 250 mg/L test and it decreased gradually to 8.6 at the end of the test. Twenty daphnids were used per treated group, in comparison with an untreated control group. Each group constituted four tubes, each containing 5 daphnids in 10 mL of test medium. Immobilizations were recorded about 24 and 48 hours after the start of the test. Measurements of pH, dissolved oxygen and temperature were performed at the beginning and at the end of the test for each test medium.

RESULTS

Concentration mg/L	*Number of D. magna*	*Number Immobilised*	
Nominal		*24 h*	*48 h*
0	20	0	0
1	20	0	2
10	20	0	0
50	20	1	1
100	20	0	0
250	20	0	10

EC50	250 mg/L at 48 hours
NOEC	100 mg/L at 48 hours
Remarks - Results	No significant deviations to the protocol occurred. Immobilizations One *Daphnia* was immobilized at 24 hours at the 50 mg/L concentration. Two and ten daphnids were immobilized at 48 hours at the 1 and 250 mg/L concentrations respectively. Observation of test media Some white particles were observed in the 250 mg/L formulation. They were removed before the medium was dispatched between the test tubes. Analysis of actual concentrations No significant loss in concentration of notified chemical over the test period was observed. Calculation using ToxCalc show that no statistically significant difference was observed at 100 mg/L, and therefore, the NOEC is 100 mg/L.

CONCLUSION The notified chemical is not harmful to daphnids on an acute basis.

TEST FACILITY Pharmakon (1997d)

C.2.3. Chronic toxicity to aquatic invertebrates

TEST SUBSTANCE Notified chemical

METHOD OECD TG 211 *Daphnia magna* Reproduction Test - semi-static system
Species *Daphnia magna*
Exposure Period 21 d
Auxiliary Solvent None
Water Hardness Approximately 150 mg $CaCO_3$/L
Analytical Monitoring HPLC for monitoring of the test concentrations
Remarks - Method Young female *Daphnia* parent animals less then 24 hours old at the test beginning were exposed to the notified chemical for 21 days at 5 nominal concentrations ranging from 1.00 to 100 mg/L with separation factor of 3.2. The test conditions were maintained at 20 - 22˚C and pH of 7.7 – 8.2. 10 parent animals were used and held individually for each concentration as well as control.

The test solutions were changed three times a week and the parent animals transferred to the fresh media. During changing of the solutions observations were made concerning mortality of parent animals and offspring, and the offspring was counted.

The obtained results of *Daphnia magna* reproductive output in exposure to the notified chemical were analysed statistically. The response used in the statistical analysis was the number of young produced per adult female, which is determined by taking the total number of young produced until either the time of death of the adult or at the end of the experiment, whichever comes first. Then mean number of young per animal parent was calculated for every concentration and control. The NOEC was calculated using ToxCalc 5.0.

Nominal loading retested, daphnid survival and cumulative mean number of offspring released (*Daphnia magna*)

Test Day 21		
Nominal Loading rate (mg/L)	Percentage of Parent Mortality	Mean Number of Offspring Released per female
Control	0	64.4
1.0	0	65.4
3.2	0	67.6
10	10	58.7
32	40	34.9
100	100	0

NOEC 10 mg/L (for both parent survival and reproduction)
Remarks - Results The test validity criteria were met. The Wilcoxon Rank Sum Test with Bonferroni Adjustment calculated the NOEC to be 100 mg/L. However, there is a significant statistical difference for the endpoints at the higher test concentrations. Therefore, ToxCalc was used and the calculation for NOECs based on both parent survival and offspring numbers showed that no statistical difference was observed at 10 mg/L. Therefore, the NOECs are determined to be 10 mg/L. The notified chemical is considered not harmful to daphnids based on this test result.

CONCLUSION The notified chemical is not harmful to daphnids on a chronic basis.

TEST FACILITY Institute of Organic Industry (2003)

C.2.4. 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	Freshwater green algae (*Scenedesmus subspicatus)*
Exposure Period	72 hours
Concentration Range	Nominal: 1- 250 mg/L Actual: 0.784 – 273.2 mg/L (end of test)
Auxiliary Solvent	None
Water Hardness	< 90 mg $CaCO_3$/L
Analytical Monitoring	HPLC for monitoring of the test concentrations
Remarks - Method	Algae were exposed to the test solutions of 1, 10, 5 100 and 250 mg/L of the notified chemical (triplicate) in water at 21.8 – 22.2˚C. Algae cell concentration was recorded about 24, 48 and 72 hours after the start of the test, by counting living cells using the absorbance method. Measurements of pH and temperature were performed at the beginning and at the end of the study. Each test medium was sampled at the start and at the end of the test, as well as a non-inoculated test flask containing the highest tested concentration but without algae.

RESULTS

Biomass (nominal)		*Growth (nominal)*	
E_bC50	*NOEC*	*E_rC50*	*NOEC*
mg/L at 72 h	*mg/L*	*mg/L at 72 h*	*mg/L*
> 250	250	> 250	250

Remarks - Results	No significant deviations to the protocol occurred. Some white particles were noted in the 250 mg/L test medium at the start of the test. They disappeared thereafter. No growth inhibition was detected for the tested algae at each of the levels.
CONCLUSION	The notified chemical is not harmful to algae.
TEST FACILITY	Pharmakon (1997e)

C.2.5. Inhibition of microbial activity

TEST SUBSTANCE	Notified chemical
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 a domestic wastewater treatment plant
Exposure Period	3 hours
Concentration Range	10-1000 mg/L
Remarks – Method	The inhibitory effect of the notified chemical on the respiration rate of aerobic wastewater micro-organisms of activated sludge was investigated in a 3-hour respiration inhibition test. The respiration rate (oxygen consumption) of an aerobic activated sludge fed with a standard amount of synthetic wastewater was measured in the presence of the notified chemical at nominal concentrations of 10, 32, 100, 320 and 1000 mg/L

after an incubation period of three hours. The inhibitory effect of the test items at the particular concentrations is expressed as a percentage of the mean respiration rate of the controls.

Two controls and three different concentrations of the reference item 3,5-dichlorophenol (5, 16, and 50 mg/L, in triplicates) were tested in parallel.

RESULTS

IC50	> 1000 mg/L
NOEC	100 mg/L
Remarks – Results	The test is regarded as valid since the oxygen consumption rates of the two controls at the start and the end of the test differed only by 5.1%, and the 3-hour EC50 of the positive control 3,5-dichlorophenol was 11 mg/L. Both values are within the guidelines-recommended range (i.e., maximum variation of 15% between the two controls and a EC50 of 5-30 mg/L for 3,5-dichlorophenol) and confirm the suitability of the activated sludge and the method used. Up to and including the nominal test concentration of 100 mg/L, the notified chemical had no significant (<15%) inhibitory effect on the respiration rate of activated sludge after the incubation period of three hours. At the higher test item concentrations of nominal 320 and 1000 mg/L the inhibitory effect increased to 24% and to 45%, respectively.

CONCLUSION The notified chemical is not inhibitory to the respiration of the micro-organisms in activated sludge.

TEST FACILITY RCC (1999c)

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