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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

DURASYN 153 POLYALPHAOLEFINS

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.

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FULL PUBLIC REPORT

DURASYN 153 POLYALPHAOLEFINS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Amochem Pty Ltd (ABN 48 095 713 269)
40 Myrna Road
STRATHFIELD NSW 2135

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical Name & Other Names
CAS Number
Molecular Formula
Structural Formula
Molecular Weight
Spectral Data
Purity
Identity and % weight of toxic or hazardous impurities
Identity of non-hazardous impurities
Identity and % weight of additives/adjuvants
Import Volume
Identity of Reformulating Sites

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
Adsorption / Desorption
Reactivity
Acute Oral Toxicity
Acute Inhalation Toxicity
Skin Irritation
Eye Irritation
Skin Sensitisation
Induction of Point Mutations
Induction of Germ Cell Damage
Chromosome Damage
Acute Fish Toxicity
Acute Daphnia Toxicity
Acute Algal Toxicity
Ready Biodegradability
Bioaccumulation

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA (2005), Canada (2006)

2. IDENTITY OF CHEMICAL

OTHER NAME(S)
Alpha Olefin Oligomer, Hydrogenated

MARKETING NAME(S)
DURASYN 153 POLYALPHAOLEFINS

Details of the five notified chemicals					
STD	**1243**	**1244**	**1245**	**1246**	**1247**
Marketing Name	DURASYN 125	DURASYN 128	DURASYN 223	DURASYN 153 POLYALPHAOLEFINS	DURASYN 156 POLYALPHAOLEFINS

METHODS OF DETECTION AND DETERMINATION

METHOD	FTIR Spectroscopy and GC
Remarks	The use of IR Spectroscopy was confirmed to sufficiently quantify and detect the presence of the notified chemical.
Test Facility	Innovene (2005)

3. COMPOSITION

DEGREE OF PURITY
> 90%

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will not be manufactured in Australia. It will be imported in 200 L closed-head steel drums or shipped in bulk in iso-containers.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	0 – 10	0 – 10	0 – 10	0 – 10	0 – 10

USE
The notified chemical is used as a base fluid for the blending of synthetic industrial lubricants as a functional fluid and used in finished industrial lubricants.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
Amochem Pty Ltd
40 Myrna Road
Strathfield NSW 2135

TRANSPORTATION AND PACKAGING
The notified chemical is transported into Australia by ship in either 200 litre robust UN approved steel drums, in bulk iso-containers or in 1000 litre totes (IBCs). Based on expected volumes and package sizes, the notified chemical is expected to be primarily transported from the dockside to the customer or contract warehouse via trucks, but rail transport may be possible. The notified chemical is then stored until required for despatch to blending customers. The notified chemical will be distributed to

numerous blending premises around Australia, with the number of blending sites expected to be up to 6. The finished lubricant may be packaged in drums (200 L) or bottles (1L or more). Packaging into bottles is usually automated.

The product is not classified as a dangerous good for transport, so there are no special storage or transport requirements.

5.2. Operation description

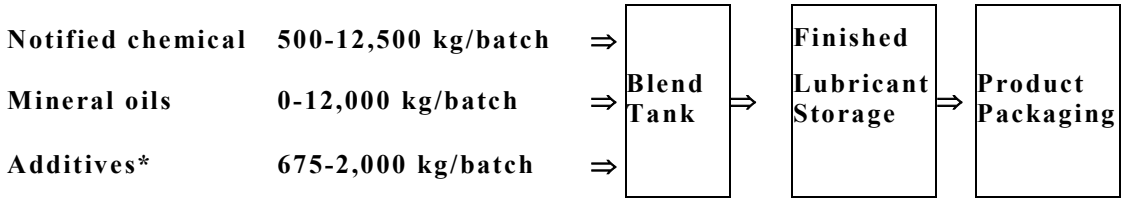
Oils formulated will be blended at facilities of major lubricant manufacturers located in Australia or imported to the country.

The notifier does not formulate lubricants and will only provide the PAO (Polyalphaolefins) base fluid to these manufacturers. However, there are certain steps that characterise all operations used to blend full synthetic oils (where only PAO or other synthetic fluids are used as the base fluid) or partial synthetic oils (where mixtures of PAO and mineral oil are used together).

Blending occurs in an enclosed blending vessel ("kettle") with appropriate nitrogen blanketing, overflow protection, and vapour capture. The notified PAO is pumped from an appropriate storage tank, via hard piping, into the blending kettle where it is heated to 50°C (± 5°C).

The blended lubricant is pumped via hard piping to a finished lubricant storage tank for subsequent packaging.

Lubricant Blending Operation Process Flow Diagram – Automotive or Industrial



*Additives can include one or more of the following – viscosity index improvers, dispersants, antioxidants, corrosion inhibitors, anti-wear additives, pour point depressants, and anti-foaming agents.

The diagram shows typical quantities of components used per batch in a closed blending operation for the preparation of automotive or industrial lubricants. The scale of operation may vary significantly depending on the size of the company preparing the finished lubricant. Depending on the end-use application of the lubricant, variance on either the high or low end of these ranges could occur.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Transport and Storage	10 – 30	30 minutes/day	100 days per year
Sampling	5 – 30	30 minutes/day	50 days per year
Maintenance	10 – 20	3 hours/day	20 days per year
Blending operations	5 – 30	8 hours/day	200 days per year
Cleaning	5 – 30	30 minutes/day	200 days per year
Industrial end users	high	1hr/day	50 days per year

Exposure Details

Dockside and Transport

Occupational exposure is not expected except in the case of a spill. Typical PPE worn by workers would be industrial standard overalls, eye protection and rubber / PVC gloves.

Formulation

While the blending of lubricants is a highly automated and enclosed process, there is some potential for exposure of workers involved in blending operations using the notified chemical. However, typical blending facilities are designed to minimise exposures to employees and are generally well ventilated

and have accidental spill containment and wastewater treatment systems in place.

Except for the collection of process samples for quality control and bottle filling, all handling of notified materials is expected to be through closed piping.

Occupational exposure is possible in the event of a spill. Skin contact is possible by contact with drips. Eye contact with the notified chemical may occur from leaks or splashes. Inhalation of the notified chemical is unlikely given its low volatility and the enclosed nature of the blending operation. The notified chemical also has a low tendency to form aerosols and ventilation systems are in place to guard against this possibility.

Potential exposures during activities such as sampling will be minimised by the use of engineering controls such as local ventilation, and personal protection equipment. Duration of potential exposure during these operations will be very short. Protective equipment to be worn during periods where exposures are likely to occur include impervious gloves and work clothing, and eye protection. Respiratory protection will be worn if there is potential inhalation exposure.

Industrial users of this material may inhale small amounts of the notified chemical in normal use; however, due to the low vapour pressure of the notified chemical, at all anticipated use temperatures, contact with vapour of this material, in an amount sufficient to cause respiratory tract irritation or other effects is unlikely. Users are expected to wear a respirator with an organic vapour cartridge and a mist filter if general ventilation is inadequate.

Use
Dermal exposure may occur during commercial and industrial applications. Respiratory exposure will be limited under normal operating conditions. Skin exposure is also limited given that the lubricants are normally applied via pumping systems thereby minimising skin contact during application.

5.4. Release

RELEASE OF CHEMICAL AT SITE

No estimates have been provided for the likely quantity of notified chemical released during reformulation, repackaging and use, though such releases are likely to be low.

Waste produced will typically be collected for incineration. Blending and pumping equipment is typically cleaned with lubricating oil (not the notified chemical) that can be recycled into future blends or captured for incineration.

Commercial and consumer products containing the notified chemical may be ultimately disposed of through used oil recycling facilities or household hazardous waste sites. Incineration would still be the expected method of disposing of this material.

Any waste of the notified chemical or products containing the notified chemical would be in liquid form. Quantities of waste will vary depending upon customers' use patterns and are thus difficult to predict.

For industrial users, drums and iso-containers may be re-used. The drum or iso-container is first steam cleaned and any wastewater containing the notified chemical is expected to be sent to on-site wastewater treatment facility. Facilities would contain an API oil and water separator and it is expected that no more than 5% of the waste chemical will be emulsified in the water. The waste water is further treated with pond aeration and sand filtration before being released to sewer. Given the low solubility of the notified chemical, it is likely that it will be present in the treated water only in very small quantities. The remaining oily portion of the waste is sent to an incinerator.

Accidental spills at the blending facilities will be contained by plant barriers. The facilities have concrete floors that allow the spilled product to be sucked up with the remaining waste product, ending up in the waste water treatment facilities. It is likely this will be sent for incineration.

Accidental spills during transport and use will be contained to prevent contamination of soil, surface water and groundwater. The liquid will be adsorbed onto suitable material, and where feasible, contaminated soil removed. These will then be disposed in accordance with local regulations. This is outlined in the Material Safety Data Sheet (MSDS).

RELEASE OF CHEMICAL FROM USE

The used lubricant products containing the notified chemical are typically incinerated or sent to used oil recyclers. The only potential for release to the environment is by individual car owners and owners of equipment who do their own oil changes and do not use correct methods for disposal of used oil.

The majority of the spent lubricant products containing the notified chemical collected at commercial outlets, such as automotive fleets, trucking firms, and servicing companies, or by industrial users will be incinerated or sent to used oil recyclers. When incinerated, the notified chemical will form water vapour and oxides of carbon. Therefore, the potential for release of the notified chemical to the environment is low from these sources. A small amount may be released to the environment through spills and leaks, with these likely to be widely dispersed. If the notified chemical is washed off road surfaces, it is expected to adsorb to adjacent soils and sediments. A sizeable release of the notified chemical to the aqueous environment is possible (*e.g.,* ship wreck), though unlikely.

According to a survey tracing the fate of used lubricating oil in Australia (Snow 1997) only around 20% of used oil removed by enthusiasts is collected for recycling, approximately 25% is buried or disposed to landfill, 5% is disposed of into stormwater drains and the remaining 50% unaccounted for.

Consequently, assuming that oil removed by professional mechanics is disposed of appropriately (i.e. sent for recycling or possibly burning as workshop heating oil), negligible release of the notified chemical should result from these professional activities. During recycling it is expected that most of the chemical will decompose and any remainder will report to the asphalt portion.

The notified chemical is not expected to bioaccumulate as it is at least inherently biodegradable. The notified chemical also has low water solubility which would reduce the availability of the notified chemical to the aquatic compartment, thus reducing the bioaccumulation potential.

5.5. Disposal

It is believed that any waste produced will typically be collected for incineration. Blending and pumping equipment is typically cleaned with lubricating oil (not the notified chemical) that can be recycled into future blends or captured for incineration. The amount of material expected to be disposed of yearly is difficult to estimate, as the market has not yet been determined for the notified chemical. Any waste of the notified chemical or products containing the notified chemical would be in liquid form. For industrial users, drums and iso-containers may be re-used. The drum or iso-container is first steam cleaned and any wastewater containing the notified chemical is expected to be sent to on-site wastewater treatment facility.

5.6. Public exposure

It is expected that during transport, storage, blending and industrial use, exposure of the general public to the notified chemical will be minimal, except in the event of an accidental spill.

There are no known uses of the notified chemical for individual consumers. Therefore, the amount of the notified chemical that consumers could be dermally exposed to is negligible. Consumers would also have little contact with vapours of the notified chemical as the oil is used only in industrial settings.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa Colourless liquid with characteristic odour

Melting Point/Freezing Point -39°C (pour point)

METHOD	OECD TG 102 Melting Point/Melting Range. EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks	Using ISL CPP-97-2 Pour Point Analyser
TEST FACILITY	Phoenix Chemical Laboratory, Inc. (2006)

Boiling Point 365.6 – 636.1°C at 101.3 kPa

METHOD ASTM D-2887 "Standard Test Method for Boiling Range Distribution of Petroleum Fractions by Gas Chromatography"
Remarks Samples were run by a high temperature simulated distillation variation of ASTM D-2887.
TEST FACILITY Phoenix Chemical Laboratory, Inc. (2006)

Density 806 kg/m^3 at 20°C

METHOD ASTM D1475 "Standard Test Method for Density and Relative Density of Liquids by Digital Density Meter"
TEST FACILITY Phoenix Chemical Laboratory, Inc. (2006)

Vapour Pressure 0.667 x 10^{-7} kPa at 25°C (or 20°C).

METHOD Determined for the chemical notified as STD/1247 (accompanying this notification) by the in-house DEA method, representing the higher molecular weight fractions.
TEST FACILITY Phoenix Chemical Laboratory, Inc. (2006)

Viscosity Average 2.548 cTs at 100°C

METHOD ASTD D-445 Standard Test Method for kinematic Viscosity of Transparent and Opaque Liquids
TEST FACILITY Phoenix Chemical Laboratory (2006)

Water Solubility > 6.1mg/L at 20°C

METHOD OECD TG 105 Water Solubility.
Remarks Flask Method was used for determination of solubility of an analogue chemical (notified chemical in STD/1245), which is expected to have a lower water solubility than the notified chemical. The result was based on total organic carbon (TOC) analysis.
TEST FACILITY Investigative Science Incorporated (2006)

Hydrolysis as a Function of pH Not Determined

Remarks On the basis of the evidence presented, it is reasonable to conclude that the notified chemical will not be susceptible to hydrolysis and, as such, conducting hydrolysis testing is not warranted. It can be concluded that hydrolysis will not be a significant degradation pathway for these substances in the environment.

Partition Coefficient (n-octanol/water) log Pow at 20°C = 11.99-13.96

METHOD OECD TG 117 Partition Coefficient (n-octanol/water), HPLC Method.
EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks The partition coefficient of the notified chemical was modelled using KOWWIN modelling software (PRTL, 2006) and was estimated to range from 11.99-13.96.
TEST FACILITY PTRL West Inc (2006)

Adsorption/Desorption – screening test log K_{oc} = > 4.96 at 20°C (K_{oc} > 91200) (based on log Koc = 0.81 log Kow + 0.10)

METHOD Estimation
Remarks The estimation of minimum soil adsorption coefficients (K_{OC}) for the notified chemical was based on an empirically derived relationship between the K_{OC} and the octanol-water partition coefficient (K_{OW}) for "predominantly hydrophobic" chemicals. Based on these values, the notified chemical is predicted to be immobile in soil, under environmentally relevant conditions.

Dissociation Constant Not tested

Remarks As the notified chemicals do not contain any ionisable groups, it is not expected that they will dissociate throughout the environmentally relevant range of pH 4-9.

Particle Size Not applicable to liquids.

Flash Point Average 185°C (pressure unspecified)

METHOD EC Directive 92/69/EEC A.9 Flash Point.
REMARKS The flash point of the notified chemical was measured by the Cleveland Open Cup Tester method (BP North America, 2005).
TEST FACILITY Phoenix Chemical Laboratory, Inc. (2006)

Flammability Limits

METHOD ASTM E 681-98 "Standard Test Method for Concentration Limits of Flammability of Chemicals (vapours and Gases)"
Remarks The notified chemical was not volatile enough under the conditions of the test (at up to 250°C incoming air temperature) to determine lower or upper flammability limits.
TEST FACILITY Texas Oiltech Laboratories, Inc. (2006)

Autoignition Temperature Hot-Flame Autoignition Temperature (AIT) 343°C
Cool-Flame Autoignition Temperature (CFT): 277°C
Reaction Threshold Temperature for pre-flame reaction (RTT) 274°C

METHOD ASTM E659 Standard Test Method for Autoignition Temperature of Liquid Chemicals
TEST FACILITY Phoenix Chemical Laboratory (2006)

Explosive Properties Not tested

Remarks Using the approach outlined by "Bretherick's Handbook of Reactive Chemical Hazards" (Bretherick, 1990), the notified chemicals are not expected to show any explosive tendencies. An examination of the structures of the notified chemical shows that it does not contain groups that are expected to cause or enhance explosibility.

Reactivity Not expected to be reactive in use.

Remarks In general, the notified chemical is not designed or expected to be reactive in use. This is confirmed by the structure of the notified chemical.

7. TOXICOLOGICAL INVESTIGATIONS

The studies below were based on the analogue chemicals.

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral (4 studies)	LD50 > 5000 mg/kg bw low toxicity
Rat, acute dermal	LD50 > 2000 mg/kg bw low toxicity
Rat, acute inhalation	LC50 < 5.1 mg/L/1 hour harmful
Rabbit, skin irritation (3 studies)	slightly irritating
Rabbit, skin irritation	moderately irritating (based on 24 hour exposure)
Rabbit, eye irritation (4 studies)	slightly irritating
Guinea pig, skin sensitisation – adjuvant test.	limited evidence of sensitisation
Guinea pig, skin sensitisation – adjuvant test (2 studies)	no evidence of sensitisation
Rat, repeat dose/developmental toxicity – 91 days.	NOEL = 500 mg/kg bw/day
Genotoxicity – bacterial reverse mutation	non mutagenic

Genotoxicity – in vitro chromosomal aberrations in human lymphocytes	non genotoxic
Genotoxicity – in vitro mutagenesis in Chinese Hamster Ovary cells	inconclusive
Genotoxicity – in vivo mouse micronucleus test	non genotoxic

7.1. Acute toxicity – oral

7.1.1 Analogue chemical 1

TEST SUBSTANCE Analogue chemical 1

METHOD Regulation for the Enforcement of the Federal Hazardous Substance Act (16 CFR 1500).

Species/Strain	Rat/Sprague-Dawley derived, albino rats
Vehicle	Undiluted
Remarks - Method	The protocol was followed without deviation.

RESULTS

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

LD50	> 5000 mg/kg bw
Signs of Toxicity	Clinical changes observed during the observation period are as follows: 1. Transient mild depression 2. Oil hair coats All animals appeared grossly normal by the fifth post-dosage day.
Effects in Organs	Gross necropsies performed at the end of the study revealed in one rat: 1. Yellow-brown spot on the stomach lining No other gross pathological findings were seen.
Remarks - Results	No deaths occurred during the observation period.

CONCLUSION The analogue chemical is of low toxicity via the oral route.

TEST FACILITY Hill Top Biolabs (1998a)

7.1.2 Analogue chemical 2

TEST SUBSTANCE Analogue chemical 2

METHOD Regulation for the Enforcement of the Federal Hazardous Substance Act (16 CFR 1500).

Species/Strain	Rat/Sprague-Dawley derived, albino rats
Vehicle	Undiluted
Remarks - Method	The protocol was followed without deviation.

RESULTS

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

LD50	> 5000 mg/kg bw
Signs of Toxicity	Clinical changes observed during the observation period are as follows: 1. Mild transitory depression 2. Oily and/or scruffy hair coats All animals appeared grossly normal by the third or fourth post-dosage day.

Effects in Organs	Gross necropsies performed at the end of the study revealed in one rat: 1. Small spleen 2. Stomach lining appeared thickened and filled with clear liquid containing a bright yellow substance No other gross pathological findings were seen.
Remarks - Results	No deaths occurred during the observation period.

CONCLUSION The analogue chemical is of low toxicity via the oral route.

TEST FACILITY Hill Top Biolabs (1998b)

7.1.3 Analogue chemical 3

TEST SUBSTANCE Analogue chemical 3

METHOD Regulation for the Enforcement of the Federal Hazardous Substance Act (16 CFR 1500).

Species/Strain	Rat/Sprague-Dawley derived, albino rats
Vehicle	Undiluted
Remarks - Method	The protocol was followed with a deviation. a. One male rat dosed on this acute oral study weighted 178 grams which is slightly below the specified weight range in the protocol. This deviation did not compromise any aspect of this study.

RESULTS

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

LD50	> 5000 mg/kg bw
Signs of Toxicity	Clinical changes observed during the observation period are as follows: 1. Mild depression 2. Scruffy hair coats 3. Oily and/or scruffy hair These signs persisted through the third or fourth post-dosage days after which the animals appeared grossly normal.
Effects in Organs	The gross necropsies performed at the end of the study revealed no gross pathological changes.
Remarks - Results	No deaths occurred during the observation period.

CONCLUSION The analogue chemical is of low toxicity via the oral route.

TEST FACILITY Hill Top Biolabs (1998c)

7.1.4 Analogue chemical 4

TEST SUBSTANCE Analogue chemical 4

METHOD Regulation for the Enforcement of the Federal Hazardous Substance Act (16 CFR 1500).

Species/Strain	Rat/Sprague-Dawley derived, albino rats
Vehicle	Undiluted
Remarks - Method	The protocol was followed without deviation.

RESULTS

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

LD50	> 5000 mg/kg bw
Signs of Toxicity	Clinical changes observed during the observation period are as follows: 1. Transient mild depression 2. Oily hair coats These oily hair coats were observed on the day of dosing and persisted through the third post-dosage day after which the rats appeared grossly normal.
Effects in Organs	Gross necropsies performed at the end of the study revealed no gross pathological changes.
Remarks - Results	No deaths occurred during the observation period.

CONCLUSION The analogue chemical is of low toxicity via the oral route.

TEST FACILITY Hill Top Biolabs (1998d)

7.2. Acute toxicity – dermal

TEST SUBSTANCE DURASYN 125

METHOD OECD TG 402 Acute Dermal Toxicity.
U.S. EPA Health Effects Guidelines, OPPTS 870.1200 (1998)

Species/Strain	Rat/Sprague-Dawley derived, albino
Vehicle	Undiluted
Type of dressing	Occlusive
Remarks - Method	The protocol was followed without deviation.

RESULTS

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

LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	There were no signs of gross toxicity, dermal irritation, adverse pharmacological effects, or abnormal behaviour.
Signs of Toxicity - Systemic	
Effects in Organs	No gross abnormalities were noted for any of the animals when necropsied at the conclusion of the 14-day observation period.
Remarks - Results	All animals survived, gained body weight, and appeared active and health during the stud (Although the report was not signed by the main investigator, the data provided corresponds with the overall toxicological profile of these compounds and is considered to be relevant).

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

TEST FACILITY Product Safety Laboratories (2006)

7.3. Acute toxicity – inhalation

TEST SUBSTANCE Analogue chemical 3

METHOD U.S. Environmental Protection Agency. Toxic Substance Control Act Test Guidelines (40 CFR Part 798).
Official Journal of the European Communities, Council Directive 67/548/EEC and all subsequent adaptations.

Species/Strain	Rat/Sprague-Dawley CD
Vehicle	None.
Method of Exposure	Whole-body exposure
Exposure Period	1 hour
Physical Form	Liquid aerosol

Particle Size	1.9 μm ± 1.8%
Remarks - Method	No deviations from protocol noted.

RESULTS

In the study, a group of 10 CD rats (5/sex) were exposed to an aerosol of analogue chemical 3 at 5170 mg/m^3 (maximum practical concentration) for 1 hour. A control group (5/sex) was similarly exposed to room air only. The animals were observed for 14 days after exposure.

The average aerosol particle size was 1.9 μm with a standard deviation of 1.8. Only one treated female survived during the study and other treated animals died or were sacrificed on days 1 - 3 after exposure. Clinical signs of toxicity included reduced activity, partly closed eyes, hunched back, lateral prostration, increased respiratory rate, laboured and irregular breathing, and muzzle and abdominal staining. The surviving female was clinically normal by day 9. No clinical signs were observed in the controls.

Gross pathological examination revealed an increased incidence of fluid in the trachea, uncollapsed lungs and discolouration of the lungs in animals that died during the study and increased lung and trachea weights in the surviving female. Microscopical examination showed acute pneumonia and/or haemorrhage in the lungs, and slight focal or multifocal degeneration and/or necrosis of the epithelium of the nasal septum in the treated animals. The surviving female had mild interstitial pneumonia of a chronic nature and slight focal hyperplasia of the respiratory epithelium. Myocardial degeneration and/or fibrosis were also observed in this animal and was considered possibly related to the treatment.

CONCLUSION The analogue chemical is harmful via inhalation.

TEST FACILITY Bio-Research Laboratories (1994)

7.4. Irritation – skin

7.4.1 Analogue chemical 1

TEST SUBSTANCE Analogue chemical 1

METHOD US 16 CFR 1500 Hazardous Substances Labelling Act.

Species/Strain	Rabbit/New Zealand White
Number of Animals	3 M, 3 F
Vehicle	None
Observation Period	72 hours
Type of Dressing	Semi-occlusive.
Remarks - Method	Gauze patch was applied for 24 hours. Scoring was at 24 and 72 hours only.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Erythema/Eschar	0.42	2	> 24 hours	0
Oedema	0	0	-	-

*Calculated on the basis of the scores at 24 and 72 hours for ALL animals.

Remarks - Results The Primary Irritation Index was found to be 0.5 based on erythema and oedema. No evidence of tissue damage was found.

CONCLUSION The analogue chemical is slightly irritating to the skin.

TEST FACILITY Hill Top Biolabs (1988e)

7.4.2 Analogue chemical 2

TEST SUBSTANCE Analogue chemical 2

METHOD
Species/Strain: Rabbit/New Zealand White
Number of Animals: 6 F
Vehicle: None
Observation Period: 72 hours
Type of Dressing: Semi-occlusive.
Remarks - Method: Gauze patch was applied for 24 hours. Scoring was at 24 and 72 hours only.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Erythema/Eschar	0.67	3	> 72 hours	1
Oedema	0.42	2	> 24 hours	0

*Calculated on the basis of the scores at 24 and 72 hours for ALL animals.

Remarks - Results: The Primary Irritation Index was found to be 1.3 based on erythema and oedema. No evidence of tissue damage was found.

CONCLUSION: The analogue chemical is slightly irritating to the skin.

TEST FACILITY: Hill Top Biolabs (1988f)

7.4.3 Analogue chemical 3

TEST SUBSTANCE: Analogue chemical 3

METHOD
Species/Strain: Rabbit/New Zealand White
Number of Animals: 6 F
Vehicle: None
Observation Period: 72 hours
Type of Dressing: Semi-occlusive.
Remarks - Method: Gauze patch was applied for 24 hours. Scoring was at 24 and 72 hours only.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Erythema/Eschar	2	3	> 72 hours	3
Oedema	1	2	> 72 hours	1

*Calculated on the basis of the scores at 24 and 72 hours for ALL animals.

Remarks - Results: The Primary Irritation Index was found to be 3.1 based on erythema and oedema. No evidence of tissue damage was found.

CONCLUSION: The analogue chemical is moderately irritating to the skin.

TEST FACILITY: Hill Top Biolabs (1988g)

7.4.4 Analogue chemical 4

TEST SUBSTANCE: Analogue chemical 4

METHOD
Species/Strain: Rabbit/New Zealand White
Number of Animals: 3 F, 3 M
Vehicle: None

Observation Period	72 hours
Type of Dressing	Semi-occlusive.
Remarks - Method	Gauze patch was applied for 24 hours. Scoring was at 24 and 72 hours only.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Erythema/Eschar	0.42	1	> 24 hours	0
Oedema	0.17	1	> 24 hours	0

*Calculated on the basis of the scores at 24 and 72 hours for ALL animals.

Remarks - Results	The Primary Irritation Index was found to be 0.5 based on erythema and oedema. No evidence of tissue damage was found.

CONCLUSION The analogue chemical is slightly irritating to the skin.

TEST FACILITY Hill Top Biolabs (1988h)

7.5. Irritation – eye

7.5.1 Analogue chemical 1

TEST SUBSTANCE Analogue chemical 1

METHOD US 16 CFR 1500 Hazardous Substances Labelling Act.

Species/Strain	Rabbit/New Zealand White
Number of Animals	3 F, 3 M
Observation Period	72 hours
Remarks - Method	No deviations from protocol noted.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	0.61	1	> 72 hours	1
Conjunctiva: chemosis	0.28	1	> 72 hours	1
Conjunctiva: discharge	0	0	-	
Corneal opacity	0	0	-	
Iridial inflammation	0	0	-	

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

Remarks - Results	The eyes of five rabbits were found to show evidence of conjunctival changes. Irritation scores in individual rabbits ranged from 0 to 4.

CONCLUSION The analogue chemical is slightly irritating to the eye.

TEST FACILITY Hill Top Biolabs (1988i)

7.5.2 Analogue chemical 2

TEST SUBSTANCE Analogue chemical 2

METHOD US 16 CFR 1500 Hazardous Substances Labelling Act.

Species/Strain	Rabbit/New Zealand White
Number of Animals	6 F
Observation Period	72 hours
Remarks - Method	No deviations from protocol noted.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	0.17	1	> 72 hours	1
Conjunctiva: chemosis	0	0	-	0
Conjunctiva: discharge	0	0	-	0
Corneal opacity	0	0	-	0
Iridial inflammation	0	0	-	0

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

Remarks - Results The eyes of two of the rabbits were found to show evidence of conjunctival changes. Irritation scores in individual rabbits ranged from 0 to 2.

CONCLUSION The analogue chemical is slightly irritating to the eye.

TEST FACILITY Hill Top Biolabs (1988j)

7.5.3 Analogue chemical 3

TEST SUBSTANCE Analogue chemical 3

METHOD US 16 CFR 1500 Hazardous Substances Labelling Act.
Species/Strain Rabbit/New Zealand White
Number of Animals 6 F
Observation Period 72 hours
Remarks - Method No deviations from protocol noted.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	0.67	1	> 72 hours	1
Conjunctiva: chemosis	0.33	2	> 72 hours	1
Conjunctiva: discharge	0	0	-	0
Corneal opacity	0	0	-	0
Iridial inflammation	0	0	-	0

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

Remarks - Results The eyes of all the rabbits were found to show evidence of conjunctival changes. Irritation scores in individual rabbits ranged from 0 to 6.

CONCLUSION The analogue chemical is slightly irritating to the eye.

TEST FACILITY Hill Top Biolabs (1988k)

7.5.4 Analogue chemical 4

TEST SUBSTANCE Analogue chemical 4

METHOD US 16 CFR 1500 Hazardous Substances Labelling Act.
Species/Strain Rabbit/New Zealand White
Number of Animals 3 F, 3 M
Observation Period 72 hours
Remarks - Method No deviations from protocol noted.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	0.50	1	> 72 hours	1
Conjunctiva: chemosis	0.22	1	> 72 hours	1
Conjunctiva: discharge	0	0	-	0
Corneal opacity	0	0	-	0
Iridial inflammation	0	0	-	0

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

Remarks - Results The eyes of three rabbits were found to show evidence of conjunctival changes. Irritation scores in individual rabbits ranged from 0 to 4.

CONCLUSION The analogue chemical is slightly irritating to the eye.

TEST FACILITY Hill Top Biolabs (1988k)

7.6. Skin sensitisation

7.6.1 Analogue chemical 1

TEST SUBSTANCE Analogue chemical 1

METHOD OECD TG 406 Skin Sensitisation - <Maximisation Test>.
EC Directive 96/54/EC B.6 Skin Sensitisation - < Maximisation Test >.
EPA Subdivision F, Series 81-6, Dermal Sensitisation. 1984.
Japanese Ministry of Agriculture Forestry and Fisheries, 59 NohSan No. 4200. 1985.

Species/Strain Guinea pig/Dunkin-Hartley

PRELIMINARY STUDY Maximum Non-irritating Concentration:
intradermal: < 1%
topical: 100%

MAIN STUDY

Number of Animals Test Group: 20 Control Group: 10

INDUCTION PHASE Induction Concentration:
intradermal: 10%
topical: 25-100%

Signs of Irritation Slight erythema in one control animal at the intradermal induction site. Slight erythema in most animals after topical induction.

CHALLENGE PHASE

1st challenge topical: 100%

2nd challenge topical: 50%, 100%

Remarks - Method No deviations from protocol noted.

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	100%	2/20	1/20	1/20	0/20
	50%	-	-	0/20	0/20
Control Group	100%	0/10	0/10	0/10	0/10
	50%			0/10	0/10

Remarks - Results *Challenge*
Positive responses were noted in 2/20 of the test group animals at 24 h after patch removal, lasting to 48 h after patch removal in 1 animal. There were no positive responses noted in Control group animals.
Rechallenge
A positive response was noted in 1/20 of the test group animals

challenged with 100% of the analogue chemical, at 24 h after patch removal only.
In this study, only one (5%) positive response was noted in the test group at the 48 h challenge observation. If the one response seen at challenge was a true sensitisation response, this animal would have been expected to respond in the same way at rechallenge; no such response was noted in this animal at rechallenge. It is known that the chemical is a mild irritant and is thought to be responsible for the reactions.
No clinical signs, other than skin reactions at the test sites, were noted.

CONCLUSION: There was limited evidence of reactions indicative of skin sensitisation to the analogue chemical under the conditions of the test.

TEST FACILITY: Inveresk Research (1997a)

7.6.2 Analogue chemical 2

TEST SUBSTANCE: Analogue chemical 2

METHOD: Magnusson and Kligman (1969)
- Species/Strain: Guinea pig/Dunkin-Hartley
- PRELIMINARY STUDY: Maximum Non-irritating Concentration:
  intradermal: 5%
  topical: 100%
- MAIN STUDY
  - Number of Animals: Test Group: 20 Control Group: 20
- INDUCTION PHASE: Induction Concentration:
  intradermal: 5%
  topical: 100%
  - Signs of Irritation: None.
- CHALLENGE PHASE
  - 1st challenge: topical: 100%
  - 2nd challenge: None.

Remarks - Method: No deviations from protocol noted.

RESULTS

Remarks - Results: No animals in either the control or test article treated groups exhibited positive signs of erythema.

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

TEST FACILITY: Pharmakon Research International (1992a)

7.6.3 Analogue chemical 3

TEST SUBSTANCE: Analogue chemical 3

METHOD: Magnusson and Kligman (1969)
- Species/Strain: Guinea pig/Dunkin-Hartley
- PRELIMINARY STUDY: Maximum Non-irritating Concentration:
  intradermal: slight erythema at 0.5%
  topical: slight erythema at 10% in 1/4 animals.
- MAIN STUDY
  - Number of Animals: Test Group: 20 Control Group: 20
- INDUCTION PHASE: Induction Concentration:
  intradermal: 5%
  topical: 10%

Signs of Irritation	None noted.
CHALLENGE PHASE	
1st challenge	topical: 10%
2nd challenge	None.
Remarks - Method	No deviations from protocol noted.

RESULTS

Remarks - Results	No animals in either the control or test article treated groups exhibited positive signs of erythema.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the analogue chemical under the conditions of the test.
TEST FACILITY	Pharmakon Research International (1992b)

7.7. Repeat dose toxicity

7.7.1 Analogue chemical 1: 91- day toxicity study with in utero exposure phase (range finding study)

TEST SUBSTANCE	Analogue chemical 1
METHOD	In-house protocol (not specified)
Species/Strain	Rat/Sprague-Dawley
Route of Administration	Oral – gavage
Exposure Information	Exposure: From gestation day 0 to lactation day 20. Dose regimen: 7 days per week Pregnant females only were treated. All F0 females in groups 2 and 3, 3 females from groups 1 and 4 and 1 female from group 5 were euthanised and necropsied following lactation. Females from groups 4 and 5 were dosed for a total of 91 days. Ten F1 pups/sex/group were selected for a 21-day study phase initiated on postpartum day 22 and continued through postpartum day 42.
Vehicle	PEG 400
Remarks - Method	No deviations from protocol were noted.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	6 F	0	0
II	6 F	100	0
III	6 F	500	0
IV	6 F	1000	0
V	6 F	2000	0

Mortality and Time to Death

F0

Two females which failed to deliver were euthanised on post-breeding day 25.

F1

There was no effect of treatment on pup viability. A slightly greater male to female ratio of pups in group 5 on lactation day 0 was of unknown significance.

Clinical Observations

F0

A range of clinical observations was recorded as minor and likely to be due the vehicle. None were attributed to the test article. However, clinical signs are more apparent in high dose animals. No significant changes in body weights or body weight gain due to treatment were found during gestation, lactation or those dosed for 91 days.

There were no test article related effects on length of gestation, parturition or lactation.

F1

A number of incidental clinical findings were noted but were not related to the test article.

Effects in Organs

F0

There were no macroscopic or microscopic observations which were test article related.

F1

No test article related macroscopic or microscopic findings were noted.

Remarks – Results

None.

CONCLUSION

No significant maternal or developmental toxicity occurred with analogue chemical 1 at dosage levels up to 2000 mg/kg bw/day and indicated levels of 100, 500 and 1000 mg/kg bw/day for the main study.

TEST FACILITY Springborn Laboratories, Inc. (1995)

7.7.2 Analogue chemical 2: 91- day toxicity study with in utero exposure phase (main study)

TEST SUBSTANCE Analogue chemical 1

METHOD In-house protocol (not specified)

Species/Strain	Rat/Sprague-Dawley
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 90 days Dose regimen: 7 days per week Both males and females were dosed four weeks prior to mating. For the males, dosing continued until scheduled euthanasia (at the end of the breeding period). For the females dosing continued through gestation and through lactation day 20 or until euthanasia for females without evidence of mating and/or failure to deliver. Dams that delivered and weaned their offspring were euthanised on lactation day 21.
Vehicle	PEG 400
Remarks - Method	Minor deviations from protocol were noted but appeared to be unlikely to affect the outcome of the study.

RESULTS

Group	*Number and Sex of Animals* F0	F1	*Dose mg/kg bw/day*	*Mortality* F0	F1
I (control)	30/sex	20/sex	0	1 female	
II (low dose)	30/sex	20/sex	100	5 females	1 female
III (mid dose)	30/sex	20/sex	500	7 females	1 male
IV (high dose)	30/sex	20/sex	1000	3 females	1 male

Mortality and Time to Death

F0

One control female was euthanised as moribund during an incomplete delivery and one low dose female died accidentally. Four low dose, seven mid dose and three high dose females were euthanised post breeding day 25 after they produced no evidence of littering. One high dose female was euthanised due to total litter loss.

F1

There were no apparent test article effects on pup viability, live litter size, mean pups per litter and male to female ratio. One male in each of the mid and high dose groups and 1 low dose female were found dead on days 94, 54 and 27, respectively.

Clinical Observations

F0

A range of clinical observations was recorded as minor and likely to be due the vehicle. None were attributed to the test article.

No changes in body weights or body weight gain due to treatment was found for F0 males. For the females the only observation related to treatment was a significant decrease in body weight gain for high dose females.

The only treatment related changes to food consumption were in high dose females over days 1 – 7 and 7 – 14 of lactation. These changes were significant in g/animal/day but not when calculated as g/kg/day.

There were no test article related effects on fertility, length of gestation, pregnancy status, parturition or lactation.

F1

A number of incidental clinical findings were noted but were not related to the test article. Significant increases in body weight in high dose animals were noted in males over weeks 11 and 12 and in females over weeks 3 to 4 but were not ascribed to the test article. Food consumption decreased in mid dose females over weeks 6 to 7, in the low, mid and high dose groups over weeks 12 to 13 and in the low and mid dose groups over weeks 13 to 14. These changes were not considered to be biologically significant due to a lack of dose response or an abnormally increased control value.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

F1

Clinical Chemistry: No test article related changes.
Haematology: Elevated prothrombin time in high dose males; no dose related changes in females.

Effects in Organs

F0

None of the macroscopic observations in the F0 males were test article related.

None of the macroscopic findings for the euthanised females could be ascribed to the test article or the vehicle.

F1

No test article related macroscopic or microscopic findings were noted.

Remarks – Results

Treatment of F0 rats with Analogue 1 at the designated dosage levels did not produce significant organ toxicity or effects on fertility nor did the F1 pups exhibit toxic effects during the parturition and lactation phases. In the F1 rats during the 91-day toxicity phase no organ toxicity could be attributed to the test article.

A significant increase in prothrombin time in high dose males was not considered to be biologically meaningful as it did not correlate with a decrease in platelets, gross necropsy or microscopic findings.

CONCLUSION
A Lowest Observed Adverse Effect Level (LOAEL) of 1000 mg/kg/d due to the clinical signs prevalent in the high dose females that indicate stress (unkempt appearance) and the loss of the entire litter in one high dose female. A No Observed Effect Level (NOEL) of 500 mg/kg/d is set based on effects seen at the higher level.

TEST FACILITY Springborn Laboratories (1994)

7.8. Genotoxicity – bacteria

TEST SUBSTANCE Analogue chemical 1

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

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100; *Escherichia coli WP2uvr*A.
Metabolic Activation System	Aroclor 1254 induced rat liver S9 fraction.
Concentration Range in Main Test	a) With metabolic activation: 0, 156.25, 312.5, 625, 1250, 2500, 5000 µg/plate b) Without metabolic activation: 0, 156.25, 312.5, 625, 1250, 2500, 5000 µg/plate
Vehicle	Sorbitan stearate and polysorbate 60.
Remarks - Method	No deviations from protocol noted.

RESULTS

Remarks - Results	No evidence of cytotoxicity was noted at any concentrations. Some precipitates were noted at 5000 µg/plate. No toxicity was noted in a preliminary test on the basis of a consistent number of spontaneous mutant colonies in TA100 up to 5000 µg/plate. Negative controls were within acceptable limits and positive controls demonstrated the sensitivity of the test. No sign of increase in revertant colonies in any test strains, with or without metabolic activation.

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

TEST FACILITY Inveresk Research (1997b)

7.9. Genotoxicity – in vitro

TEST SUBSTANCE Analogue chemical 5

METHOD OECD TG 473 In vitro Mammalian Chromosome Aberration Test.
EC Directive 92/69/EC B.10 Mutagenicity - In vitro Mammalian Chromosome Aberration Test.

Cell Type/Cell Line	Human lymphocytes
Metabolic Activation System	Aroclor 1254 induced rat liver S9 fraction
Vehicle	Ethanol
Remarks - Method	No deviations from protocol noted.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	39, 78.1, 156.25, 312.5, 625, 1250*, 2500*, 5000*	4 hr	20 hr
Test 2	625, 1250*, 2500*, 5000**	4 hr	20, 44 hr

Present			
Test 1	39, 78.1, 156.25, 312.5, 625, 1250*, 2500*, 5000*	4 hr	20 hr
Test 2	625, 1250*, 2500*, 5000**	4 hr	20, 44 hr

*Cultures selected for metaphase analysis. ** Cultures selected for metaphase analysis at both harvest times

RESULTS

Remarks - Results	The negative controls were within historical limits and the positive controls demonstrated the sensitivity of the test. In test 2 one of the positive control cultures was negative due to excessive toxicity but this did not negate the conclusions of the experiment.

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

TEST FACILITY Safepharm Laboratories Limited (1995a)

7.10. Genotoxicity – in vitro

TEST SUBSTANCE Analogue chemical 5

METHOD OECD TG 476 In vitro Mammalian Cell Gene Mutation Test.
EC Directive 2000/32/EC B.17 Mutagenicity - In vitro Mammalian Cell Gene Mutation Test.

Cell Type/Cell Line	Chinese Hamster Ovary cells
Metabolic Activation System	Aroclor 1254 induced rat liver S9 fraction
Vehicle	Ethanol
Remarks - Method	The activated portion of test 1 was lost due to contamination and was repeated. In the confirmatory assay the number of cells seeded in all but one replicate and the highest dose was less than 2×10^5 cells/plate.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Expression Time*	*Selection Time*
Absent				
Test 1	313, 625, 1250, 2500, 5000	4 hrs	8 days	7 days
Test 2	313, 625, 1250, 2500, 5000	"	"	"
Present				
Test 1	313, 625, 1250, 2500, 5000	"	"	"
Test 2	313, 625, 1250, 2500, 5000	"	"	"

RESULTS

Remarks - Results	The first trial exhibited no differences in relative cloning efficiencies (RCEs) without metabolic activation. Contamination of cells conducted with metabolic activation invalidated the results and therefore this portion of the study was re-initiated. An increase in the number of mutants at 625 µg/ml was observed as compared to the control with metabolic activation. During the confirmatory trial, this increase in mutants was not observed at the same dose level, but at 2500 µg/ml. As there was no dose relationship and the number of mutants fell within the historical laboratory number, the test article utilised in the study was concluded to be non mutagenic. The positive control (with activation) had a range of average number of mutants per dose from approximately 200-400, while the analogue chemical had an average number of mutants of 8-9. Overall, the mutagenic potential of analogue chemical in this study was inconclusive.

CONCLUSION Under the study conditions, the mutagenic potential of the analogue chemical, was equivocal.

TEST FACILITY Sitek Research Laboratories (2001)

7.11. Genotoxicity – in vivo

TEST SUBSTANCE Analogue chemical 6

METHOD OECD TG 474 Mammalian Erythrocyte Micronucleus Test.
EC Directive 84/449/EC B.12 Mutagenicity - Mammalian Erythrocyte Micronucleus Test.

Species/Strain Mouse/CD-1
Route of Administration Oral – gavage
Vehicle Arachis oil
Remarks - Method No deviations from protocol noted.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
I (vehicle control)	5/sex	0	24, 48, 72 hrs
II (low dose)	"	1250	"
III (mid dose)	"	2500	"
IV (high dose)	"	5000	"
V (positive control, CP)	"	50	24 hrs

CP=cyclophosphamide.

RESULTS

Doses Producing Toxicity No clinical signs noted.
Genotoxic Effects There was no indication of toxicity at any dose level.
Remarks - Results There was no statistically significant increase in micronucleated PCEs in any test group when compared to vehicle control. There were no differences in the PCE/NCE ratio in any dose group as compared to the control.

Positive control group showed a marked increase in the incidence of micronucleated polychromatic erythrocytes, confirming the system.

CONCLUSION The analogue chemical was not clastogenic under the conditions of this in vivo mouse micronucleus test..

TEST FACILITY Safepharm Laboratories Limited (1995b)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE Durasyn 125, Durasyn 128, Durasyn 223, Durasyn 153 and Durasyn 156

The following is a table summary of results provided. This table summarises biodegradation testing performed on Durasyn 125, 128, 153 and 156 (while the third is the notified chemical, the others have been notified as STD 1243, 1245 1246 and 1247 respectively).

	Test Lab	**Test Type**	**Product Tested**	**Test Start Date**	**% Biodegradability**
1	[BfB Oil Research S.A, Belgium]	OECD 301B	[Durasyn 125]	2/9/2005	22.1
2	[ABC Laboratories, Inc, Columbia]	OECD 301D	[Durasyn 125]	8/2/1991	0.0
3	[BfB Oil Research S.A, Belgium]	OECD 301B	[Durasyn 128]	2/9/2005	7.9
4	[BfB Oil Research S.A, Belgium]	OECD 301B	[Durasyn 223]	25/10/2000	69.5
5	[BfB Oil Research S.A, Belgium]	OECD 301B	[Ethylflo 153]	22/10/1993	38.6

6	[BfB Oil Research S.A, Belgium]	OECD 301B	[Durasyn 153]	29/7/1996	87.3
7	[BfB Oil Research S.A, Belgium]	OECD 301B	[Durasyn 153]	23/10/1996	68.8
8	[Swiss Federal Laboratories for Material Testing and Research]	CEC-L33-T82	[Durasyn 153]	9/12/1997	35.0
9	[BfB Oil Research S.A, Belgium]	CEC-L33-T82	[Durasyn 153]	30/6/1993	71.0
10	[BfB Oil Research S.A, Belgium]	CEC-L33-T82	[Durasyn 153]	29/7/1993	72.8
12	[BfB Oil Research S.A, Belgium]	OECD 301B	[Ethylflo 156]	22/10/2003	34.2
13	[BfB Oil Research S.A, Belgium]	OECD 301B	[Durasyn 156]	29/7/1996	71.1
14	[BfB Oil Research S.A, Belgium]	OECD 301B	[Durasyn 156]	23/10/1996	49.2
15	[BfB Oil Research S.A, Belgium]	OECD 301B	[Durasyn 156]	4/6/1997	36.3
16	[BfB Oil Research S.A, Belgium]	OECD 301B	[Durasyn 156]	4/6/1997	60.8
17	[BfB Oil Research S.A, Belgium]	OECD 301B	[Durasyn 156]	2/7/1999	61.9
18	[BfB Oil Research S.A, Belgium]	OECD 301B	[Durasyn 156]	2/7/1999	62.4
19	[BfB Oil Research S.A, Belgium]	OECD 301B	[Durasyn 156]	3/8/2000	49.0
20	[BfB Oil Research S.A, Belgium]	OECD 301B	[Durasyn 156]	3/8/2000	41.5
21	[TNO Nutrition & Food Research, The Netherlands]	OECD 301B	[Durasyn 156]	24/11/2000	69.5
22	TNO Nutrition & Food Research, The Netherlands]	OECD 301B	[Durasyn 156]	16/1/2002	27.2
23	[Norwegian Institute for Water Research, Norway]	OECD 301F	[Durasyn 156]	9/12/1997	46.7
24	[Swiss Federal Laboratories for Material Testing and Research]	CEC-L33-T82	[Durasyn 156]	30/06/1993	63.1
25	[BfB Oil Research S.A, Belgium]	CEC-L33-T82	[Durasyn 156]	30/6/1993	56.0
26	[BfB Oil Research S.A, Belgium]	CEC-L33-T82	[Durasyn 156]	29/7/1993	59.3
27	[BfB Oil Research S.A, Belgium]	CEC-L33-A93	[Durasyn 156]	24/10/1996	35.1
28	[BfB Oil Research S.A, Belgium]	CEC-L33-A93	[Durasyn 156]	7/3/1997	41.1
29	[BfB Oil Research S.A, Belgium]	CEC-L33-A93	[Durasyn 156]	7/3/1997	40.5

Remarks - Results

Different levels of reporting ranging from 1-2 pages to full test reports have been provided.
Of these biodegradability tests Durasyn 153 was tested at 6 different times using OECD 301B guidelines, while Durasyn 156 had 19 such test results. Only in a few cases was the 10 day window met to confirm ready biodegradability.
The results for Durasyn 153 are summarised in more detail below.

TEST SUBSTANCE: Durasyn 153 (Ethylflo 153)

ETHOD: In accordance with OECD TG 301 B

Inoculum: Not reported

Exposure Period: 28 Days

Auxiliary Solvent: None specified

Analytical Monitoring: TOC

Remarks - Method: The sample biodegradability is calculated from the released CO_2 compared to blank and the reference.

RESULTS

Day	Sodium benzoate	Durasyn 153
	% CO_2 Total	% CO_2 Total
0	0.00	0.0
4	40.0	1.7
5	47.0	7.4
11	57.6	21.1
13	60.5	26.5
14	61.2	32.1
19	61.7	35.3
22	62.1	38.2
23	62.1	38.2
28	62.2	38.6

Remarks - Results: Sample biodegradability = 38.62 % after 28 days. The reference degradation indicates criteria are met.

CONCLUSION: The test substance is biodegradable but is not considered readily biodegradable.

TEST FACILITY: BfB Oil Research S.A. Belgium (1993)

TEST SUBSTANCE: Durasyn 153

METHOD: In accordance with OECD TG 301 B

Inoculum: Station Wavre Epuration 2nd stage

Exposure Period: 28 Days

Auxiliary Solvent: None specified

Analytical Monitoring: TOC

Remarks - Method: The sample biodegradability is calculated from the released CO_2 compared to blank and the reference.

RESULTS

Day	Sodium benzoate	Durasyn 153
	% CO_2 Total	% CO_2 Total
0	0.00	0.0
4	62.9	35.4
8	78.3	57.6
11	83.7	80.4
15	86.4	82.7
21	87.1	86.8
30	89.0	87.3

Remarks - Results: Sample biodegradability = 87.3 % after 30 days

CONCLUSION: The test substance is readily biodegradable

TEST FACILITY: BfB Oil Research S.A. Belgium (1996)

TEST SUBSTANCE: Durasyn 153

METHOD: In accordance with OECD TG 301 B

Inoculum: Station Wavre Epuration 2nd stage

Exposure Period: 28 Days

Auxiliary Solvent: None specified

Analytical Monitoring: TOC

Remarks - Method: The sample biodegradability is calculated from the released CO_2 compared to blank and the reference.

RESULTS

Day	Sodium benzoate	Durasyn 153
	% CO_2 Total	% CO_2 Total
0	0.00	0.0
2	53.8	3.8
5	73.9	24.1
14	78.5	45.6
20	94.8	61.6
23	95.8	64.8
28	96.5	68.8

Remarks - Results: Sample biodegradability = 68.8 % after 28 days

CONCLUSION: The test substance is readily biodegradable

TEST FACILITY: BfB Oil Research S.A. Belgium (1996)

CONCLUSION: Based on the results of biodegradability studies conducted it can

reasonably be assumed that Durasyn 153 is inherently biodegradable.

TEST FACILITY BfB Oil Research S.A., Belgium (1993 – 2005)

8.1.2. Bioaccumulation

While the molecular weight < 1000, the notified chemical is not expected to bioaccumulate, since the notified chemical is expected to be inherently biodegradable. Ready biodegradability tests specifically on the notified chemical showed ~39-87% biodegradation in 28 days. While this does not meet the requirements for ready biodegradability in all cases, these results are sufficient to indicate that the notified chemical is expected to be at least inherently biodegradable and is therefore not expected to bioaccumulate. Release to the aquatic compartment is also expected to be low.

8.2. Ecotoxicological investigations

Results are available for several of the notified chemicals or acceptable surrogates. Considering the range of structures, molecular weights and lack of water solubility, it is concluded the results are relevant to all notified chemicals**.**

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Durasyn 162 (equivalent to Durasyn 223)
METHOD	OECD TG 203 Fish, Acute Toxicity Test -static. EC Directive 92/69/EEC C.1 Acute Toxicity for Fish static
Species	*Brachydanio rerio*
Exposure Period	96 h LC_{50}
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	TOC analysis
Remarks – Method	The test substance was prepared as a Water Accommodated Fraction (WAF) due to its expected low water solubility. The test substance was tested for toxicity towards fish only up to the limit of its water solubility. For this purpose a suspension of the test substance was prepared to 10 g in 1 litre of drinking water. The notified chemical was introduced into the dilution water whilst shaking. Shaking was further continued for a further 24 h at room temperature. Thereafter the suspension was filtered through a filter paper. The pH of the elute was not corrected.
RESULTS	Under the conditions used for the test no toxic effect of the test substance to the fish was observed.

Water extract of X g Test substance per litre	*Number of Fish*	*Mortality*			
Nominal		*24 h*	*48 h*	*72 h*	*96 h*
Control (0)	7	0	0	0	0
10	7	0	0	0	0

LC50	> 1000 mg/L WAF nominal at 96 h
NOEC	1000 mg/L WAF nominal at 96 h
Remarks – Results	All organisms of the control and the treatment at 1000 mg/L survived the 96 h WAF toxicity test. The report analysed the levels of substance by IR which indicated the water soluble fraction was stable over time. However, there seems to be no indication of the concentration.
CONCLUSION	The test substance is considered to be non toxic to *Brachydanio rerio* up to the limit of its water solubility.
TEST FACILITY	Institut Fresenius, Chemische und Biologische Laboratorien GmBH (1997).

8.2.2.a Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Analogue chemical 6 (acceptable surrogate for Durasyn 156)
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test - static. EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia.
Species	*Daphnia magna*
Exposure Period	48 hours ELR_{50}
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	TOC analysis
Remarks - Method	In the range finding study Daphnia magna was exposed to a series of 100 and 1000 mg/L Water Accommodated Fractions of the test material at loading rates of 100 and 1000 mg/L. For the purpose of range finding study, amounts of test materials (0.20 and 2.00 g) were each separately dispersed onto the surface of 2 litres of reconstituted water to give 100 and 1000 mg/L loading rates respectively and then stirred by magnetic stirrer for 24 prior to the study start, care was taken to avoid vortex formation or gross mixing. Stirring was stopped after 24 hours and the mixture allowed to stand for 1 hour prior to removal of the aqueous phase or Water Accommodated Fraction (WAF) for testing. The WAF were not prepared by stirring the test water to give a vortex of 20-25 % of the water column height. At 24 hours prior to the study start, at the start of the mixing period, the test substance was observed to be contained within the vortex and present as clear, oily globules on the water surface. However, after 20 hours stirring and 4 hours standing the test material was observed at the water surface only. During testing, the WAF was observed to be a clear colourless solution at 0, 24 and 48 hours.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h [acute]*	*48 h [acute]*
Control		10	0	0
100		10	0	0
1000		10	0	0

ELR_{50}	> 1000 mg/L WAF at 48 hours
NOEC	1000 mg/L WAF at 48 hours
Remarks - Results	Total organic carbon (TOC) analyses were performed at 0 and 48 h, with no significant change compared to control, though levels were low (0.87-2.77 mg C/L). The pHs, temperatures, conductivities and dissolved oxygen concentrations were within acceptable levels.
CONCLUSION	The test substance is considered to be non-toxic to *Daphnia magna* up to the limit of its water solubility.
TEST FACILITY	Safepharm Laboratories Limited U.K.(1995c)

8.2.2. b Chronic toxicity to aquatic invertebrates

TEST SUBSTANCE	Durasyn 166 (equivalent to Durasyn 125)
METHOD	OECD TG 211 Daphnia sp. Acute Immobilisation Test and Reproduction test - static .

	EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia.
Species	*Daphnia magna*
Exposure Period	21 day ELR_{50}
Auxiliary Solvent	None
Water Hardness	Total hardness as $CaCO_3$: 160-170 mg/L
Analytical Monitoring	TOC analysis
Remarks - Method	Culture and WAF were prepared in 1900-L batches by fortifying well water according to the formula for hard water (U.S. EPA, 1975) Water Accommodated Fraction (WAF) of the loading rate (125 mg/L) were prepared daily at each renewal period by adding 0.539 mL of test substance directly into 3.5 L of fortified well water in a 4.0-L screw cap glass jar. The mass of test substance (0.4372 g) to be added was based on the experimentally-determined specific gravity of 0.8112 g/L. Prior to the addition of the fortified well water and test substance, a 2½-inch Teflon®-coated stir bar was added to the 4.0-L screw capped glass jar. The screw capped glass jar was then placed on a magnetic stir plate and stirred with no vortex for 48 hours. The WAF was then allowed to settle for 1 hour prior to use. The individual WAFs were drawn off directly into each replicate exposure vessel. A control solution was also prepared following the same procedures outlined except without the addition of the test substance. At the termination of the study, data obtained on organism survival, reproduction and growth were statistically analysed to identify significant effects. Analyses were performed using the organism response in each replicate vessel. All statistical conclusions were made at the 95 % level of certainty except in the case of Shapiro-Wilk's and F-Test for equality of two variances, in which the 99 % level of certainty was applied. The TOXTAT program was used to perform the computations and determine the No-Observed-Effect Loading Rate (NOELR) for survival, reproduction and growth. The NOELR is defined as the highest nominal rate that resulted in no statistically significant difference from the controls.

Below table shows survival of parental daphnids and number of offspring released per female daphnid (*Daphnia magna*) in control during the 21 day static-renewal exposure to Durasyn 166 (equivalent to Durasyn 125).

Day	A	B	C	D	E	F	G	H	I	J	NoADI	% Survival
Total Number of Offspring Released per Daphnid												
21	167	128	162	206	137	215	166	192	196	174	0	100

NoADI = Number of Adult Daphnids Immobilised

Below table shows survival of parental daphnids and number of offspring released per female daphnid (*Daphnia magna*) in the 125 mg/L loading rate during the 21 day static-renewal exposure to Durasyn 166 (equivalent to Durasyn 125).

Day	A	B	C	D	E	F	G	H	I	J	NoADI	% Survival
Total Number of Offspring Released per Daphnid												
21	172	137	157	151	138	141	155	179			2	80

NoADI = Number of Adult Daphnids Immobilised

Below table shows nominal loading retested, daphnid survival and cumulative mean number of offspring released, mean total body length and dry weight of daphnids (*Daphnia magna*) during 21 day static- renewal exposure to Durasyn 166 (equivalent to Durasyn 125).

Test Day 21				
Nominal Loading (mg/L)	**Mean % Survival**	**MNoOR per female (SD)**	**MTBL in mm (SD)**	**MDW in mg (SD)**

Control	100	174(28)	5.15 (0.14)	1.03 (0.14)
125	80	154 (15)	5.20 (0.09)	1.04 (0.11)
NOELR (mg/L)	125	125	125	125

SD = Standard deviation
MNoOR = Mean Number of Offspring Released
MTBL = Mean Total Body Length
MDW = Mean Dry Weight
NOELR = No-Observed-Effect loading Rate

Remarks - Results	Survival, reproduction and growth rate data from chronic exposure of *Daphnia magna* to Durasyn 166 are presented in the three tables above. Following 21 days of exposure, the control daphnid survival and reproduction (100 % and 174 offspring per female, respectively) met the minimum standard criteria established by OECD Guideline No 211 (i.e., ≥ 80 % survival, ≥ 60 offspring per female). As demonstrated by the performance of control organisms, the exposure system provided conditions which are appropriate for promoting acceptable survival, reproduction and growth of the test species.
CONCLUSION	Based on the results of this study, 21-day exposure to WAF of nominal loading rate of 125 mg Durasyn 166/L had no adverse effect on the survival, growth and reproduction of daphnids (*Daphnia magna*). The No-Observed-Effect Loading Rate (NOELR) for all biological endpoints was determined to be 125 mg/L. While there were differences in mean percent survival and mean number of offspring, they were not statistically significant.
TEST FACILITY	Springborn Smithers Laboratories U.S.A (2002a)

8.2.2. c Chronic toxicity to aquatic invertebrates

TEST SUBSTANCE	Durasyn 162 (equivalent to Durasyn 223)
METHOD	OECD TG 211 Daphnia sp. Acute Immobilisation Test and Reproduction test static . EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia.
Species	*Daphnia magna*
Exposure Period	48 hours ELR_{50}
Auxiliary Solvent	None
Water Hardness	Total hardness as $CaCO_3$: 160-170 mg/L
Analytical Monitoring	TOC analysis
Remarks - Method	Culture and WAF were prepared in 1900-L batches by fortifying well water according to the formula for hard water (U.S. EPA, 1975) Water Accommodated Fraction (WAF) of the loading rate (125 mg/L) were prepared daily at each renewal period by adding 0.544 mL of test substance directly into 3.5 L of fortified well water in a 4.0-L screw cap glass jar. The mass of test substance (0.4373 g) to be added was based on the experimentally-determined specific gravity of 0.8039 g/L. Prior to the addition of the fortified well water and test substance, a 7 cm Teflon®-coated stir bar was added to the 4.0-L screw capped glass jar. The screw capped glass jar was then placed on a magnetic stir plate and stirred with no vortex for 48 hours. The WAF was then allowed to settle for 1 hour prior to use. The individual WAFs were drawn off directly into each replicate exposure vessel. A control solution was also prepared following the same procedures outlined except without the addition of the test substance. At the termination of the study, data obtained on organism survival, reproduction and growth were statistically analysed to identify significant effects. Analyses were performed using the organism response in each replicate vessel. All statistical conclusions were made at the 95 % level of

certainty except in the case of Shapiro-Wilk's and F-Test for equality of two variances, in which the 99 % level of certainty was applied.

The TOXTAT program was used to perform the computations and determine the No-Observed-Effect Loading Rate (NOELR) for survival, reproduction and growth. The NOELR is defined as the highest nominal rate that resulted in no statistically significant difference from the controls.

Below table shows survival of parental daphnids and number of offspring released per female daphnid (*Daphnia magna*) in control during the 21 day static-renewal exposure to Durasyn 162 (equivalent to Durasyn 223).

Day	A	B	C	D	E	F	G	H	I	J	NoADI	% Survival
Total Number of Offspring Released per Daphnid												
21	192	213	216	163	186	142	158	144	153	177	0	100

NoADI = Number of Adult Daphnids Immobilised

Below table shows survival of parental daphnids and number of offspring released per female daphnid (*Daphnia magna*) in the 125 mg/L loading rate during the 21 day static-renewal exposure to Durasyn 162 (equivalent to Durasyn 223).

Day	A	B	C	D	E	F	G	H	I	J	NoADI	% Survival
Total Number of Offspring Released per Daphnid												
21	172	189	166	200	179		189	150		193	2	80

NoADI = Number of Adult Daphnids Immobilised

Below table shows nominal loading retested, daphnid survival and cumulative mean number of offspring released, mean total body length and dry weight of daphnids (*Daphnia magna*) during 21 day static- renewal exposure to Durasyn 162 (equivalent to Durasyn 223).

	Test Day 21			
Nominal Loading (mg/L)	**Mean % Survival**	**MNoOR per female (SD)**	**MTBL in mm (SD)**	**MDW in mg (SD)**
Control	100	174(27)	5.13 (0.22)	1.03 (0.14)
125	80	180 (16)	5.25 (0.08)	0.99 (0.06)
NOELR (mg/L)	125	125	125	125

SD = Standard deviation
MNoOR = Mean Number of Offspring Released
MTBL = Mean Total Body Length
MDW = Mean Dry Weight
NOELR = No-Observed-Effect loading Rate

Remarks - Results

Survival, reproduction and growth rate data from chronic exposure of *Daphnia magna* to Durasyn 162 are presented in the three tables above. Following 21 days of exposure, the control daphnid survival and reproduction (100 % and 174 offspring per female, respectively) met the minimum standard criteria established by OECD Guidelines No 211 (i.e., ≥ 80 % survival, ≥ 60 offspring per female). As demonstrated by the performance of control organisms, the exposure system provided conditions which are appropriate for promoting acceptable survival, reproduction and growth of the test species.

CONCLUSION

Based on the results of this study, 21-day exposure to WAF of nominal loading rate of 125 mg Durasyn 162/L had no adverse effect on the survival, growth and reproduction of daphnids (*Daphnia magna*). The No-Observed-Effect Loading Rate (NOELR) for all biological endpoints was determined to be 125 mg/L. While there were differences in mean percent survival, they were not statistically significant.

TEST FACILITY

Springborn Smithers Laboratories U.S.A (2002b)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	Analogue chemical 6 (acceptable surrogate for Durasyn 156)
METHOD	OECD TG 201 Alga, Growth Inhibition Test.- static EC Directive 92/69/EEC C.3 Algal Inhibition Test.
Species	*Selenastrum capricornutum*
Exposure Period	96 hours ELR_{50}
Concentration Range	1000 mg/L
Auxiliary Solvent	None
Water Hardness	Not given
Analytical Monitoring	TOC analysis
Remarks - Method	For the purpose of definitive study approximately 24 hours prior to the study start an amount of test material (4000 mg) was dispensed onto the surface of 2 litres of culture medium to give a 2000 mg/L loading rate and stirred for 20 hours. The stirrer rate (rpm) of the magnetic stirrer and the depth of the vortex (approximately 20-25 % of the depth of the mixing vessel) was recorded. After 20 hours stirring was stopped and the mixture allowed to stand for 4 hours prior to removal of the aqueous phase or Water Accommodated Fraction (WAF) for testing. An aliquot (300 mL) of the 2000 mg/L loading rate WAF was diluted 50:50 with algal suspension to give a final test concentration of 1000 mg/L loading Water Accommodated Fraction. Total organic carbon (TOC) analyses were performed at 0 and 96 h, with no significant change compared to control, though levels were low (0.53-2.35 mg C/L). The pHs, temperatures, conductivities and dissolved oxygen concentrations were within acceptable levels.

RESULTS

Biomass		Growth	
Nominal (WAF) E_bLR_{50} mg/L at 96 h	Nominal (WAF) NOEC mg/L at 96 h	Nominal (WAF) E_bLR_{50} mg/L at 96 h	Nominal (WAF) NOEC mg/L at 96 h
>1000	1000	>1000	1000

Remarks - Results	The 24, 48, 72 and 96 h E_bLR_{50} were > 1000 mg/L when calculated using biomass or growth rate.
CONCLUSION	The results showed no effect on growth at a concentration of 1000 mg/L.
TEST FACILITY	Safepharm Laboratories Limited U.K.(1995d)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified chemical will be imported and reformulated into lubricant oils at blending facilities. The used oil and the sludge collected from the on-site wastewater treatment facilities may be incinerated. This will generate water vapour and oxides of carbon and hydrogen.

The amount released to could be expected to become associated with suspended organic material (due to the calculated high Pow), settle out into the sediments and eventually be biodegraded.

9.1.2. Environment – effects assessment

Based on the ecotoxicity data provided, the notified chemical is not toxic up to the limit of water solubility where TOC = 0.53-2.35 mg/L. A PNEC could not be calculated based on the TOC value.

9.1.3. Environment – risk characterisation

The notified chemical is not toxic to the aquatic organisms tested up to the limit of its water solubility where the TOC = 0.53-2.35 mg/L. No PEC can be calculated but there is expected to be orders of magnitude safety margin. Further, the low water solubility of the notified chemical and its limited release to the aquatic environment (mainly via stormwater drainage) reduce the possibility of sufficient amounts remaining in solution to cause acute toxicity. The notified chemical released to water is expected to become associated with sediments, and biodegradation will further reduce the risk to the aquatic life.

Overall, the environmental risk from the proposed blending and use of the notified chemical is expected to be low.

As the notified chemical forms a component of an oil based product, which in itself poses a risk to the aquatic environment, the product should be prevented from entering waterways.

While the molecular weight < 1000, the notified chemical is not expected to bioaccumulate, since the notified chemical is expected to be inherently biodegradable. However, under normal usage, the notified chemical is not expected to enter the aquatic environment and to pose a hazard to aquatic organisms.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Based on the very high Kow, there could be potential for uptake of the chemical through intact skin following exposure. However its low solubility and molecular size prevent it from passage through biological membrane. Also the vapour pressure indicates there is potential for inhalation exposure for uses, such as changing oils. Inhalation exposure is not expected to be significant as it is likely to be controlled by general and local exhaust ventilation.

Dermal and ocular exposure while connecting and disconnecting pumps and lines and to a lesser extent during system cleaning and maintenance is expected to be low given that PPE will be employed in all blending establishments to control dermal and ocular exposure. While the use of couplings and pumps designed to minimise spillage is desirable, the extent of their use by customers for the notified chemical is unknown.

The estimated dermal exposure to the notified chemical, based on EASE model (EASE) using reasonable worst case defaults for particular activity (European Commission, 2003) is as follows:

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

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

For end use of oils or fluids containing the notified chemical estimated exposure can reasonably be described under the above category of "manual addition of liquids" with a similar value.

9.2.2. Public health – exposure assessment

Exposure of the public to the notified chemical will be minimal during transport, storage, blending and industrial use, except in the event of an accidental spill, as the products containing the notified chemical are not available to consumers.

9.2.3. Human health – effects assessment

Acute toxicity

Based on the analogue data, the notified chemical is of low acute oral toxicity (LD50 > 5000

mg/kg bw) and of low acute dermal toxicity (LD50 > 2000 mg/kg bw). Toxicity by inhalation is unlikely due to the viscosity of the notified chemical (2.548 cTs at 100ºC) compared to the analogue chemical (2 cSt at 100ºC). The data demonstrate however the potential for significant injury resulting from any inhalation into the respiratory tract.

Irritation and Sensitisation
The notified chemical is likely to be slightly irritating to rabbit skin and eyes and not skin sensitising in guinea pigs.

The skin irritation study showing a positive response was reported following 24 hours of exposure. It is likely that the extended timeframe may result in increased irritation as compared to a shorter exposure period.

Based on the skin irritation studies available for analogue chemicals 5 and 6 conducted over 4 hours, the notified chemical is likely to be non-irritating or slightly irritating.

One sensitisation study showed limited evidence of skin sensitisation. However, the irritation seen in 2 animals was considered to be due to the irritating nature of the notified chemical. Overall, the notified chemical is not likely to be sensitising to the skin.

Repeated Dose Toxicity
A preliminary dose range finding study was conducted with an analogue chemical to evaluate dose levels for a definitive toxicity/reproduction study.

Male and female Sprague dawley rats (30/sex/group) were dosed 0, 100, 500 or 1000 mg/kg bw/day, by oral gavage, once daily, for 4 weeks prior to mating and through lactation day 20. Twenty male and female pups/group (the F1 generation) were then dosed commencing on Day 22 of parturition for a total of a minimum of 90 days.

There were no test article related deaths during the study. Some animals were euthanised in all dose groups due to not producing litters. One F0 female in the high dose group was euthanised due to the loss of her entire litter. One F1 male in the 500 and 1000 mg/kg bw/d group and one F1 female in the 100 mg/kg bw/d group were found dead. As these animals had no clinical signs corresponding to toxicity, the deaths of these animals are likely due to gavage error as indicated by the perforated esophagus of the low dose female.

Body weight gain and food consumption were generally comparable to control animals at all dose levels, with the exception of decreased body weight gains in high dose females during week 4. Clinical signs or gross necropsy findings were sporadically manifested throughout the dose groups (F0 and F1) and included, but not limited to, hair loss, soft stools, scabs, unkempt appearance (which was more apparent in high dose F0 females), reddish staining, discharge or fluid, dark material around the eyes, nose and mouth, malalignment, incisor trimming, lacrimation, salivation, urine staining, rales, oily material around the neck, digit swelling, dehydration, mammary swelling, and axillary palpable masses. There were no dose relation or effects that could be correlated to the test substance noted amongst the findings, except for the exception above.

There were no differences in fertility indices (including pup viability, body weights, external observations) in any group as compared to the control group. There were no abnormal macroscopic findings in the pups that were not selected or were found dead prior to necropsy.

At study termination, a slight increase of prothrombin time was noted in F1 high dose males. The toxicological significance of this remains unclear. Although there were some changes in the 500 mg/kg bw/d F1 females (decreased MCHC and prothrombin time and increased erythrocytes and hematocrit). These were considered slight and of no toxicological significance. There were no treatment related biochemical, gross or microscopic histopathology findings.

Minor clinical signs and slight differences in hematology parameters were observed in animals dosed 1000 mg/kg bw/day and no toxicologically significant adverse effects were observed in animals dosed at 500 mg/kg bw/day. Therefore a LOAEL of 1000 mg/kg bw/d is provided

indicating low systemic and reproductive hazard.

Mutagenicity
The notified chemical is not considered mutagenic in bacteria reverse mutation, not genotoxic in chromosomal aberrations in human lymphocytes in vitro, and not genotoxic in mouse micronucleus test in vivo. The mutagenic potential of an analogue chemical in the study of mutagensis in Chinese Hamster Ovary cell in vitro was inconclusive under the study condition. The study contained a confirmatory trial which tested the chemical from 313 to 5000 μg/ml. The first trial exhibited no differences in relative cloning efficiencies (RCEs) without metabolic activation. Contamination of cells conducted with metabolic activation invalidated the results and therefore this portion of the study was re-initiated. An increase in the number of mutants at 625 μg/ml was observed as compared to the control with metabolic activation. During the confirmatory trial, this increase in mutants was not observed at the same dose level, but at 2500 μg/ml. As there was no dose relationship and the number of mutants fell within the historical laboratory number, the test article utilised in the study was concluded to be non mutagenic. The positive control (with activation) had a range of average number of mutants per dose from approximately 200-400, while analogue chemical 5 had an average number of mutants of 8-9 indicating a lower potential for inducing mutations. Overall, the mutagenic potential of analogue chemical 5 in this study was inconclusive.

Overall, the notified chemical is not mutagenic.

Based on the available data, the notified chemical is not classified as a hazardous substance in accordance with the *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004).

However, the notified chemical should be classified as R65 if it meets viscosity criteria.

9.2.4. Occupational health and safety – risk characterisation

Acute exposure
There is a risk of skin irritation experienced by lubricant blenders and end users as the lubricant contains up to 100% of notified chemical. Dermal exposure is likely to be minimal due to the highly controlled environment and may occur if the workers do not conform to safe practices. The risk of skin irritation will need to be controlled by the use of adequate PPE, particularly impervious gloves and protective clothing. Workers should also avoid eye contact as the notified chemical is slightly irritating to the eyes.

Repeated dose exposure
Based on a NOEL of 500 mg/kg bw/day, derived from a 91-day rat oral study the margin of exposure (MOE) for various activities are as follows:

Activity	*Estimated exposure for notified chemical <mg/kg bw/day>*	*Margin of Exposure (MOE)*
Manual addition of liquids	6	83
Coupling and decoupling of transfer line	0.6	830
Quality control sampling	0.3	1670

The MOE for blenders under “manual addition of liquids” will be the same as for end users of products containing the notified chemical. MOE greater than or equal to 100 accounting for intra- and inter-species differences are considered acceptable. The above table suggests that the risk of systemic effects may not be acceptable during manual operations, unless workers have appropriate skin protection during blending and end use.

9.2.5. Public health – risk characterisation

Public exposure to the notified chemical is expected to be minimal and therefore the public health risk is expected to be negligible.

10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

10.1. Hazard classification

Based on the available data, the notified chemical is not classified as a hazardous substance in accordance with the *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004).

However, the notified chemical should be classified as R65 if it meets viscosity criteria.

and

As a comparison only, the classification of 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.

Based on available data it is not possible to categorise the notified chemical according to the GHS for either health or environmental effects.

10.2. Environmental risk assessment

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

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

10.3.2. Public health

There is Negligible Concern to public health when used in the proposed manner.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified chemical provided by the notifier was in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 2003). It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

The label for the notified chemical provided by the notifier was in accordance with the *National Code of Practice for the Labelling of Workplace Substances* (NOHSC 1994). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical:
  - Local exhaust ventilation

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical:
  - Spillage should be avoided; spills should be should be cleaned up promptly with absorbents which should be put into containers for disposal; avoid contact with

eyes and skin

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical:
  - Goggles, respirator, chemical resistant gloves, overalls, and 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

- The following concentration limits should be implemented for release of the notified chemical to the environment:
  - If emergency personnel are unavailable, contain spilled material. For small spill add absorbent material, scoop up and place in a sealed, liquid proof container for disposal. For large spills dike spilled material or otherwise contain material to ensure runoff does not reach waterways.

Disposal

- Avoid contact of spilled material and runoff with soil and surface waterways. Consult an environmental professional to determine if local, regional or national regulations would classify spilled or contaminated materials as hazardous waste. Dispose of in accordance with all applicable local and national regulations.

Storage

  - Keep container tightly closed. Keep container in a cool, well ventilated area. Empty containers may contain harmful, flammable/combustible or explosive residue or vapours. Do not cut, grind, weld, reuse or dispose of containers unless adequate precautions are taken against these hazards.

Emergency procedures

- Contain spilled material. For small spill add absorbent. Scoop up material in a sealed, liquid-proof container for disposal. For large spills contain material to ensure runoff does not reach waterway.

12.1. Secondary notification

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 any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

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