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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Chemical B in AEROJET 5

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:

Street Address:	334 - 336 Illawarra Road MARRICKVILLE NSW 2204, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

Director
NICNAS

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FULL PUBLIC REPORT

Chemical B in AEROJET 5

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
BP Australia Pty Ltd (ABN: 53 004 085 616)
132 McCredie Rd
Guildford NSW 2161

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, analytical data, degree of purity, Hazardous impurities, additives/adjuvants, introduction volume and details of use.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT
Variation to the schedule of data requirements is claimed as follows: Hydrolysis as a function of pH, Dissociation constant, Particle size, Flammability limits, Explosive properties, Acute Inhalation Toxicity and Bioaccumulation.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
United Kingdom

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Chemical B in AEROJET 5 (Imported product)
Chemical B in L-97-034-PB

ANALYTICAL DATA
Reference NMR, IR, GC-MS, UV spectra were provided

3. COMPOSITION

DEGREE OF PURITY
30-70%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
All hazardous impurities are present at below the relevant cut off's for classification of the notified chemical as a hazardous substance.

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight)
None

4. PHYSICAL AND CHEMICAL PROPERTIES

All physiochemical testing was carried out on a mixture containing 30-70% of the notified chemical.

APPEARANCE AT 20°C AND 101.3 kPa
Colourless liquid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	< -20°C	Measured
Boiling Point	Decomposes at 177°C at 102 kPa	Measured
Density	963 kg/m^3 at 20°C	Measured
Vapour Pressure	2.7×10^{-11} kPa at 25°C	Measured
Water Solubility	$< 6.50 \times 10^{-5}$ g/L at 20°C	Measured
Hydrolysis as a Function of pH	Not determined	Not expected to hydrolyse due to the low water solubility of the notified chemical.
Partition Coefficient (n-octanol/water)	log Pow = > 6.2	Measured
Adsorption/Desorption	log K_{oc} = > 5.63	Measured
Dissociation Constant	Not determined	The notified chemical does not contain dissociable groups.
Particle Size	Not applicable	Not determined as the notified chemical is a liquid
Flash Point	229°C at 101.3 kPa	Measured
Autoignition Temperature	396°C	Measured
Explosive Properties	Not determined	Based on the chemical structure of the notified chemical a negative result is predicted.

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

Reactivity
Expected to be stable under normal conditions.

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 as component of a jet turbine lubricant (30-70% of notified chemical) in 1L polypropylene packs or 208 L steel drums. There will be no reformulation or repackaging of the lubricant.

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

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

The notifier has indicated that the introduction volume of the notified chemical may increase to 15 tonnes and therefore 15 tonnes was the value used in the risk assessment.

PORT OF ENTRY
Sydney NSW

IDENTITY OF RECIPIENTS
BP Australia Pty Ltd
132 McCredie Rd
Guildford NSW 2161

TRANSPORTATION AND PACKAGING

The notified chemical will be imported into Australia as a component at 30-70% of the finished lubricant in 208L drums or 1 L polypropylene packs. The notified chemical will be transported and stored in these containers prior to use. Transport of lubricant containing the notified chemical will be by road or rail to end use sites.

USE
The notified chemical is a component in jet turbine lubricant used in power generation.

OPERATION DESCRIPTION
Transportation and storage
The notified chemical will be imported in a finished lubricant. There will be no manufacture, reformulation or repackaging of the lubricant containing the notified chemical in Australia. The lubricant will be warehoused at the notifier's site prior to transport to commercial customers around Australia.
Use
Technicians and maintenance workers will be exposed to the notified chemical during charging, topping up and maintenance activities on turbines in which the lubricant is used. The method of charging and topping up jet turbine machinery with the notified chemical will depend on the size of containers and volumes to be transferred. It is expected that for the most part this will be a manual process.
Accredited waste management contractors will dispose of the notified chemical after it has been removed from the turbines.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Transport workers	4	5 hrs/day	60 days/year
Storage workers	4	1 day	60 days/year
End users	~100's	2 hrs/day	100 days/year

EXPOSURE DETAILS
Transport and warehouse personnel will only be exposed to the notified chemical in case of an accident involving the breach of the import containers.
End users are unlikely to be exposed to the notified chemical except in cases of drips and spills during charging or top up activities or during turbine maintenance work. End users are likely to be exposed via the dermal route to the notified chemical in concentrations of 30-70%, ocular exposure may also occur. Exposure will be minimised by the secure containment of the lubricant within a closed system and the use of PPE such as gloves, safety eyewear and overalls when handling the product. During end use, the lubricant containing the notified chemical will be retained within a high integrity lubrication system; accidental loss therefore will be negligible. The mixture containing the notified chemical has a very low vapour pressure and is not heated during transfer, charging or topping up operations. Thus there is negligible risk of exposure to vapour during these processes. There may be a potential for worker exposure to oil mist during operation of the machinery.

6.1.2. Public exposure
Public exposure to the notified chemical is expected to be low. The product containing the notified chemical will be imported, warehoused and then transported to commercial customers only. Exposure to the public will only occur in the event of spill or industrial accident during the transport and storage of the lubricants containing the notified chemical.

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 >5000 mg/kg bw, Low toxicity
Rat, acute dermal toxicity	LD50 >2000 mg/kg bw, Low toxicity
Rat, acute inhalation toxicity	Not available
Rabbit, skin irritation	Slightly irritating
Rabbit, eye irritation	Slightly irritating
Guinea pig, skin sensitisation – adjuvant test	No evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days.	NOAEL 500 mg/kg bw/day (female)
Genotoxicity – bacterial reverse mutation	Non mutagenic
Genotoxicity – in vitro Chromosome aberration in human lymphocytes	Non genotoxic

Acute toxicity.
The notified chemical is of low acute toxicity *via* the oral and dermal routes. The notified chemical has a low vapour pressure of 2.7 x 10^{-11} kPa at 25°C and hence is not volatile.

Irritation and Sensitisation.
The notified chemical is slightly irritating to the skin and eyes; there was no indication of skin sensitisation.

Repeated Dose Toxicity
Animals of either sex treated with 1000 mg/kg bw/day of L-97-034-PB showed a statistically significant increase in liver weight both absolute ($p<0.05$) and relative ($p<0.05$) when compared with controls. This effect extended to the 500 mg/kg bw/day but statistical significance ($p<0.05$) was only achieved for male relative liver weights.
Kidney weights in the males only were elevated at 1000 and 500 mg/kg bw/day. The difference achieved statistical significance ($p<0.05$) at 1000 mg/kg bw/day. The intergroup difference at 500 mg/kg bw/day failed to achieve statistically significance. A statistically significant ($p<0.05$) increase in the relative kidney weight was observed at 500 and 1000 mg/kg bw/day. No effects were observed at 150 mg/kg bw/day.
All males treated with 1000 mg/kg bw/day showed speckled kidneys at terminal kill whilst two females from this treatment group showed pallor of the liver. One female treated with 500 mg/kg bw/day showed a pale liver at necropsy
The remaining macroscopic findings including reddened or dark areas of the lungs, hydronephrosis and isolated gastric changes, while showing no dose-related response, were consistent with normally expected low incidence findings in laboratory maintained rats and therefore were considered to be of no toxicological significance.
The No Observed Adverse Effect Level (NOAEL) was established as 500 mg/kg bw/day in this study, based on changes in the liver at higher doses.

Mutagenicity.
L-97-034-PB containing the notified chemical was found to not be mutagenic using a bacterial reverse mutation test, and is not clastogenic to human lymphocytes in vitro.

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

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

Based on the toxicity data provided for the notified chemical it is a slight eye and skin irritant, and is not considered a skin sensitiser. The chemical is not acutely toxic via the oral or dermal routes, but treatment-related effects were seen during sub-chronic exposure.

Acute toxic potential
The potential for acute exposure is greatest during end use where the notified chemical will primarily be manually poured from containers into the turbines. Exposure is most likely to occur via a dermal route although ocular and inhalation exposure to the notified chemical during topping up, charging and maintenance activities is also possible. As the notified chemical is slightly irritating to eyes and skin, the workers should avoid skin and eye contact with the product containing the notified chemical at a concentration of 30-70%. The risk is acceptable on the basis that the notified chemical is not classified as hazardous and exposure will be limited b y engineering controls and good worker practises.

Repeat-dose toxic potential
There is potential for dermal exposure to the notified chemical during charging, topping up and maintenance activities. Dermal exposure will be limited by the use of PPE such as safety eyewear, gloves and overalls when handling products containing the notified polymer.

Dermal exposure to the notified chemical during topping up, charging and maintenance activities can be estimated using the EASE model assuming reasonable worst case defaults and based on non-dispersive use with intermittent direct handling (European Commission, 2003). This gives an estimated daily exposure of 0.4 mg/kg bw/day for a 70 kg worker and a 100% dermal absorption factor. Based on a 500 mg/kg bw/day NOAEL for the notified chemical derived from a 28-day rat oral repeat dose study the margin of exposure (MOE) for the proposed use is 1250. A MOE greater than or equal to 100 is considered acceptable to account for intra- and inter-species differences. Therefore, the risk of systemic effects using modelled worker data is acceptable for workers involved in topping up, charging and maintenance activities.

The risk of repeated exposure is therefore considered acceptable considering the estimated MOE and the toxilogical profile of the notified chemical.

6.3.2. Public health
The risk to the public from exposure to the notified chemical is expected to be negligible, given that it will only be used by industry and will not be in any products available to the public.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE
The notified chemical will not be manufactured, reformulated or repackaged in Australia; hence there are no environmental releases associated with these processes. Environmental release of the notified chemical is unlikely during importation, storage and transportation, and accidental spills and leaks. Emergency clean-up procedures (i.e. spill response instructions on the Material Safety Data Sheet and label) will limit the impact on the environment in the unlikely event of such incidents.

RELEASE OF CHEMICAL FROM USE

The lubricants containing the notified chemical will not be sold to the public, and will only be available to commercial users. The lubricant will be contained within sealed systems during their useful life until removed during decommissioning or routine maintenance. Small spills are possible during first-fill, top-up and maintenance operations, however, these operations will only be performed by field engineers. Any spillages are therefore likely to be small and easily contained. Environmental release as a result of spills and drips is estimated at 1% (150 kg) of the annual import volume (based on 15 tonnes). Spillages will be contained with sand, vermiculite or other suitable absorbent material, and in the event of large spills, a dike will be created to prevent the spill spreading or entering drains. The waste material will be swept up or shovelled into labelled containers for recycling or disposal to landfill.

Loss of the notified chemical through routine leakage from the system is expected to be negligible, due to the high integrity closed system housing the lubricant. Release may occur in the unlikely event of containment failure due to physical penetration of seals or sealed units, and would be contained in the manner described above.

The amount of lubricant containing the notified chemical remaining as residue in the import drums and containers is estimated at 1% (150 kg) of the annual import volume.

RELEASE OF CHEMICAL FROM DISPOSAL

Lubricant containing the notified chemical that is removed from generators at the end of its useful life, or collected as waste from spill and drips may be recycled or disposed to landfill or by incineration, although landfill is more likely. Lubricants are changed infrequently and it is assumed that skilled engineers will undertake all first-fill, top-up, maintenance and decommissioning operations. Therefore spillages and used oil will be disposed in accordance with state regulations to landfill.

Empty containers will be recycled by licensed contractors and any residue is expected to be incinerated.

7.1.2 Environmental fate

For details of the environmental fate studies please refer to Appendix C. The lubricant containing the notified chemical will be handled only by skilled engineers in filling, maintenance and decommissioning operations. In addition, measures for containing and disposing of spillages, leaks, container residues, and used lubricant provide a high level of confidence that none of the imported notified chemical will be released to the sewer. The notifier stated that releases will be disposed of to landfill or by incineration, however, landfill is more likely.

The notified chemical has very low water solubility at $<6.5 \times 10^{-5}$ g/L. With a high adsorption/desorption coefficient of log $K_{OC} > 5.62$, and high partition coefficient of log $P_{OW} > 6.2$, the notified chemical is expected to partition to organic matter and to sediments and soils in the environment, and is therefore considered highly immobile within a landfill environment. In the event that the notified chemical is released to the aquatic environment, despite a high log K_{OW} value indicating potential for bioaccumulation, any amounts released are expected to adsorb to sludge and not be available to aquatic species.

Despite the presence of a hydrolysable functionality, the potential for hydrolysis is low due to poor water solubility of the notified chemical, however, a reasonable level of biotic degradation (62% in 28 days) has been detected. Therefore, the notified chemical is expected to quickly break down in either a landfill or aquatic environment.

7.1.3 Predicted Environmental Concentration (PEC)

The lubricant containing the notified chemical is not expected to enter the sewer during normal use, and any used lubricant, spillages and residues will be contained and disposed of in accordance with state regulations, mainly to landfill. It is therefore not possible to calculate a PEC.

7.2. Environmental effects assessment

The results from ecotoxicological investigations conducted on the notified chemical (30-70% of mixture) are summarised in the table below. Details of these studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	EC50 > 100 mg/L (WAF)	Non-toxic

Daphnia Toxicity	EC50 > 100 mg/L (WAF)	Non-toxic
Algal Toxicity	EC50 > 100 mg/L (WAF)	Non-toxic
Inhibition of Bacterial Respiration	EC50 > 1000 mg/L (WAF)	Non-toxic

The notified chemical is non-toxic to three trophic levels of aquatic organisms up to the level of its water solubility. The measured concentrations within the nominal 100 mg/L Water Accommodated Fractions (WAF) were very low, with a maximum time-weighted mean measured concentration of 0.53 mg/L.

7.2.1 Predicted No-Effect Concentration

The lubricant containing the notified chemical is non-toxic up to the limit of its water solubility, measured at a maximum time-weighted mean concentration of 0.53 mg/L. It is therefore not possible to calculate a Predicted No effect Concentration (PNEC).

7.3. Environmental risk assessment

As neither a PEC nor PNEC were able to be calculated, it is not possible to determine the Risk Quotient. Although the high log P_{OW} value indicates potential for bioaccumulation, the notified chemical is expected to partition to soil and organic matter, and break down when disposed to landfill, due to its low water solubility and high log K_{OC} value. In addition, release to sewers is expected to be very low as a result of the proposed use pattern and containment and disposal procedures. However, in the event that the notified chemical is released to the sewer, most is expected to partition to sludge. On this basis, the notified chemical is not expected to pose an unacceptable risk to the environment.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available data the notified chemical is not classified as hazardous under the A*pproved 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***
Environmental Hazard	Chronic category 4	Poorly soluble with no acute toxicity, lacks potential to rapidly biodegrade, and has potential to bioaccumulate.

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

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 the product Aerojet 5:
  - Avoid eye contact
  - Avoid skin contact

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced in the product Aerojet 5:
  - Protective eyewear
  - Impervious gloves
  - Protective clothing

  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.

Environment

Disposal

- The notified chemical should be disposed of to landfill.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by containment with sand, vermiculite or other suitable absorbent material, and in the event of large spills, a dike should be created to prevent the spill spreading or entering drains. The waste material should be swept up or shovelled into labelled containers for recycling or disposal to landfill.

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 a jet turbine lubricant, or is likely to change significantly;
  - the amount of chemical being introduced has increased from 15 tonnes per year, 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 product Aerojet 5 provided by the notifier was reviewed by NICNAS and is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point/Freezing Point < -20°C

Method	EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks	No evidence of solidification or freezing of the test substance was observed down to a temperatures of -20°C
Test Facility	Safepharm Laboratories (1998a)

Boiling Point Decomposes at 177°C at 102 kPa

Method	EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks	The test substance decomposes from approximately 177°C at an atmospheric pressure of 102 kPa. Based on the vapour pressure of the test substance, the estimated boiling temperature is 372°C at 101.325kPa
Test Facility	Safepharm Laboratories (1998a)

Density 963 kg/m^3 at 20°C

Method	EC Directive 92/69/EEC A.3 Relative Density.
Remarks	A pycnometer was used to determine the density of the test substance
Test Facility	Safepharm Laboratories (1998a)

Vapour Pressure 2.7 x 10^{-11} kPa at 25°C

Method	EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks	The vapour pressure balance was used to determine the vapour pressure of the test substance. Readings were taken between 106-146°C and extrapolated back to 25°C.
Test Facility	Safepharm Laboratories (1998b)

Water Solubility <6.50 x 10^{-5} g/L at 20°C

Method	EC Directive 92/69/EEC A.6 Water Solubility.
Remarks	Based on a preliminary study, the water solubility was determined to be <4.2 x 10^{-4} g/L, indicating the Column Elution method should be used, however, the Flask method was chosen due to expected blocking of the column resultant from the physical properties of the test substance. In the main test, samples (~0.4 g/L) were prepared in triplicate and shaken at 30°C for 24, 28 and 72 hours respectively after standing for a minimum of 24 hours at 20°C. The concentration was determined by gas chromatography and was less than the detection limit.
Test Facility	Safepharm Laboratories (1998a)

Hydrolysis as a Function of pH Not measured

Method	N/A
Remarks	The hydrolysis potential for the notified chemical was not tested due to its low water solubility. It contains hydrolysable groups, however, this is not expected to be significant under environmental conditions (pH 4-9) given the low water solubility of the notified chemical.
Test Facility	

Partition Coefficient (n-octanol/water) log Pow = >6.2

Method	OECD TG 117 Partition Coefficient (n-octanol/water). EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks	Based on a preliminary assessment of the solubility ratios, a test solution of ~2 g/L was analysed by HPLC. The test material was strongly retained by the stationary phase, and was forced to elute by adjusting the mobile phase to 100% methanol at 65 minutes. The partition coefficient was determined from a calibration curve prepared with a range of reference

substances of known log P_{OW}. A fraction of the eluate was collected and the notified chemical positively identified by GC.

Test Facility Safepharm Laboratories (1998a)

Adsorption/Desorption – screening test log K_{oc} = >5.63

Method OECD TG 121 Estimation of Adsorption Coefficient (Koc) on Soil and on Sewage Sludge using High Performance Liquid Chromatography.

Remarks A test solution of ~2 g/L was analysed by HPLC. The test material was strongly retained by the stationary phase, and was forced to elute by adjusting the mobile phase to 100% methanol at 25 minutes. The adsorption coefficient was determined from a calibration curve prepared with a range of reference substances of known log K_{OC}. A fraction of the eluate was collected and the notified chemical positively identified by GC.

Test Facility Safepharm Laboratories (1998a)

Dissociation Constant Not determined

Method N/A

Remarks The dissociation constant was not determined due to the low water solubility of test substance. In addition, the notified chemical contains no functionality capable of dissociating within the environmentally relevant pH (4-9) range.

Test Facility

Particle Size Not determined

Method

Remarks The notified polymer is a liquid

Test Facility

Flash Point 229°C at 101.3 kPa

Method EC Directive 92/69/EEC A.9 Flash Point.

Remarks Determined using a closed cup equilibrium method.

Test Facility Safepharm Laboratories (1998c)

Flammability Not determined

Method

Remarks Based on the chemical and physical properties of the notified substance, its chemical structure and experience in use, a negative result is expected.

Test Facility

Autoignition Temperature 396°C

Method 92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases).

Remarks Determined by injecting 70 to 1400 µL aliquots into a heated flask.

Test Facility Safepharm Laboratories (1998c)

Explosive Properties Not determined

Method

Remarks Based on the chemical structure of the test substance and experience in use, a negative result is predicted.

Test Facility

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Mixture containing 30-70% of the notified chemical.
METHOD	OECD TG 401 Acute Oral Toxicity – Limit Test. EC Directive 92/69/EEC B.1 Acute Toxicity (Oral) – Limit Test.
Species/Strain	Rat/Sprague-Dawley CD (Crl:CD BR)
Vehicle	Test substance administered as supplied
Remarks - Method	No significant deviation in protocol.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	5000	0/10

LD50	> 5000 mg/kg bw
Signs of Toxicity	No signs of systemic toxicity were noted during the study. All animals showed an expected gain in bodyweight during the study.
Effects in Organs	No abnormalities were noted at necroscopy.
Remarks - Results	

CONCLUSION	The notified chemical is of low toxicity via the oral route
TEST FACILITY	Safepharm Laboratories (1998d)

B.2. Acute toxicity – dermal

TEST SUBSTANCE	Mixture containing 30-70% 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 CD (Crl:CD BR)
Vehicle	Test substance administered as supplied
Type of dressing	Semi-occlusive.
Remarks - Method	

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/Sex	2000	0/10

LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	There were no signs of skin irritation.
Signs of Toxicity - Systemic	There were no signs of systemic toxicity. All animals showed an expected gain in bodyweight during the study.
Effects in Organs	No abnormalities were noted a necroscopy.
Remarks - Results	

CONCLUSION	The notified chemical is of low toxicity via the dermal route.
TEST FACILITY	Safepharm Laboratories (1998d)

B.3. Acute toxicity – inhalation

Test data has been omitted for the following reasons. The acute toxicity of the mixture containing the notified chemical has been assessed by the oral and dermal routes of exposure. These were conducted as limit tests. The LD50 values were in excess of 2000 mg/kg and thus the substance is not considered to be harmful. The mixture containing the notified chemical is not volatile [vapour pressure 2.7 x 10^{-11} Pa at 25ºC; boiling point 372ºC] and there is a low risk of misting in normal conditions of use. In addition, it is used in closed systems. On this basis there is little or no potential for human exposure by the inhalation route, either as an aerosol or a vapour, and hence a 3rd acute toxicity study is not considered necessary for this substance.

B.4. Irritation – skin

TEST SUBSTANCE	Mixture containing 30-70% 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
Vehicle	Test substance administered as supplied
Observation Period	7 Days
Type of Dressing	Semi-occlusive.
Remarks - Method	No significant deviation on protocol.

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	0.33	1.3	0.33	2	72 hours	0
Oedema	0	0.33	0	1	24 hours	0

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

Remarks - Results	Very slight erythema was noted at two treated skin sites at the 1 hour observation period. Very slight to well-defined erythema was noted at all treated skin sites at 24 hour observation. Very slight erythema was noted at one treated site at 48 and 72 hours. Very slight oedema was noted at one treated skin site at 1 and 24 hour observation. All treated skin sites appeared normal at 7 days.
CONCLUSION	The notified chemical is slightly irritating to the skin.
TEST FACILITY	Safepharm Laboratories (1998e)

B.5. Irritation – eye

TEST SUBSTANCE	Mixture containing 30-70% 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
Observation Period	72 hours
Remarks - Method	No significant deviation in protocol.

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 hour	0
Conjunctiva: chemosis	0	0	0	1	1 hour	0
Conjunctiva: discharge	0	0	0	2	1 hour	0
Corneal opacity	0	0	0	0	0	0
Iridial inflammation	0	0	0	0	0	0

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

Remarks - Results
No corneal or iridal effects were noted during the study.
Moderate conjunctival irritation was note in all treated eyes at 1 hour.
All treated eyes appeared normal at the 24 hour observation.

CONCLUSION
The notified chemical is slightly irritating to the eye.

TEST FACILITY
Safepharm Laboratories (1998f)

B.6. Skin sensitisation

TEST SUBSTANCE
Mixture containing 30-70% notified chemical

METHOD
OECD TG 406 Skin Sensitisation - Magnusson and Kligman Maximisation Study in Guinea Pigs.
EC Directive 96/54/EC B.6 Skin Sensitisation - Magnusson and Kligman Maximisation Study in Guinea Pigs.

Species/Strain
Guinea pig/ Dunkin Hartley

PRELIMINARY STUDY
Maximum Non-irritating Concentration:
Intradermal induction: could not be determined, at 1% (lowest concentration tested) very slight to moderate/severe irritation was observed.
Topical induction: could not be determined, at 25% (lowest concentration tested) very slight irritation was observed.
Challenge: 100% at 24 and 48 hours.

MAIN STUDY

Number of Animals
Test Group: 20 Control Group: 10

INDUCTION PHASE
Induction Concentration:
Intradermal injection 25% w/v in arachis oil BP
topical application 100%

Signs of Irritation

Intradermal induction
Very slight or well defined erythema was noted at the intradermal induction site of all test group animals at 24 hours observation and 19 test animals at the 48 hour observation. Very slight erythema was noted at the intradermal induction sites of all control group animals at the 24 and 48 hour observation.

Topical induction
Very slight or well defined erythema and incidents of very slight oedema were noted at the induction sites of all test group animals at the 1 hour observation with very slight erythema and incidents of very slight oedema in ten test group animals at the 24 hour observation. Bleeding from the intradermal induction sites of four test group animals was noted at the 1 hour observation. Isolated incidents of small superficial scattered scabs or a hardened dark brown/black coloured scab were noted at 24 hour observation.

Bleeding from the intradermal induction sites were noted in one control animal at the 1 hour observation. No signs of erythema or oedema were noted at the treatment sites of control group animals at 1 and 24 hour observation.

CHALLENGE PHASE

1st challenge
intradermal: 100 %
topical: 75 %

Remarks - Method
No significant deviations in protocol.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after: 1st challenge*	
		24 h	*48 h*
Test Group	100 %	0	0
	75 %	0	0
Control Group	75 %	0	0
	100 %	0	0

Remarks - Results
No skin reactions were observed at the challenge sites of the control or test animals. Isolated incidents of small superficial scattered scabs or a hardened dark brown/black coloured scab were noted at the 24-hour observation.

Bodyweight gains of guinea pigs in the test group, between Day 0 and Day 24 were comparable to those observed in the control group animals over the same period.

CONCLUSION
There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.

TEST FACILITY
Safepharm Laboratories (1998g)

B.7. Repeat dose toxicity

TEST SUBSTANCE
Mixture containing 30-70% 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 BR

Route of Administration
Oral – gavage

Exposure Information
Total exposure days: 28 days

	Dose regimen: 7 days per week
	Post-exposure observation period: None
Vehicle	Arachis oil BP
Remarks - Method	No significant deviations in protocol.

RESULTS

Mortality and Time to Death
There were no deaths during the study.

Clinical Observations
No clinical signs of toxicity were observed during the study.
One male treated at the high dose showed red/brown staining around the eye on Day 18 and 19 whilst one female showed red/brown staining around the ano-genital area from Day 18 onward. A second female showed red/brown staining around the ano-genital area from Day 22 to Day 27. These isolated, incidental external changes considered of no toxicological importance.

Functional observations
All the inter and intra group differences in urination, defecation and transfer arousal scores were considered to be a result of normal variation of rats of the strain and age used in the study and therefore are of no toxicological significance.

There were no treatment related changes in the functional performance parameter measured. Statistical analysis of the data revealed no intergroup differences.

Sensory reactivity assessment did not reveal any treatment related changes. All inter and intra group differences in sensory scores were considered to be the result of normal variation for rats of the strain and age used in the study therefore they are considered of no toxicological significance. Statistical analysis of the startle reflex data revealed no intergroup differences.

No adverse effect on bodyweight development was detected during the study. A statistically significant ($p<0.01$) reduction weight was detected for 150 mg/kg bw/day females during the first week. However, in the absence of a dose response relationship, the slight intergroup difference was regarded as incidental and of no toxicological significance.

A slight reduction in food consumption was detected for females treated with 1000 mg/kg bw/day throughout the dosing period when compared with controls. Food efficiency (the ratio of bodyweight gain to dietary intake) however was similar to that of the controls for the same period. No adverse effect on dietary intake was observed for 1000 mg/kg bw/day males or animals of either sex treated at 500 or 150 mg/kg bw/day. Daily visual inspection of water bottles revealed no intergroup difference.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
Haematology
A statistically significant ($p<0.05$) increase in haemoglobin was detected for 1000 mg/kg bw/day males when compared to the control animals but in the absence of any other changes in haematological correlates, this was considered of no toxicological significance.

A statistically significant ($p<0.05$) increase in plasma inorganic phosphorous was detected for 1000 mg/kg bw/day males when compared to the control, however in isolation this minimal intergroup difference was not considered to be toxicological significant.

Effects in Organs
Animals of either sex treated with 1000 mg/kg bw/day showed a statistically significant increase in liver weight both absolute ($p<0.05$) and relative ($p<0.05$) when compared with controls. This effect extended to the 500 mg/kg bw/day but statistical significance ($p<0.05$) was only achieved for male relative liver weights.

Kidney weights in the males only were elevated at 1000 and 500 mg/kg bw/day. The difference achieved statistical significance ($p<0.05$) at 1000 mg/kg bw/day. The intergroup difference at 500 mg/kg bw/day failed to achieve statistically significance. A statistically significant ($p<0.05$) increase in the relative kidney weight was observed at 500 and 1000 mg/kg bw/day. No effects were observed at 150 mg/kg bw/day.

All males treated with 1000 mg/kg bw/day showed speckled kidneys at terminal kill whilst two females from this treatment group showed pallor of the liver. One female treated with 500 mg/kg bw/day showed a pale liver at necropsy.

The remaining macroscopic findings including reddened or dark areas of the lungs, hydronephrosis and isolated gastric changes, while showing no dose-related response, were consistent with normally expected low incidence findings in laboratory maintained rats and therefore were considered to be of no toxicological significance.

Histopathology
Treatment related kidney changes were observed. Globular accumulations of the eosinophilic material were observed in the renal proximal tubular epithelium of males treated at 1000, 500 and 150 mg/kg bw/day. The presence of globular accumulations of eosinophilic material in the tubular epithelium is consistent with appearance of hydrocarbon nephropathy which results form the excessive accumulation of α_2 microglobulin in renal proximal tubular epithelial cells. This is a well-documented effect, peculiar to the male rat, which occurs in response to treatment with certain hydrocarbons. Female rats and other species do not develop "hydrocarbon nephropathy" and for this reason, the effect is not indicative of a hazard to human health.

All the remaining morphological changes were those commonly observed in laboratory maintained rats at the age and strain employed and there were no difference in incidence or severity between control and treatment group that were considered to be toxicological significance.

Remarks – Results
Terminal studies revealed an increased group mean liver weight at a dose of 1000 and 500 mg/kg bw/day and macroscopic examination of the tissues revealed two 1000 mg/kg bw/day and one 500 mg/kg bw/day female showing pallor of the liver. There was no histopathological evidence of histopathological change so the reason for the increased weight is unknown. Elevated liver weights can be associated with adaptive changes following treatment with xenobiotics but in the absence of detectable hepatocyte enlargement this is only speculative.

Treatment related effects were observed for males at all doses and for females at 1000 mg/kg bw. The No Observed Adverse Affect Level (NOAEL) for females in considered 500 mg/kg bw/day. A clear NOAEL for males could not be determined. The treatment related effects were confined to increased liver weight with no concomitant histopathology and male rat specific conditions, hydrocarbon nephropathy.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as 500 mg/kg bw/day in this study, based on changes in the liver at higher doses.

TEST FACILITY Safepharm Laboratories (1998h)

B.8. Genotoxicity – bacteria

TEST SUBSTANCE	Mixture containing 30-70% 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. *E. coli*: WP2uvrA$^-$.
Metabolic Activation System	Aroclor 1254 induced rat liver S9 fraction.
Concentration Range in Main Test	a) With metabolic activation: 50 - 5000µg/plate. b) Without metabolic activation: 50 - 5000µg/plate.
Vehicle	Acetone
Remarks - Method	No significant deviations in protocol.

RESULTS

Remarks - Results

The test material caused no visible reduction in the growth o f the bacterial lawn at any dose level. The test material was therefore tested up to the maximum recommended dose of 5000 μg/plate. An oily precipitate was observed at 5000 μg/plate, this did not prevent the testing of revertant colonies.

No significant increases in frequency of revertant colonies were recorded for any of the bacterial strain, with any dose of the test material, with or without metabolic activation.

CONCLUSION

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

TEST FACILITY

Safepharm Laboratories (1998i)

B.9. Genotoxicity – in vitro

TEST SUBSTANCE

Mixture containing 30-70% 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.

Cell Type/Cell Line: Cultured human peripheral lymphocytes
Metabolic Activation System: Aroclor 1254 induced rat liver S9 fraction.
Vehicle: Acetone
Remarks - Method: In experiment 2, the final S9 concentration was increased from 1 to 2%.

Metabolic Activation	*Test Substance Concentration (μg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0*, 30.96, 78.13, 156.25, 312.25, 625*, 1250*, 2500*, 5000*	4	20
Test 2	0*, 39, 78.1, 156.25, 312.5, 625*, 1250*, 2500*, 5000*	20	20
Present			
Test 1	0*, 39.06, 78.13, 156.25*, 312.5, 625*, 1250*, 2500*, 5000*	4	20
Test 2	0*, 156.25, 312.5, 625, 1250*, 2500*, 5000*	4	20

*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 1		>5000	≥625	None
Test 2		>5000	≥2500	None
Present				
Test 1		>5000	≥625	None
Test 2		>5000	≥1250	None

Remarks - Results

Experiment 1
The test substance induced a statistically significant ($p \leq 0.05$) increases in the frequency of the cells with gap-type aberrations at 2500 and 5000 μg/mL in the absence of S9 and at 5000 μg/mL in the presence of S9.

The test material did not induce a significant increase in the numbers of polypoid cells at any dose level in either of the treatment cases.

Experiment 2

The test material did not induce any statistically significant increases in the frequency of cells with chromosome aberrations, either including or excluding gaps, in the presence of metabolic activation (at 2% concentration) or with continuous 20 hour exposure in the absence of S9. Therefore the small increases observed in Experiment 1 were confirmed to be of no toxicological significance.

The test material did not induce a significant increase in the numbers of polypoid cells at any dose level in either of the treatment cases.

CONCLUSION

The test substance was not clastogenic to cultured human peripheral lymphocytes treated in vitro under the conditions of the test.

TEST FACILITY

Safepharm Laboratories (1998j)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE: Mixture containing 30-70% of the notified chemical

METHOD: OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test.

Inoculum	Activated sludge from domestic sewer.
Exposure Period	28 days
Auxiliary Solvent	None specified
Analytical Monitoring	TOC analyser
Remarks - Method	Test samples were run along with inoculum controls, positive controls (sodium benzoate as the control) in duplicate at 10 mg C/L, and one toxicity control at 20 mg C/L. The test was performed in the dark at 21°C. Samples were analysed for CO_2 immediately except for the samples taken on days 6, 10 and 16, which were stored deep-frozen at -20°C prior to analysis.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
0	0	0	0
1	5	1	24
2	17	2	53
3	23	3	59
6	25	6	52
8	39	8	66
10	39	10	72
14	42	14	76
16	46	16	79
20	48	20	80
22	50	22	81
24	59	24	86
27	62	27	89
28	62	28	91
29*	64	29*	92

*Day 29 values corrected to include any carry over of CO_2 detected in Absorber 2.

Remarks - Results: The total CO_2 evolution in the control vessels on day 28 was 45 mg/L, however, this was below the upper level of 70 mg/L given in the OECD guidelines. Despite the test substance attaining >60% degradation, this level was not reached within 10 days of reaching 10% degradation. Therefore the notified chemical cannot be classed as readily biodegradable.

The positive control confirmed the suitability of the inoculum and the toxicity control confirmed the test substance was not toxic to sewage organisms used in the study.

CONCLUSION: The test substance cannot be classed as readily biodegradable.

TEST FACILITY: Safepharm Laboratories (1998k)

C.1.2. Bioaccumulation

The test substance has the potential to bioaccumulate based on its high log K_{OW} value, however, the notified chemical is poorly soluble in water, has a high K_{OC} value, and despite not being readily biodegradable may be expected to degrade moderately over time. Also, exposure to the aquatic compartment will be limited. Therefore, it is unlikely that the chemical will bioaccumulate.

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Mixture containing 30-70% of the notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test - semi-static. EC Directive 92/69/EEC C.1 Acute Toxicity for Fish - semi-static.
Species	Rainbow trout (*Onchorynchus mykiss*)
Exposure Period	96 hours
Auxiliary Solvent	None specified
Water Hardness	109 mg $CaCO_3$/L
Analytical Monitoring	TOC analysis; gas chromatography
Remarks – Method	The test substance was prepared as a Water Accommodated Fraction (WAF) due to its low water solubility. The mixture was stirred at room temperature for 24 hours, with a vortex depth of 25% of the water column height, and allowed to settle for 1 hour, after which time the aqueous phase containing the WAF was siphoned (not indicated from where). The stirring time was considered sufficient based on the results of increasing the stirring period to 144 hours, which showed no significant difference in the amount of carbon in the WAF. The nominal loading rate was determined from a range finding study in which fish were exposed to 10 and 100 mg/L loading rate. The test vessels were maintained at between 14-15°C, with a photoperiod of 16 hours and 8 hours darkness, pH at 7.8-8.0, and oxygen at 87-95% saturation. Any mortalities and sublethal effects of exposure were recorded at 3, 6, 24, 48, 72 and 96 hours after exposure.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
0		10	0	0	0	0	0
0		10	0	0	0	0	0
100 (WAF)		10	0	0	0	0	0
100 (WAF)		10	0	0	0	0	0
100 (WAF)		10	0	0	0	0	0

LC50	>100 mg/L (WAF) at 96 hours.
NOEC	100 mg/L (WAF) or 0.53 mg/L measured concentration (time-weighted) at 96 hours.
Remarks – Results	Samples of the WAFs were taken for quantitative analysis at 0, 24, 72 and 96 hours, with measured concentrations ranging from the limit of quantitation to 2.95 mg/L. The variation in recoveries may have been caused by variable adsorption of test material to the glassware, and the formation of globules of various sizes upon addition of the test substance, as is consistent with a pre-study stability analysis. Also, analysis of total organic carbon (TOC) was done. The NOEC was calculated based on the time-weighted mean concentrations. There were no sublethal effects observed over the testing period.
CONCLUSION	Under the study conditions the test substance is not toxic to rainbow trout

up to the limit of its water solubility.

TEST FACILITY Safepharm Laboratories (1998l)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Mixture containing 30-70% of the notified chemical

METHOD OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test - static.
EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia - static.

Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None specified
Water Hardness	116 mg $CaCO_3$/L
Analytical Monitoring	TOC analysis; gas chromatography
Remarks - Method	The test substance was prepared as a Water Accommodated Fraction (WAF) due to its low water solubility. The mixture was stirred at room temperature for 24 hours, with a vortex depth of 25% of the water column height, and allowed to settle for 1 hour, after which time the aqueous phase containing the WAF was siphoned (not indicated from where). The nominal loading rate was determined from a range finding study in which daphnids were exposed to 10 and 100 mg/L loading rate. The test vessels were maintained at between 21°C, with a photoperiod of 16 hours and 8 hours darkness, pH at 8.0, and oxygen at 81-84% saturation.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0		10	0	0
0		10	0	0
100		10	0	0
100		10	0	0
100		10	0	0
100		10	0	0

EC50	>100 (WAF) mg/L at 48 hours
NOEC	100 (WAF) mg/L or 0.4 mg/L measured concentration (time-weighted) at 48 hours
Remarks - Results	Samples of the WAFs (R1/R2 and R3/R4 pooled) were taken for quantitative analysis at 0 and 48 hours, with measured concentrations at 0 hours of 0.658 and 0.674 mg/L but below the limit of quantitation at 48 hours. The instability may have been caused by variable adsorption of test material to the glassware, and the formation of globules of various sizes upon addition of the test substance, as is consistent with a pre-study stability analysis. Also, analysis of total organic carbon (TOC) was done. The NOEC was calculated based on the time-weighted mean concentrations.

CONCLUSION Under the study conditions the test substance is not toxic to *Daphnia magna* up to the limit of its water solubility.

TEST FACILITY Safepharm Laboratories (1998m)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE	Mixture containing 30-70% of the notified chemical
METHOD	OECD TG 201 Alga, Growth Inhibition Test. EC Directive 92/69/EEC C.3 Algal Inhibition Test.
Species	*Pseudokirchneriella subcapitata*
Exposure Period	96 hours
Concentration Range	Nominal: 100 mg/L Actual: Below the limit of detection
Auxiliary Solvent	None specified
Water Hardness	Not provided
Analytical Monitoring	TOC analysis; gas chromatography
Remarks - Method	The test substance was prepared as a Water Accommodated Fraction (WAF) due to its low water solubility. The mixture was stirred at room temperature for 24 hours, with a vortex depth of 25% of the water column height, and allowed to settle for 1 hour, after which time the aqueous phase containing the WAF was siphoned at mid-depth. The nominal loading rate was determined from a range finding study in which algae were exposed to 10 and 100 mg/L loading rate. At 0 hours the algal culture contained a nominal cell density of 1 x 10^4 cells/mL. The test vessels were maintained at between 24°C with continuous illumination (~7000 lux) and pH at 7.5-10.

RESULTS

Biomass		*Growth*	
E_bC50	*NOEC*	*E_bC50*	*NOEC*
mg/L at 96 h	*mg/L*	*mg/L at 96 h*	*mg/L*
>100 (WAF)	100 (WAF)	>100 (WAF)	100 (WAF)

Remarks - Results	Samples of the WAFs (R1-R3 and R4-R6 pooled) were taken for quantitative analysis at 0 and 96 hours, with measured concentrations all below the limit of quantitation at 0 and 48 hours, and therefore the EC50 and NOEC values are expressed only as nominal loading rates. Adsorption of test material to the glassware and/or algae, and the formation of globules upon addition of the test substance is the likely cause of the low bioavailability to algal cells of the test substance. The large pH increase is due to the large number of cells in the log phase of growth, and is typical under conditions of no inhibition.
CONCLUSION	Under the study conditions the test substance is not toxic to *Pseudokirchneriella subcapitata* up to the limit of its water solubility.
TEST FACILITY	Safepharm Laboratories (1998n)

C.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Mixture containing 30-70% of the 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 domestic sewer.
Exposure Period	3 hours
Concentration Range	Nominal: 1000 mg/L Actual: Not tested
Remarks – Method	A range-finding study was conducted in which activated sewage was

	exposed to 100 and 1000 mg/L loading rates of the test substance. Based on the results, a nominal loading rate of 1000 mg/L was run in triplicate in the main study. Duplicate controls and a reference substance (3,5-dichlorophenol) were also run.
RESULTS	
IC50	>1000 mg/L
NOEC	1000 mg/L
Remarks – Results	There was no reduction in respiration rate for the test substance compared to the controls, while ~90% reduction occurred in bacteria exposed to the reference substance, thereby validating the test. The relatively large increase in respiration rates within the test vessels after 30 minutes is likely due to the hormetric response of the bacteria to the test material.
CONCLUSION	The test material is not inhibitory to activated sludge microorganisms.
TEST FACILITY	Safepharm Laboratories (1998o)

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