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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

DLA

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Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Mobil Oil Australia Pty Ltd (ABN 88 004 052 984)
12 Riverside Quay
Southbank Vic 3006

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(s)
Structural Formula
Molecular Formula
Molecular Weight
CAS number
Spectral data
Hazardous & Non-Hazardous impurities and additives/adjuvants
Import volumes
Concentration in lubricating grease applications

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Melting Point/Freezing point
Boiling point
Density
Vapour pressure
Water solubility
Hydrolysis as a Function of pH
Partition Co-efficient
Adsorption/Desorption
Dissociation Constant
Particle Size
Flash Point
Flammability Limits
Autoignition Temperature
Explosive Properties
Reactivity
Toxicological studies

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Canada

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
DLA

Finished product marketing names:
Mobilith SHC 220, Mobilith SHC 460, Mobilith SHC 100, Mobilith SHC 007, Mobilith SHC PM (in general Mobilith SHC series)

METHODS OF DETECTION AND DETERMINATION

METHOD	IR spectroscopy
Remarks	Reference spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
Unknown, expected to be very high.

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None

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

ADDITIVES/ADJUVANTS
None

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
Imported in finished grease in sealed steel 174 kg drums and 16 kg pails.

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

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

USE
A thickener agent (< 5.0 % (w/w)) used in lubricating grease for industrial and automotive applications.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Melbourne.

IDENTITY OF MANUFACTURER/RECIPIENTS
Mobil Oil Australia Pty Ltd
Quality Packaging Services Pty Ltd
535 Somerville Road
Sunshine Vic

TRANSPORTATION AND PACKAGING
Finished grease products containing < 5% (w/w) notified chemical will be shipped and road transported in 174 kg drums and 16 kg pails directly from the dockside to a contract packaging company for storage and/or repackaging into end use containers comprising 2.5 kg tubs and 450 g cartridges.

5.2. Operation description

The notified chemical will not be manufactured in Australia but will be imported as a component of a fully formulated grease for industrial applications.

At the contract packaging company in Melbourne, the imported product will be repacked and this will involve pumping the grease from 174 kg drums or from 16 kg pails into smaller containers with the remains normally scraped out and placed on top of the next drum, prior to the pump being put in place. The drum pump has a follower plate with a tight seal around the edges, so the drum is usually "clean" at the completion of the run.

Prior to repackaging a small amount of sample is withdrawn form the head of the line and sent to laboratory for a QA check.

During industrial use, the grease will be predominantly applied using grease cartridges in a grease gun. The user cracks the seal on the cartridge and places it into the gun. The gun is then applied to "grease nipples" on the relevant piece of the equipment being lubricated and the grease is pumped into the bearing until a small amount of fresh grease is seen coming out of the relief system on the opposite side of the bearing.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Waterside, transport and whare house workers	low	1 hr/day	Monthly
Packaging workers	2	1.5 hrs/day	Monthly
Laboratory staff	1	0.5 hrs/day	Monthly
Industrial end users	high	1 hr/day	Monthly

Exposure Details

During transport and storage, workers are unlikely to be exposed to the notified chemical except when packaging is accidentally breached. Should a spill occur, it is expected to be contained and collected using suitable absorbents (eg sand), and placed into a suitable containers for disposal in accordance with information supplied on the MSDS and State legislation.

It is estimated that two packaging workers will be potentially exposed to the grease via skin & eye contact due to residues and spillages when they are involved in pumping and metering the imported grease into 2.5 kg tubs and 450 g cartridges or during connecting/disconnecting pump lines from a semi-automated filling machine. During equipment maintenance and cleaning procedures exposures are anticipated to be less frequent and in smaller quantities. The workers will wear suitable protective clothing, impervious gloves, and safety glasses and observe safe work practices. Additionally all work done will be done with adequate general ventilation.

One worker will be exposed to analysis of the notified chemical in a laboratory Quality Control check. Dermal exposure to the notified chemical at concentrations < 5% is possible during the analysis. Such exposure will be limited to a few minutes per batch. Laboratory workers will wear appropriate personal protective equipment - laboratory coats, safety glasses and gloves, when analysing the sample.

A large number of industrial workers will be end users of the grease product, predominantly by means of grease cartridges. During its end use, the cartridge will be applied on a grease gun and the grease pumped into the bearing. Exposure of these workers therefore is expected to be confined to dermal contamination and spillage when replacing the spent cartridges or while handling equipment components that have been in contact with the grease. Exposure would be minimised by personal protective equipment, industrial hygiene and good work practices. Grease applications using 2.5 kg tubs are also expected to be via enclosed and semi-automated pumps that will be operated by trained staff.

5.4. Release

RELEASE OF CHEMICAL AT SITE

During repackaging of the 174 kg drums and 16 kg pails, there is approximately 2 kg and 0.4 kg respectively of the grease product remaining in the containers when the pump breaks suction. This represents between 1-2.5% of the product remaining in the packaging as residue. It is normal practice for these residues to be collected with a scraper on an extension arm and placed on top of the next drum prior to attaching the pump. Assuming that scraping removes a further 95% of the residue in packaging, approximately 0.1% (< 3 kg per annum) of the notified chemical will ultimately require disposal from residues in packaging. Precautions are taken at the repacking facility to ensure residual material is not released to the environment.

Spills are only likely to occur if packaging is accidentally breached. Spilt material is expected to be contained and collected, and placed into suitable containers for disposal in accordance with MSDS instructions and State legislation.

RELEASE OF CHEMICAL FROM USE

During normal use, the grease containing the notified chemical is generally applied using sealed cartridges and grease guns and is in the form of a semi-solid or paste. Grease guns have a plunger which scrapes the walls and ensure efficient emptying of the cartridge. Residue in empty cartridges is therefore expected to be approximately 0.1% (< 3 kg per annum).

It is expected that the grease in the bearing will be lost over time. In automotive applications the losses to the environment are expected to be in a disperse manner, whilst losses from industrial applications will occur in a localised fashion. During repacking and lubricating of bearings it is expected that some grease may be spilled, dissolved in organic solvents or require disposal. Due to its viscosity the grease may be easily physically recovered by simply collecting the material with rags or paper for disposal. As this product is a long life grease it is likely that less than 5% (< 150 kg per annum) of the grease product will require disposal from repacking of bearings.

Release of the notified chemical due to spills will be limited and easily contained for disposal due to the physical nature of the grease.

5.5. Disposal

Waste grease from packaging residues, spills and from servicing bearings containing the notified chemical (up to 1%) is expected to be disposed of by licensed waste disposal contractors, (methods of disposal may include incineration, re-refining or use in low grade burner oil), in accordance with State regulations. It is expected that approximately 5% (< 150 kg per annum) of the notified chemical will be disposed of in this manner.

The notified chemical is part of long-life grease used in components such as bearings. At the end of the components' useful lives they are expected to be disposed of to landfill or used for recycled metal. The notified chemical is expected to be thermally destroyed during recycling of metal parts.

5.6. Public exposure

DIY enthusiasts may be exposed to grease containing the notified chemical at < 5% and will not normally be wearing gloves.

6. PHYSICAL AND CHEMICAL PROPERTIES

Studies of physical and chemical properties were carried out on an analogue DLG, a chemical of similar structure being assessed as STD/1213.

Appearance at 20ºC and 101.3 kPa White powder

Melting Point/Freezing Point > 260ºC

Remarks The result is expected to be similar to that of analogue DLG. Not able to be determined as the substance decomposes at > 260ºC without melting (metal block method).

TEST FACILITY Huntingdon Life Sciences Ltd (2004)

Boiling Point > 260ºC

Remarks The result is expected to be similar to that of analogue DLG. Not able to be determined as the substance decomposes at > 260ºC without melting (metal block method).
TEST FACILITY Huntingdon Life Sciences Ltd (2004)

Density 1420 kg/m^3 at 22ºC (estimate)

Remarks Based on result from analogue DLG. Measured using a pyknometer.
TEST FACILITY Huntingdon Life Sciences Ltd (2004)

Vapour Pressure < $2x10^{-6}$ kPa at 25 ºC

Remarks Value is based on analogue DLG. Measured using a vapour pressure balance.
TEST FACILITY Huntingdon Life Sciences Ltd (2004)

Water Solubility Approximately 317 g/L at 20ºC

Remarks The value is based on analogue DLG, measured using the flask method. The notified chemical is likely to have slightly lower water solubility than the analogue, based on their respective chemical structures.
TEST FACILITY Huntingdon Life Sciences Ltd (2004)

Hydrolysis as a Function of pH Not tested

Remarks Not relevant, as there are no functional groups likely to hydrolyse.

Partition Coefficient (n-octanol/water) log Pow = -0.25 ± 0.01 at 20ºC

Remarks Test conducted on the free acid form of the analogue DLG. The ionised form of the notified chemical is expected to have a lower log Pow than the free acid of the analogue whose log Pow was estimated by KOWWIN v 1.67 to be -5.03.

Adsorption/Desorption – screening test log K_{oc} < 1.33

Remarks A test on analogue DLG was conducted by HPLC, with the mobile phase at pH 3 and 9. The results for both tests were < 1.25. The notified chemical is likely to have slightly higher log K_{oc} than the analogue, based on its respective chemical structure. The value of 1.33 is an extrapolation by the notifier of the log K_{oc} value of the analogue to the notified chemical.
TEST FACILITY Huntingdon Life Sciences Ltd (2004)

Dissociation Constant pKa = 4.7

METHOD OECD TG 112 Dissociation Constants in Water.
Remarks The value is based on analogue DLG, measured using the titration method. The notified chemical and analogue have two equivalent functional groups capable of undergoing dissociation. Two dissociation constants would be expected from consecutive dissociations, but the test for DLG was unable to differentiate them and a single value is reported.
TEST FACILITY Huntingdon Life Sciences Ltd (2004)

Particle Size Not applicable

Remarks Substance is formed in a grease matrix and will not exist as a free particle.

Flash Point Not determined.

Remarks Given the lack of volatility for this substance, and expected occurrence of decomposition at elevated temperatures (analogue chemical data), it is unlikely that sufficient vapour phase concentrations will exist to sustain ignition.

Flammability Limits Not determined.

Remarks Based on analogue DLG, substance is expected to decompose > 260°C without melting.

Autoignition Temperature Not determined.

Remarks Since the substance is expected to decompose above approximately 260°C with no further changes up to 400°C. Based on analogue (DLG) melting point determinations, self-ignition is not expected.

Explosive Properties Not determined.

Remarks The notified chemical is not expected to have explosive properties, since there are no chemical groups that would infer explosive properties.

Reactivity

Remarks The notified chemical is expected to be stable under normal environmental conditions and would not be expected to exhibit any oxidising properties.

7. TOXICOLOGICAL INVESTIGATIONS

Some studies shown below were carried out on the notified chemical or grease containing the notified chemical. Some are carried out using analogues. Analogues 1 and 3 are salts while analogues 2 and 4 are fatty acids.
Published references on analogue chemicals which contain confidential information are listed in the Exempt Information section, not in the Full Public Report.

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50 ≈ 1098 mg/kg bw	harmful (Notified chemical)
Rat, acute dermal LD50 = 4000 mg/kg bw	low toxicity (Analogue chemical 1)
Rat, acute inhalation	not available
Rabbit, skin irritation	slightly irritating (Analogue chemical 2)
Rabbit, skin irritation	non-irritating (Analogue chemical 2)
Rabbit, skin irritation	slightly irritating (Analogue chemical 2)
Rabbit, skin irritation	non-irritating (Analogue chemical 2)
Rabbit, skin irritation	non-irritating (Analogue chemical 2)
Guinea pig, skin irritation	slightly irritating (Analogue chemical 2)
Rabbit, rat, skin irritation	non-irritating (Analogue chemical 2)
Human volunteer, skin irritation	slightly irritating (Analogue chemical 3)
Human volunteer, skin irritation	slightly irritating (Analogue chemical 3)
Human volunteer, skin irritation	slightly irritating (Analogue chemical 4)
Rabbit, eye irritation	irritating (Analogue chemical 2)
Rabbit, eye irritation	irritating (Analogue chemical 2)
Rabbit, eye irritation	moderately irritating (Analogue chemical 2)
Rabbit, eye irritation	moderately irritating (Analogue chemical 2)
Rabbit, eye irritation	moderately irritating (Analogue chemical 2)
Rabbit, eye irritation	moderately irritating (Analogue chemical 2)
Rabbit, rat, eye irritation	Irritating (Analogue chemical 2)
Human, repeat insult patch test	dermal irritation/no allergic contact sensitisation (Grease containing the notified chemical)
Guinea pig, skin sensitisation	no evidence of sensitisation (Analogue chemical 2)
Rat, repeat dose <inhalation> toxicity – 6 hours.	unspecified (Analogue chemical 2)

Rat, repeat dose <oral feed> toxicity – 28 days.	NOEL = 40 mg/kg bw/day (Analogue chemical 2)
Rat, repeat dose <oral feed> toxicity – 35 days.	NOEL = 400 mg/kg bw/day (Analogue chemical 2)
Rat, repeat dose <oral feed> toxicity – 33 weeks.	unspecified (Analogue chemical 2)
Rat, repeat dose <oral feed> toxicity – 19 weeks.	NOEL = 200 mg/kg bw/day (Analogue chemical 2)
Rat, repeat dose <oral feed > toxicity – 21 days.	unspecified (Analogue chemical 2)
Rat, repeat dose <oral feed > toxicity.	unspecified (Analogue chemical 2)
Rat, repeat dose <oral feed > toxicity – 14 weeks.	unspecified (Analogue chemical 2)
Rat, repeat dose <oral gavage> toxicity – 28 days.	unspecified (Analogue chemical 2)
Rat, repeat dose <oral gavage> toxicity – 28 days.	unspecified (Analogue chemical 2)
Rat, repeat dose <oral> toxicity – 35 days.	unspecified (Analogue chemical 2)
Rat, repeat dose <oral> toxicity – 5 days.	NOEL = 3615 mg/kg bw/day (Analogue chemical 2)
Rabbit, repeat dose <s.c.> toxicity – 4 days.	unspecified (Analogue chemical 2)
Guinea pig, repeat dose <oral> toxicity – 5 weeks.	unspecified (Analogue chemical 2)
Genotoxicity – bacterial reverse mutation	non mutagenic (DLG)
Genotoxicity – in vitro <Ames>	non genotoxic (Analogue chemical 2)
Genotoxicity – in vitro <Bacterial gene mutation assay>	non genotoxic (Analogue chemical 2)
Genotoxicity – in vitro <Cytogenic assay>	non genotoxic (Analogue chemical 2)
Genotoxicity – in vitro <Escherichia coli reverse mutation assay>	non genotoxic (Analogue chemical 2)
Genotoxicity – in vitro <Yeast gene mutation assay>	non genotoxic (Analogue chemical 2)
Genotoxicity – in vivo <Cytogenetic assay>	non genotoxic (Analogue chemical 2)
Genotoxicity – in vivo <Cytogenetic assay>	non genotoxic (Analogue chemical 2)
Genotoxicity – in vivo <Cytogenetic assay>	non genotoxic (Analogue chemical 2)
Genotoxicity – in vivo <Dominant lethal assay>	non genotoxic (Analogue chemical 2)
Genotoxicity – in vivo <Dominant lethal assay>	non genotoxic (Analogue chemical 2)
Genotoxicity – in vivo <Dominant lethal assay>	non genotoxic (Analogue chemical 2)
Genotoxicity – in vivo <Dominant lethal assay>	non genotoxic (Analogue chemical 2)
Genotoxicity – in vivo <Other>	non genotoxic (Analogue chemical 2)
Genotoxicity – in vivo <Host mediated assay>	non genotoxic (Analogue chemical 2)
Genotoxicity – in vivo <Host mediated assay>	non genotoxic (Analogue chemical 2)
Genotoxicity – in vivo <Host mediated assay>	non genotoxic (Analogue chemical 2)
Genotoxicity – in vivo <Host mediated assay>	non genotoxic (Analogue chemical 2)
Developmental and reproductive effects	non teratogenic (Analogue chemical 2)
Developmental and reproductive effects	non teratogenic (Analogue chemical 2)
Developmental and reproductive effects	non teratogenic (Analogue chemical 2)
Developmental and reproductive effects	non teratogenic (Analogue chemical 2)
Carcinogenicity	non carcinogenic (Analogue chemical 2)

7.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 425 Acute Oral Toxicity: Up-and-Down Procedure.
Species/Strain	Rat/Crl:CD (SD) IGSBR
Vehicle	De-ionised water
Remarks - Method	No circumstances occurred that would have affected the quality or integrity of the data.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	1 F	175	0
2	3 F	550	0
3	4 F	2000	4, between days 1-5

LD50	≈ 1098 mg/kg bw
Signs of Toxicity	All animals that were found dead during the study lost weight from their Day 1 (pre-fast) weight. All surviving animals gained weight over the study

	period.
	Clinical signs were noted in the 550 mg/kg and the 2000 mg/kg treated rats. The signs included decreased food consumption, emaciation, prostration, hypopnea, hypothermia, dried red ocular discharge, small amount of stool, mucoidal stool, soft stool, no stool and staining of fur in the anogenital area. Clinical signs were not evident in the animals dosed with 175 mg/kg.
Effects in Organs	Gross postmortem examination of the animals that were found dead revealed ano-genital staining, red and/or dark red areas or foci of the stomachs glandular mucosa, black ingesta in the stomach, small spleen, large adrenal glands, bright red lungs, abnormal contents of the stomach and gastrointestinal tract distended with gas.
	All other animals were free of gross postmortem abnormalities.
Remarks - Results	In conclusion, oral intubation of the test substance at dose levels of 2000 mg/kg bw produced mortality and overt signs of toxicity under the conditions of the study. Oral intubation of the test substance at 175 and 550 mg/kg bw did not produce mortality. However, oral intubation with 550 mg/kg bw produced some signs of toxicity. Based on these results, the acute oral LD_{50} was estimated to be 1098 mg/kg bw with 95% confidence limits of 550 mg/kg bw and 2000 mg/kg bw.
CONCLUSION	The notified chemical is harmful via the oral route.
TEST FACILITY	ExxonMobil Biomedical Sciences, Inc. (2004)

7.2. Acute toxicity – dermal

TEST SUBSTANCE	Analogue chemical 1
METHOD	Intraperitoneal injection
Species	Mice
Remarks - Method	No details available
RESULTS	No details available
LD50	4000 mg/kg bw
CONCLUSION	The analogue chemical is of low toxicity via the dermal route.
TEST FACILITY	Published reference on analogue chemical (1965)

7.3. Acute toxicity – inhalation

There were no acute inhalation toxicity test data submitted.

7.4. Irritation-skin

7.4.1 Analogue chemical 2, Study No.1

TEST SUBSTANCE	Analogue chemical 2
METHOD	500 mg of a 50% paste was applied to the clipped, intact skin, covered and held in contact for 24 h.
Species	Rabbit
Number of Animals	6
Vehicle	Propylene glycol
Remarks - Results	3/6 rabbits had slight to mild irritation.
CONCLUSION	The analogue chemical is slightly irritating to the skin.

TEST FACILITY	Published reference on analogue chemical (2000)

7.4.2 Analogue chemical 2, Study No.2

TEST SUBSTANCE	Analogue chemical 2
METHOD	500 mg was applied to the intact skin, covered and held in contact for 24 h.
Species	Rabbit
Number of Animals	6
Remarks - Results	0/6 rabbits showed skin corrosion.
CONCLUSION	The analogue chemical is non-irritating to the skin.
TEST FACILITY	Published reference on analogue chemical (2000)

7.4.3 Analogue chemical 2, Study No.3

TEST SUBSTANCE	Analogue chemical 2
METHOD	According to paragraph 1500.41 in Federal Register Vol. 38, No. 187, p. 26019 09/27/73
Species	Rabbit
CONCLUSION	The analogue chemical is slightly irritating to the skin.
TEST FACILITY	Published reference on analogue chemical (2000)

7.4.4 Analogue chemical 2, Study No.4

TEST SUBSTANCE	Analogue chemical 2
METHOD	Pure substance and 80% aqueous paste on a gauze patch on the skin of the back and ear, exposure duration: 1, 5, 15 min. (back) and 20 h (ear, back), response scored at 24, 72 h and 8 d.
Species	Rabbit
CONCLUSION	The analogue chemical is non-irritating to the skin.
TEST FACILITY	Published reference on analogue chemical (2000)

7.4.5 Analogue chemical 2, Study No.5

TEST SUBSTANCE	Analogue chemical 2
METHOD	BASF-Test
Species	Rabbit
CONCLUSION	The analogue chemical is non-irritating to the skin.
TEST FACILITY	Published reference on analogue chemical (2000)

7.4.6 Analogue chemical 2, Study No.6

TEST SUBSTANCE	Analogue chemical 2
METHOD	Tested on the shaved intact skin at a concentration of 50%
Species	Guinea pig

Vehicle	Propylene glycol
CONCLUSION	The analogue chemical is slightly irritating to the skin.
TEST FACILITY	Published reference on analogue chemical (2000)

7.4.7 Analogue chemical 2, Study No.7

TEST SUBSTANCE	Analogue chemical 2
METHOD	Not known
Species	Rabbit, rat
CONCLUSION	The analogue chemical is non-irritating to the skin.
TEST FACILITY	Published reference on analogue chemical (2000)

7.4.8 Analogue chemical 3, Study No.1

TEST SUBSTANCE	Analogue chemical 3 (8%)
METHOD	Cream in topical treatment
Species	Human volunteers
Number of Subjects	19 and 100 in a multicentre study
Vehicle	Water-in-oil emulsified ointment containing 0.05% zinc sulphate in a base containing wool alcohols, hard, soft and liquid paraffins.
Remarks - Method	A double-blind, placebo controlled, crossover study.
RESULTS	
Remarks - Results	Mild and transient irritation has been reported following application to the skin and near eyelids. Since no significant changes in serum were detected during the multicentre trial, it is considered that local application is unlikely to cause toxic effects.
CONCLUSION	The analogue chemical is slightly irritating to the skin.
TEST FACILITY	Published reference on analogue chemical (1991)

7.4.9 Analogue chemical 2, Study No.2

TEST SUBSTANCE	Analogue chemical 3 (8%)
METHOD	Ointment in topical treatment
Species	Human volunteers
Number of Subjects	227
Remarks - Method	A double-blind, placebo controlled study in nine centres (200) and parallel in two centres (27)
RESULTS	
Remarks - Results	A total of 72 adverse events were reported by patients and/or clinicians during the study, of which 56% occurred during placebo treatment. Of all events 71% were related to skin irritation and 19% to eyelid irritation. Generally the events were mild and transient and only 11 patients withdrew from the trial because of adverse event, all as a result of skin irritation (7 taking placebo, 4 taking ointment). No hematologic or biochemical abnormalities were detected during the study. Serum metal

levels were not significantly changed as a result of treatment.

After the controlled trial and posttreatment follow-up period, 75 patients volunteered to use ointment on an open basis. These patients were well controlled by long-term intermittent usage (for up to 2 years in some patients). The incidence of adverse events was low (7%) and related to mild and transient skin irritation. Long-term treatment did not reveal any unexpected or untoward adverse events or any haematological or biochemical abnormalities.

CONCLUSION The analogue chemical is slightly irritating to the skin.

TEST FACILITY Published reference on analogue chemical (1992)

7.4.10 Analogue chemical 4, Study No.1

TEST SUBSTANCE Analogue chemical 4 (20%)

METHOD
Species Human volunteers
Number of Subjects 340
Remarks - Method 24-week randomised double-blind study in conjunction with a broad-spectrum sunscreen
Test substance group: 167
Control group: 173

RESULTS

Remarks - Results Neither treatment elicited any serious adverse events. Local adverse events were encountered in both treatment groups. These events were mostly mild and transient and bore no implications for the continuation of the treatment. However, 4 patients in the test substance group and two patients of the control group discontinued treatment because of these local irritation symptoms.

In 8 test substance group and 4 control group patients a sensitisation to the study preparations was suspected. However, standard patch tests only revealed positive reactions with the sunscreen in 4 cases. After changing the brand of sunscreen those patients continued treatment uneventfully.

Mild cutaneous adverse effects were encountered in 61 test substance group patients (36.5%) and in 22 control group patients (12.7%). They mostly ceased following an adjustment of the amount of cream applied and/or temporarily reducing the frequency of application. Itching was the most frequently noted symptom, followed by stinging and burning sensations (27 of 61 test substance group patients; 10 of 22 control group patients). The more objectively assessable symptoms such as scaling (test substance group patients 1.8%; control group patients 1.7%), erythema (test substance group patients 6.6%; control group patients 5.8%) were observed at low incidence rates.

Marked local irritation was noted by 15 patients of the test substance group (9%) and by 2 patients of the control group (1.2%). Again, itching was the most prominent subjective symptom in the test substance group (11 of 15).

CONCLUSION The analogue chemical is slightly irritating to the skin.

TEST FACILITY Published reference on analogue chemical (1995)

7.5. Irritation-eye

7.5.1 Analogue chemical 2, Study No.1

TEST SUBSTANCE	Analogue chemical 2
METHOD	10 mg in the eyes; 20 sec. after contact the eye of one rabbit was washed.
Species	Rabbit
Number of Animals	2
Remarks - Results	The washed eye (mild conjunctival irritation) was normal within 3 days, the unwashed eye (mild conjunctival irritation, minimal iritic effect) was normal at 14 days.
CONCLUSION	The analogue chemical is irritating to the eye.
TEST FACILITY	Published reference on analogue chemical (2000)

7.5.2 Analogue chemical 2, Study No.2

TEST SUBSTANCE	Analogue chemical 2
METHOD	57.1 mg in the eyes; 20 sec. after contact the eye of one rabbit was washed.
Species	Rabbit
Number of Animals	2
Remarks - Results	The washed eye (moderate to mild conjunctival irritation, transient, mild opacity) was normal within 3 days, the unwashed eye (moderate to mild conjunctival irritation, minimal iritic effect, mild opacity) was normal at 7 days.
CONCLUSION	The analogue chemical is irritating to the eye.
TEST FACILITY	Published reference on analogue chemical (2000)

7.5.3 Analogue chemical 2, Study No.3

TEST SUBSTANCE	Analogue chemical 2
METHOD	Federal Register, Vol. 38, No. 187, paragraph 1500.42 and Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics, FDA, Austin 1959, P.51
Species	Rabbit
CONCLUSION	The analogue chemical is moderately irritating to the eye.
TEST FACILITY	Published reference on analogue chemical (2000)

7.5.4 Analogue chemical 2, Study No.4

TEST SUBSTANCE	Analogue chemical 2
METHOD	Pure substance and 805 aqueous paste was placed in the conjunctival sac, with responses scored at 24, 48 h and 8 d.
Species	Rabbit
CONCLUSION	The analogue chemical is moderately irritating to the eye.
TEST FACILITY	Published reference on analogue chemical (2000)

7.5.5 Analogue chemical 2, Study No.5

TEST SUBSTANCE	Analogue chemical 2
METHOD	Not available
Species	Rabbit
CONCLUSION	The analogue chemical is moderately irritating to the eye.
TEST FACILITY	Published reference on analogue chemical (2000)

7.5.6 Analogue chemical 2, Study No.6

TEST SUBSTANCE	Analogue chemical 2
METHOD	BASF-Test
Species	Rabbit
CONCLUSION	The analogue chemical is moderately irritating to the eye.
TEST FACILITY	Published reference on analogue chemical (2000)

7.5.7 Analogue chemical 2, Study No.7

TEST SUBSTANCE	Analogue chemical 2 (1 and 10% solution)
METHOD	Not available
Species	Rabbit, rat
Remarks - Results	Redness of the conjunctivae which was normal within 3 days
CONCLUSION	The analogue chemical is irritating to the eye.
TEST FACILITY	Published reference on analogue chemical (2000)

7.6. Skin sensitisation

7.6.1. Skin sensitisation – human volunteers

TEST SUBSTANCE	Grease containing notified chemical
METHOD	
Study Design	Induction Procedure: The grease was occlusively applied to the infrascapular area of the back of 157 human volunteers, either to the right or left of the midline, using a non-porous, plastic film adhesive bandage with a 2 cm × 2 cm Webril pad containing an even coating of the grease (0.2 g) affixed to the skin with Scanpor tape, as needed, The induction phase consisted of 9 consecutive occlusive applications of the test material. The patches were removed approximately 24 hours after application. The subjects returned to the facility at 48 hour intervals for evaluation of the treated sites, and to have identical patches re-applied. Those patches applied on Friday were removed on Saturday and the sites evaluated on Monday, i.e., 72 hours after application. Rest Period: 14 days Challenge Procedure was initiated during the sixth week of the study, with identical patches applied to previously unexposed sites. These patches were removed after 24 hours. The sites were inspected 48 and 72 hours after patch application and skin reactions were graded.

Study Group	170 male and female subjects, ranging from 18-76 years participated the study.
Remarks - Method	Thirteen of the starting 170 test subjects discontinued their participation in the study for various reasons unrelated to the testing material, therefore the results are based on the 157 subjects who completed the study.

RESULTS

Remarks - Results	One subject had reactions upon initial challenge indicative of possible sensitisation. Rechallenge conducted under both occlusive and semi-occlusive conditions was indicative of irritation and not sensitisation.

CONCLUSION	A Repeated Insult Patch Test (RIPT) was conducted using a grease containing < 5% of the notified chemical under occlusive dressing. The notified chemical was irritating and non-sensitising under the conditions of the test.
TEST FACILITY	TKL Research Inc. (1989)

7.6.2. Analogue chemical 2, Study No.1

TEST SUBSTANCE	Analogue chemical 2
METHOD	Tested on the shaved intact skin at a concentration of 50% in propylene glycol
Species	Guinea pig
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the analogue chemical under the conditions of the test.
TEST FACILITY	Published reference on analogue chemical (2000)

7.7. Repeat dose toxicity

7.7.1 Analogue chemical 2, Study No.1

TEST SUBSTANCE	Analogue chemical 2
METHOD	Unspecified
Species/Sex	Rat/Male and female
Route of Administration	Inhalation – unspecified
Exposure Information	Duration of exposure (inhalation): 6 hours, 15 applications Post-exposure observation period: no data
Physical Form	Unspecified
Remarks - Method	Doses: 126 mg/m^3

Remarks – Results

No toxic signs, blood tests normal, autopsy, organs normal

TEST FACILITY	Published reference on analogue chemical (2000)

7.7.2 Analogue chemical 2, Study No.2

TEST SUBSTANCE	Analogue chemical 2
METHOD	Unspecified
Species/Sex	Rat/Female
Route of Administration	Oral – feed
Exposure Information	Total exposure days: 28 days Post-exposure observation period: no data
Remarks - Method	Doses: 10, 20, 40 mg/d

RESULTS
Remarks – Results
No effects

CONCLUSION
The No Observed Effect Level (NOEL) was established as 40 mg/kg bw/day in this study based on the results.

TEST FACILITY Published reference on analogue chemical (2000)

7.7.3 Analogue chemical 2, Study No.3

TEST SUBSTANCE Analogue chemical 2

METHOD Unspecified
Species/Sex Rat/Male
Route of Administration Oral – feed
Exposure Information Total exposure days: 35 days
Post-exposure observation period: no data
Remarks - Method Doses: 200, 400, 800 mg/d

RESULTS
Remarks – Results
200 and 400 mg/d: no effects.
800 mg/d: growth retardation, temporary diarrhoea

CONCLUSION
The No Observed Effect Level (NOEL) was established as 400 mg/kg bw/day in this study based on the results.

TEST FACILITY Published reference on analogue chemical (2000)

7.7.4 Analogue chemical 2, Study No.4

TEST SUBSTANCE Analogue chemical 2

METHOD Unspecified
Species/Sex Rat/Male and female
Route of Administration Oral – feed
Exposure Information Total exposure days: 33 weeks
Post-exposure observation period: no data
Remarks - Method Doses: 400, 800 mg/d
Interim kill after 8, 23 and 25 w with histological examination.

RESULTS
Remarks – Results
400 mg/d: no clinical effects
800 mg/d: increased mortality, temporary growth retardation and diarrhoea
400 and 800 mg/d: chronic inflammatory alterations of the intestine

TEST FACILITY Published reference on analogue chemical (2000)

7.7.5 Analogue chemical 2, Study No.5

TEST SUBSTANCE Analogue chemical 2

METHOD Unspecified
Species/Sex Rat/Male
Route of Administration Oral – feed
Exposure Information Total exposure days: 19 weeks
Post-exposure observation period: no data

Remarks - Method	Doses: 50, 100, 200, 400 mg/d For feeding a protein deficient diet was used at each dose level, interim sacrifices in all dose groups after 7 w.

RESULTS

Remarks – Results

No clinical signs at dose levels < 400 mg/d, with the exception persistent growth retardation no clinical signs after 400 mg/d.

CONCLUSION

The No Observed Effect Level (NOEL) was established as 200 mg/kg bw/day in this study based on the results.

TEST FACILITY Published reference on analogue chemical (2000)

7.7.6 Analogue chemical 2, Study No.6

TEST SUBSTANCE Analogue chemical 2

METHOD	Unspecified
Species/Strain	Rat/Male Fischer
Route of Administration	Oral – feed
Exposure Information	Total exposure days: 3 weeks Post-exposure observation period: no data
Remarks - Method	Doses: 2% (approximately 1500 mg/kg bw) Test groups: 4 rats, control group: 13 rats

RESULTS

Remarks – Results

No hepatic peroxisome proliferation =, no increase in liver size, in hepatic activities of catalase and carnitine acetyltransferase and no hypolipidemia were observed

TEST FACILITY Published reference on analogue chemical (2000)

7.7.7 Analogue chemical 2, Study No.7

TEST SUBSTANCE Analogue chemical 2

METHOD	Unspecified
Species	Rat
Route of Administration	Oral – feed
Exposure Information	Total exposure days: unspecified Post-exposure observation period: no data
Remarks - Method	Doses: 0.1, 1, 3 and 5% (approximately 75, 750, 2250, 3750 mg/kg bw) Total number of animals: 169

RESULTS

Remarks – Results

3 and 5% dose rats: growth retardation, no other evidence of toxicity was seen.

TEST FACILITY Published reference on analogue chemical (2000)

7.7.8 Analogue chemical 2, Study No.8

TEST SUBSTANCE Analogue chemical 2

METHOD	Unspecified
Species	Rat
Route of Administration	Oral – feed
Exposure Information	Total exposure days: 14 w Post-exposure observation period: 8 w

Remarks - Method	Doses: 5% (approximately 3750 mg/kg bw)

RESULTS

Remarks – Results

Retardation of growth during the feeding, rapid weight gain during the postexposure observation period.

TEST FACILITY	Published reference on analogue chemical (2000)

7.7.9 Analogue chemical 2, Study No.9

TEST SUBSTANCE	Analogue chemical 2
METHOD	Unspecified
Species	Rat
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 4 w Post-exposure observation period: no data
Remarks - Method	Doses: 243 mg/rat/d Control group: water-treated control, young rats

RESULTS

Remarks – Results

No behavioural abnormalities, unchanged growth

TEST FACILITY	Published reference on analogue chemical (2000)

7.7.10 Analogue chemical 2, Study No.10

TEST SUBSTANCE	Analogue chemical 2
METHOD	Unspecified
Species	Adult rat
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 4 w Post-exposure observation period: no data
Remarks - Method	Doses: 730 mg/rat/d Control group: no data specified

RESULTS

Remarks – Results

Constant body weight, no behavioural abnormalities, no dysfunction of the kidney, normal level of blood residual nitrogen at the end of the study.

TEST FACILITY	Published reference on analogue chemical (2000)

7.7.11 Analogue chemical 2, Study No.11

TEST SUBSTANCE	Analogue chemical 2
METHOD	Unspecified
Species	Rat
Route of Administration	Oral – unspecified
Exposure Information	Total exposure days: 5 w Frequency of treatment: 5 d/w Post-exposure observation period: no data
Remarks - Method	Doses: 310-386 mg/kg, 610-922 mg/kg 4 rats/dose group

RESULTS

Remarks – Results

One rat died from pneumonia, normal weight gain, no adverse pathology.

TEST FACILITY	Published reference on analogue chemical (2000)

7.7.12 Analogue chemical 2, Study No.12

TEST SUBSTANCE	Analogue chemical 2
METHOD	Unspecified
Species/Strain	Rat/Male Sprague-Dawley CD
Route of Administration	Oral – unspecified
Exposure Information	Total exposure days: 5 d Frequency of treatment: daily Post-exposure observation period: 14 d
Remarks - Method	Doses: 3600, 4000, 5000, 5600 mg/kg

RESULTS

Remarks – Results

The subacute oral LD 50 was estimated to be 3615 mg/kg. No abnormal findings at gross necropsies of the surviving animals after the period of observation.

TEST FACILITY	Published reference on analogue chemical (2000)

7.7.13 Analogue chemical 2, Study No.13

TEST SUBSTANCE	Analogue chemical 2
METHOD	Unspecified
Species/Sex	Rabbit/Male
Route of Administration	s.c.
Exposure Information	Total exposure days: 4 d Frequency of treatment: once a day for 2 consecutive days, third application on the 4th day Post-exposure observation period: 2 d
Remarks - Method	Doses: 2000 mg/kg (applications 1 and 2), 4000 mg/d (application 3)

RESULTS

Remarks – Results

The authors called the salt of acid a mildly nephropathic agent due to the examined blood parameters (e.g. non-protein nitrogen, urea-N, creatinine, sugar, NaCl).

TEST FACILITY	Published reference on analogue chemical (2000)

7.7.14 Analogue chemical 2, Study No.14

TEST SUBSTANCE	Analogue chemical 2
METHOD	Unspecified
Species	Guinea pig
Route of Administration	Oral-unspecified
Exposure Information	Total exposure days: 5 w Frequency of treatment: 5 d/w Post-exposure observation period: no data
Remarks - Method	Doses: 682-942 mg/kg , 1032-1739 mg/kg 5 guinea pigs/dose group

RESULTS

Remarks – Results

No sign of toxicity, one animal died from pneumonia, no adverse pathology.

TEST FACILITY Published reference on analogue chemical (2000)

7.8. Genotoxicity – bacteria

TEST SUBSTANCE DLG

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

Species/Strain	*S. typhimurium*: TA 1535, TA 1537, TA 98, TA 100, TA 102.
Metabolic Activation System	Aroclor 1254-activated Sprague Dawley Rat liver S9 fraction
Concentration Range in Main Test	a) With metabolic activation: 25, 80, 250, 800, 2500 µg/plate. b) Without metabolic activation: 25, 80, 250, 800, 2500 µg/plate.
Vehicle	Reagent grade water for test substance
Remarks - Method	No circumstances occurred that would have affected the quality or integrity of the data.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 2500	> 2500	> 2500	negative
Test 2	> 2500	> 2500	> 2500	negative
Present				
Test 1	> 2500	> 2500	> 2500	negative
Test 2	> 2500	> 2500	> 2500	negative

Remarks - Results The analogue chemical did not induce an increase in mean revertant colony numbers equal to or greater than two or three times the vehicle control in any tester strain at any dose level tested with or without metabolic activation in either the initial or repeat assays. Negative controls were within historical limits.

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

TEST FACILITY ExxonMobil Biomedical Sciences, Inc. (2004a)

7.9. Genotoxicity-in vitro

7.9.1 Analogue chemical 2, Study No.1

TEST SUBSTANCE Analogue chemical 2

METHOD Ames test

Species/Strain	Study 1: *S. typhimurium*: TA 1535, TA 1537, TA 1538, TA 98, TA 100 Study 2*: S. typhimurium*: TA 100, TA 98, TA 1535, TA 1537, TA 1538
Remarks - Method	Metabolic activation: with and without

RESULTS negative

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

TEST FACILITY Published reference on analogue chemical (2000)

7.9.2 Analogue chemical 2, Study No.2

TEST SUBSTANCE Analogue chemical 2

METHOD	Bacterial gene mutation assay
Species/Strain	Study 1: E. coli *WP2uvrA* Study 2: *S. typhimurium*: TA-1530, G-46
Remarks - Method	Study 1: Metabolic activation: with and without Study 2: Metabolic activation: no data
RESULTS	negative
CONCLUSION	The analogue chemical was not mutagenic under the conditions of the test.
TEST FACILITY	Published reference on analogue chemical (2000)

7.9.3 Analogue chemical 2, Study No.3

TEST SUBSTANCE	Analogue chemical 2
METHOD	Cytogenic assay
Species/Strain	Human fibroblasts (WI-38)
Remarks - Method	Metabolic activation: no data
RESULTS	negative
CONCLUSION	The analogue chemical was not clastogenic under the conditions of the test.
TEST FACILITY	Published reference on analogue chemical (2000)

7.9.4 Analogue chemical 2, Study No.4

TEST SUBSTANCE	Analogue chemical 2
METHOD	Escherichia coli reverse mutation assay
Species/Strain	E. coli WP2
Remarks - Method	Metabolic activation: with and without
RESULTS	negative
CONCLUSION	The analogue chemical was not mutagenic under the conditions of the test.
TEST FACILITY	Published reference on analogue chemical (2000)

7.9.5 Analogue chemical 2, Study No.5

TEST SUBSTANCE	Analogue chemical 2
METHOD	Yeast gene mutation assay
Species/Strain	Saccharomyces cerevisiae D-3
Remarks - Method	Metabolic activation: no data
RESULTS	negative
CONCLUSION	The analogue chemical was not mutagenic under the conditions of the test.
TEST FACILITY	Published reference on analogue chemical (2000)

7.10. Genotoxicty-in vivo

7.10.1 Analogue chemical 2, Study No.1

TEST SUBSTANCE	Analogue chemical 2

METHOD	Cytogenetic assay
Species/Sex	Rat/Male
Route of Administration	Oral – unspecified
Remarks – Method	Exposure period: once a day for 5 consecutive days Doses: 3.75, 37.5, 375 mg/kg bw
RESULTS	
Remarks - Results	No detectable significant aberration of the bone marrow metaphase chromosomes at the dosage levels tested.
CONCLUSION	The analogue chemical was not clastogenic under the conditions of the test.
TEST FACILITY	Published reference on analogue chemical (2000)

7.10.2 Analogue chemical 2, Study No.2

TEST SUBSTANCE	Analogue chemical 2
METHOD	Cytogenetic assay
Species/Sex	Rat/Male
Route of Administration	Oral – unspecified
Remarks – Method	Exposure period: single administration Doses: 5000 mg/kg bw
RESULTS	
Remarks - Results	No detectable significant aberration of the bone marrow metaphase chromosomes.
CONCLUSION	The analogue chemical was not clastogenic under the conditions of the test.
TEST FACILITY	Published reference on analogue chemical (2000)

7.10.3 Analogue chemical 2, Study No.3

TEST SUBSTANCE	Analogue chemical 2
METHOD	Cytogenetic assay
Species/Sex	Rat/Male
Route of Administration	Oral – unspecified
Remarks – Method	Exposure period: once a day at 5 consecutive days Doses: 2500 mg/kg bw
RESULTS	
Remarks - Results	No detectable significant aberration of the bone marrow metaphase chromosomes.
CONCLUSION	The analogue chemical was not clastogenic under the conditions of the test.
TEST FACILITY	Published reference on analogue chemical (2000)

7.10.4 Analogue chemical 2, Study No.4

TEST SUBSTANCE	Analogue chemical 2
METHOD	Dominant lethal assay
Species/Sex	Rat/Male and female
Route of Administration	Oral – gavage

Remarks – Method	Exposure period: single administration Doses: 3.75, 37.5, 375 mg/kg bw Following treatment, the males were sequentially mated to 2 females per week for 8 weeks. 2 weeks after mating, female rats were sacrificed.
RESULTS	
Remarks - Results	Significant decreases in average implantations at weeks 1 and 4, and corpora lutea at weeks 4 and 7 were seen in the intermediate dose level. Increases in preimplantation losses were shown at week 1 for both dose groups (3.75 and 37.5 mg/kg bw). The compound was considered to be non-mutagenic.
CONCLUSION	The analogue chemical did not induce heritable mutations under the conditions of the test.
TEST FACILITY	Published reference on analogue chemical (2000)

7.10.5 Analogue chemical 2, Study No.5

TEST SUBSTANCE	Analogue chemical 2
METHOD	Dominant lethal assay
Species/Sex	Rat/Male and female
Route of Administration	Oral – gavage
Remarks – Method	Exposure period: once a day for 5 consecutive days Doses: 3.75, 37.5, 375 mg/kg bw Following treatment, the males were sequentially mated to 2 females per week for 7 weeks. 2 weeks after mating, female rats were sacrificed.
RESULTS	
Remarks - Results	Significant differences between the negative control and experimental groups were shown in a few instances, but no strong indications of change were seen. The compound was considered to be non-mutagenic.
CONCLUSION	The analogue chemical did not induce heritable mutations under the conditions of the test.
TEST FACILITY	Published reference on analogue chemical (2000)

7.10.6 Analogue chemical 2, Study No.6

TEST SUBSTANCE	Analogue chemical 2
METHOD	Dominant lethal assay
Species/Sex	Rat/Male and female
Route of Administration	Oral – gavage
Remarks – Method	Exposure period: single administration Doses: 5000 mg/kg bw Following treatment, the males were sequentially mated to 2 females per week for 8 weeks. 2 weeks after mating, female rats were sacrificed.
RESULTS	
Remarks - Results	The results did not significantly vary from those obtained from negative controls. The compound was considered to be non-mutagenic.
CONCLUSION	The analogue chemical was not clastogenic under the conditions of the test.
TEST FACILITY	Published reference on analogue chemical (2000)

7.10.7 Analogue chemical 2, Study No.7

TEST SUBSTANCE	Analogue chemical 2
METHOD	Dominant lethal assay
Species/Sex	Rat/Male and female
Route of Administration	Oral – gavage
Remarks – Method	Exposure period: once a day for 5 consecutive days Doses: 2500 mg/kg bw Following treatment, the males were sequentially mated to 2 females per week for 7 weeks. 2 weeks after mating, female rats were sacrificed.
RESULTS	
Remarks - Results	The results did not significantly vary from those obtained from negative controls. The compound was considered to be non-mutagenic.
CONCLUSION	The analogue chemical was not clastogenic under the conditions of the test.
TEST FACILITY	Published reference on analogue chemical (2000)

7.10.8 Analogue chemical 2, Study No.8

TEST SUBSTANCE	Analogue chemical 2
METHOD	Other
Species/Sex	Prosophila melanogaster/ Male and female
Route of Administration	Oral feed
Remarks – Method	Exposure period: during the whole larval period Doses: 4000 ppm
RESULTS	
Remarks - Results	Nondisjunction and loss of sex chromosomes No effects
CONCLUSION	The analogue chemical was not clastogenic under the conditions of the test.
TEST FACILITY	Published reference on analogue chemical (2000)

7.10.9 Analogue chemical 2, Study No.9

TEST SUBSTANCE	Analogue chemical 2
METHOD	Host mediated assay
Species/Sex	Mouse/Male
Route of Administration	Oral unspecified
Remarks – Method	Exposure period: single administration Doses: 3.75, 37.5, 375 mg/kg bw The indicator organism used in this study were: S. typhimurium TA-1530, G-46 and Saccharomyces cerevisiae D-3.
RESULTS	
Remarks - Results	S. typhimurium TA-1530, G-46: no increase in mutant frequencies. Saccharomyces D-3: the test produced a dose-response and indicated the compound as a weak mutagen.
CONCLUSION	The analogue chemical was not clastogenic under the conditions of the test.

TEST FACILITY	Published reference on analogue chemical (2000)

7.10.10 Analogue chemical 2, Study No.10

TEST SUBSTANCE	Analogue chemical 2
METHOD	Host mediated assay
Species/Sex	Mouse/Male
Route of Administration	Oral unspecified
Remarks – Method	Exposure period: once a day for each of 5 consecutive days (24 h apart) Doses: 3.75, 37.5, 375 mg/kg bw The indicator organism used in this study were: S. typhimurium TA-1530, G-46 and Saccharomyces cerevisiae D-3.
RESULTS	
Remarks - Results	S. typhimurium TA-1530, G-46, Saccharomyces D-3: no increase in mutant frequencies.
CONCLUSION	The analogue chemical was not clastogenic under the conditions of the test.
TEST FACILITY	Published reference on analogue chemical (2000)

7.10.11 Analogue chemical 2, Study No.11

TEST SUBSTANCE	Analogue chemical 2
METHOD	Host mediated assay
Species/Sex	Mouse/Male
Route of Administration	Oral unspecified
Remarks – Method	Exposure period: single administration Doses: 5000 mg/kg bw The indicator organism used in this study were: S. typhimurium TA-1530, G-46 and Saccharomyces cerevisiae D-3.
RESULTS	
Remarks - Results	S. typhimurium TA-1530, G-46, Saccharomyces D-3: no increase in mutant frequencies.
CONCLUSION	The analogue chemical was not mutagenic under the conditions of the test.
TEST FACILITY	Published reference on analogue chemical (2000)

7.10.12 Analogue chemical 2, Study No.12

TEST SUBSTANCE	Analogue chemical 2
METHOD	Host mediated assay
Species/Sex	Mouse/Male
Route of Administration	Oral unspecified
Remarks – Method	Exposure period: once a day for 5 consecutive days (24 h apart) Doses: 2500 mg/kg bw The indicator organism used in this study were: S. typhimurium TA-1530, G-46 and Saccharomyces cerevisiae D-3.
RESULTS	
Remarks - Results	S. typhimurium TA-1530, G-46, Saccharomyces D-3: no increase in mutant frequencies.

CONCLUSION	The analogue chemical was not mutagenic under the conditions of the test.
TEST FACILITY	Published reference on analogue chemical (2000)

7.11. Developmental toxicity/Teratogenicity

7.11.1 Analogue chemical 2, Study No.1

TEST SUBSTANCE	Analogue chemical 2

METHOD

Species/Strain	Rat/Wistar
Route of Administration	Oral – gavage
Exposure Information	Exposure days: 10 d Post-exposure observation period: 5 d
Remarks - Method	6-15 day of gestation Doses: 2.9, 13, 62, 288 mg/kg

Remarks - Results

No clearly discernible effect on nidation or on maternal or foetal survival were observed. The number of abnormalities in soft and skeletal tissues did not differ from the number occurring in the controls.

CONCLUSION

The analogue chemical was not teratogenic under the conditions of this test.

TEST FACILITY	Published reference on analogue chemical (2000)

7.11.2 Analogue chemical 2, Study No.2

TEST SUBSTANCE	Analogue chemical 2

METHOD

Species/Strain	Female mouse/albino CD-1
Route of Administration	Oral – gavage
Exposure Information	Exposure days: 10 d Post-exposure observation period: 2 d
Remarks - Method	6-15 day of gestation Doses: 2.6, 12, 56, 263 mg/kg

Remarks - Results

No clearly discernible effect on nidation or on maternal or foetal survival were observed The number of abnormalities in soft and skeletal tissues did not differ from the number occurring in the controls.

CONCLUSION

The analogue chemical was not teratogenic under the conditions of this test.

TEST FACILITY	Published reference on analogue chemical (2000)

7.11.3 Analogue chemical 2, Study No.3

TEST SUBSTANCE	Analogue chemical 2

METHOD

Species/Strain	Female rabbit/Dutch-belted
Route of Administration	Oral – gavage
Exposure Information	Exposure days: 13 d Post-exposure observation period: 10 d
Remarks - Method	6-18 day of gestation Doses: 2.5, 12, 54, 250 mg/kg

Remarks - Results
No clearly discernible effect on nidation or on maternal or foetal survival were observed The number of abnormalities in soft and skeletal tissues did not differ from the number occurring in the controls.

CONCLUSION
The analogue chemical was not teratogenic under the conditions of this test.

TEST FACILITY Published reference on analogue chemical (2000)

7.11.4 Analogue chemical 2, Study No.4

TEST SUBSTANCE Analogue chemical 2

METHOD

Species/Sex	Hamster/Female
Route of Administration	Oral – gavage
Exposure Information	Exposure days: 5 d Post-exposure observation period: 4 d
Remarks - Method	6-10 day of gestation Doses: 2, 9.5, 44, 205 mg/kg

Remarks - Results
No clearly discernible effect on nidation or on maternal or foetal survival were observed The number of abnormalities in soft and skeletal tissues did not differ from the number occurring in the controls.

CONCLUSION
The analogue chemical was not teratogenic under the conditions of this test.

TEST FACILITY Published reference on analogue chemical (2000)

7.12. Carcinogenicity

TEST SUBSTANCE Analogue chemical 2

METHOD

Species/Strain	Rat/Carworth farm
Route of Administration	Oral feed
Exposure Information	Not available
Remarks - Method	20 male rats/group, 10 female rats/control group, 19 female rats/1% group, no females in the other dose-groups

Mortality and Time to Death
Unchanged mortality

Clinical Observations
The weight gains of the 3 and 5% groups were significantly less than the controls.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
No evidence of gross pathology.

Effects in Organs – General
The results of microscopic examination were within normal limits.

CONCLUSION
The analogue chemical was not carcinogenic under the conditions of this test.

TEST FACILITY Published reference on analogue chemical (2000)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

Not tested. The free acid of the salt is expected to be inherently biodegradable in the environment. Estimates of biodegradability using EPI suite model BIOWIN (v4.01) indicate that biodegradation will be rapid. Modelling data indicates that the half-life is less than 182 days but may not be less than 28 days to satisfy the ready biodegradability criterion.

The reported biodegradability of the free acid is 36-42% after 5 days (Verschueren).

8.1.2. Bioaccumulation

Not tested. An assessment of the potential for analogue DLG to bioaccumulate based on both octanol water-partition coefficient data and water solubility indicates a very low probability for bioaccumulation to occur. The notified chemical is expected to have slightly lower water solubility and higher log Pow than the analogue, but is still unlikely to bioaccumulate.

8.2. Ecotoxicological investigations

8.2.1. Acute/chronic toxicity to aquatic invertebrates

TEST SUBSTANCE	MRD-05-528 (Grease containing 6% of an analogue)
METHOD	OECD TG 211 Daphnia sp. Reproduction Test - semi-static.
Species	*Daphnia magna*
Exposure Period	21 days
Auxiliary Solvent	None
Water Hardness	148 mg $CaCO_3$/L
Analytical Monitoring	Visual Observation
Remarks - Method	A range finding test was conducted by exposing 4 replicates of five daphnia to water available fractions (WAFs) of nominal concentrations of 1, 10 and 100 mg/L for 48 hours. A control was also run. The WAFs were prepared by loading the appropriate amount of test substance to dilution water in an aspirator bottle and stirring for 24 hours. The treatments were allowed settle for approximately 45 mins and the WAF was removed. The main test was conducted by subjecting ten replicates of a single daphnid to WAF of nominally 1mg/L of test substance and a control. The WAF was prepared as above except the stirring was 24 ± 1 hour; settling was 1 hour ± 15 mins with cooling to test temperature. Renewals of the test solution were performed daily by transferring each parent daphnid to a fresh WAF of the test substance, (by pipette with minimal transfer of medium.) Light: 16 hours light 8 hours dark; intensity 1137 – 1253 Lux. Dissolved Oxygen: 8.2 – 8.9 mg/L pH 7.9 – 8.0 Temperature 19.8 – 20.5 °C

RESULTS

Acute range finding test

Concentration mg/L		*Number of D. magna*	*Number Immobilised*
Nominal	*Actual*		*48 h [acute}*
0	NM	20	0
1	NM	20	0
10	NM	20	0
100	NM	20	0

NM = Not measured

RESULTS
Chronic test

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	*Mean offspring per female*
Nominal	*Actual*	*(Parents Only)*	*21 days*	*21 days*
0	NM	10	0	126
1	NM	10	1	111*

ND = Not measured

- This value did not include the replicate where the daphnid died on between day 20 and 21. The total number of offspring from this daphnid before mortality was 119. The notifier's test report indicated erroneously that the average number of offspring per female was 118.

LC50 > 100 mg/L WAF at 48 hours *[acute]*
> 1 mg/L WAF at 21 days *[chronic]*

NOEC 100 mg/L WAF at 48 hours *[acute]*
1 mg/L WAF at 21 days *[chronic]*

Remarks - Results The range finding acute test resulted in no mortality at any of the test concentrations. The WAFs for the main test appeared clear and colourless. The average body length for the control was 4.5 cm and 4.3 cm for the test substance. This was considered not significant within the 99% confidence limit of the measurements (though it was at 95%).

CONCLUSION The test substance is neither acutely nor chronically toxic to Daphnia.

TEST FACILITY ExxonMobil (2006)

8.2.2. Acute toxicity to fish

Aquatic toxicity was predicted was predicted for analogue DLG using ECOSAR v0.99, U.S. Environmental Protection Agency, EPI Suite v3.12, 2000. The value for the LC50 is > 1000 mg/L. It is therefore unlikely to be toxic to fish.

The reported toxicity (Verschueren) of the free acid to:

Species	Endpoint	Concentration mg/L
Leuciscus idus	48h LC0	> 1000
Brachydanio rerio	96h LC50	> 1000
Macrochirus	96h LC0	< 330
Pimephales promelas (Fathead Minnows)	96h LC50	97

8.2.3. Acute toxicity to aquatic invertebrates

Aquatic toxicity was predicted for analogue DLG using ECOSAR v0.99, U.S. Environmental Protection Agency, EPI Suite v3.12, 2000. The value for the LC50 is > 1000 mg/L. It is therefore unlikely to be acutely toxic to Daphnia.

8.2.4. Algal growth inhibition test

Aquatic toxicity was predicted for analogue DLG using ECOSAR v0.99, U.S. Environmental Protection Agency, EPI Suite v3.12, 2000. The value for the EC50 is > 1000 mg/L. It is therefore unlikely to be acutely toxic to algae.

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified chemical is a component of grease. The vast majority of this grease will be used for its intended purpose as a lubricant in bearings (or the like). The majority of the grease is expected to share the same fate as the bearings and be disposed of to landfill or be used in metal recycling at the end of the bearings' useful life. The grease and the notified chemical will undergo eventual abiotic and biotic degradation to landfill gases namely, oxides of carbon and methane; and water vapour and metal oxide. Grease contained in components used for recycled metal, will be combusted during metal recycling to form oxides of carbon and water vapour, with the metal oxide formed reporting to the slag.

Some losses of the grease are expected during normal use or during servicing and repacking of bearings. In automotive applications the losses to the environment are expected to be in a disperse manner, whilst losses from industrial applications will occur in a localised fashion. It is assumed that < 150 kg of the notified chemical will require disposal from repacking of bearings. This will mostly be done by professionals, who will dispose of the grease via licensed waste disposal. It is unlikely that any significant amount will be released to the environment by do-it-yourself (DIY) enthusiasts.

9.1.2. Environment – effects assessment

The test on the grease containing an analogue chemical and modelling data of the notified chemical show that it is unlikely to be toxic to aquatic organisms. The grease showed no acute or chronic toxicity to daphnia to the levels tested (100 and 1 mg/L WAF respectively). The modelling data show that the toxicity of the notified chemical to three trophic levels in the aquatic environment (algae, daphnia and fish) is likely to be > 1000 mg/L. The evidence for low aquatic toxicity is further supported by the published data for the free acid.

9.1.3. Environment – risk characterisation

No predicted environmental concentration (PEC) nor predicted no effect concentration (PNEC) can be calculated. However, the vast majority of the notified chemical will be disposed of by authorised landfill or by licensed waste treatment as a component of waste grease or contained in components in which the grease was used. The grease is viscous and water insoluble and therefore will be immobile. Although the notified chemical is water soluble, it is intimately mixed with the grease and it is unlikely to leach to the aquatic environment.

The notified chemical is unlikely to be toxic to aquatic organisms based on the modelling and analogue data.

The notified chemical is therefore unlikely to pose an unacceptable risk to the environment.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

The notified chemical is imported as a component of lubricating grease. In the event of a transport accident, workers can be exposed to the final grease products but their physical nature means they would not be distributed widely and waste should be easily collected for disposal.

The limited opportunity for dermal and/or ocular exposure during repackaging is further reduced by workers wearing chemical resistant gloves, safety glasses and long sleeved overalls. Laboratory staff wearing chemically resistant disposable gloves, safety goggles and long sleeved laboratory coats test small volumes of the grease and therefore exposure should be low.

Industrial end users may apply grease containing the notified chemical via a gun and flat spatula. Dermal exposure to the grease is likely to be common and protective gloves may not necessarily be used.

9.2.2. Public health – exposure assessment

As for industrial end users, DIY enthusiasts may experience frequent and prolonged dermal exposure to grease containing the notified chemical. Protective gloves may not necessarily be used during grease application.

9.2.3. Human health – effects assessment

Acute toxicity
The notified chemical is harmful via the oral route. It is likely to be of low acute toxicity via the dermal route based on the study of analogue chemical, a fatty acid, using rats.

Irritation
Based on the studies provided on the analogue chemicals, including fatty acids and a salt, the notified chemical is considered to be slightly irritating to skin, using rabbits, guinea pigs, rats and human volunteers. It is likely to be irritating to the eyes based on study of an analogue chemical, a fatty acid, using rabbits and rats.

Sensitisation
A Repeated Insult Patch Test (RIPT) was conducted using the grease containing < 5% of the notified chemical under occlusive dressing. The notified chemical was irritating and non-sensitising under the conditions of the test. There was no evidence of reactions indicative of skin sensitisation to the analogue chemical, a fatty acid, in the guinea pig test.

Overall, the notified chemical is considered not to be a potential skin sensitiser.

Repeated Dose Toxicity
In inhalation and oral repeat dose studies in rats, rabbits and guinea pigs for an analogue chemical, a fatty acid, No Observed Effect Levels (NOEL) were estimated to be 40 (rat, 28 days), 400 (rat, 35 days), 200 (rat, 19 weeks) and 3615 (rat, 5 days) mg/kg bw/day, based on the absence of treatment related effects.

Genotoxicity
Analogue chemical DLG was not mutagenic to bacteria. Analogue chemical 2, a fatty acid, is not mutagenic or clastogenic when treated in vitro (Ames test, bacterial gene mutation assay, cytogenetic yeast gene mutation assay) and in vivo (cytogenetic assay, dominant lethal assay, and host mediated assay) under the conditions of the tests. The notified chemical is likely to be non genotoxic.

Developmental and reproductive effects
The notified chemical is likely to be non teratogenic based on the study of an analogue chemical, a fatty acid, under the conditions of the test.

Carcinogenicity
The notified chemical is likely to be non carcinogenic based on the study of an analogue chemical, a fatty acid, under the conditions of the test.

Observations on Human Exposure
It is noted that the notified chemical is closely related to a chemical category being considered by the US HPV Chemical Challenge Program for grease thickeners. The chemicals in the HPV program are considered very low in toxicity based on extensive use in industry without reports of significant adverse effects for many decades. The fatty acids from which the salts are made are either edible or similar in structure to edible fatty acids. The salts formed in the presence of mineral or synthetic oils are not readily bioavailable due to size and limited solubility in the grease matrix.

Results from testing fatty acid salts compositionally similar to salts in this category and greases containing thickeners from this category, demonstrate that these materials are not acutely toxic by the oral or dermal route, are not irritating to the eyes or skin and do not induce skin sensitisation. Repeat dose studies in rats by the oral route or with dermal treatment did not show any significant adverse effects. Treatment with a grease dermally for 2 years did not cause skin cancer in C3H mice. Mutations were not induced in bacterial assays by fatty acids used to make salts in this category. Soluble salts were not mutagenic *in vitro*, and slight chromosomal effects occurred only from a very high dose of salt administered intraperitoneally. Considering, along with these data, the low solubility of salts of fatty acids in the grease thickeners category, the compounds are not likely to be mutagenic. No developmental or reproductive toxicity assays are available for salts of fatty acids in this category. Salt did not induce developmental effects in

orally treated pregnant rabbits.

Based on the available data, the notified chemical is classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004). The following risk phases for the notified chemical are recommended:
Xn: Harmful
R22: Harmful if swallowed
Xi: Irritant
R36: Irritating to eyes

9.2.4. Occupational health and safety – risk characterisation

The maximum concentration of notified chemical in grease is < 5% (w/w) but industrial workers can be exposed frequently and for a prolonged period if gloves are not worn. The toxicological profile does not identify any significant hazard at this concentration level and repeated or prolonged exposure will be unlikely to result in any systemic toxicity. Clinical trials of an analogue at 8% used to treat dermatitis have shown that long term use in humans appears not to have harmful effects at this concentration. Therefore, the risk to workers involved in transport and storage, use or disposal of the notified chemical is considered to be low.

9.2.5. Public health – risk characterisation

DIY enthusiasts may be exposed to grease for a prolonged period (several hours) but infrequently (a few times and year). Due to the low concentration of notified chemical in grease products and its expected low hazard at this concentration level together with low exposure, the risk of adverse health effects is considered to be low.

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

10.1. Hazard classification

Based on the available data the notified chemical is classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*. The classification and labelling details are:

Xn: Harmful
R22: Harmful if swallowed
Xi: Irritant
R36: Irritating to eyes
S25: Avoid contact with eyes
S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice

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.

	Hazard category	*Hazard statement*
Acute toxicity	4	Harmful if swallowed
Mild irritant	2B	Causes eye irritation

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 No Significant Concern to public health when used in the proposed manner.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of product containing the notified chemical provided by the notifier was in accordance with the NOHSC *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 products containing the notified chemical provided by the notifier was in accordance with the NOHSC *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

REGULATORY CONTROLS
Hazard Classification and Labelling

- The Office of the ASCC, Department of Employment and Workplace Relations (DEWR), should consider the following health hazard classification for the notified chemical:
  - Xn: Harmful
  - R22: Harmful if swallowed
  - Xi: Irritant
  - R36: Irritating to eyes

- The following safety phases for the notified chemical are recommended:
  - S25: Avoid contact with eyes
  - S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - 25% $\leq$ concentration: R22
  - 20% $\leq$ concentration: R36

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical in the grease product:
  - Avoid contact with skin and eyes
  - Wash eye promptly if exposed

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical in the grease product:

- Suitable protective clothing
- Eye/face protection
- Suitable gloves

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 NOHSC *Approved Criteria for Classifying Hazardous Substances*, 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 by incineration or landfill.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by physical collection and recycled or re-used to the extent practicable. If the spill is to water, stop leak if safe to do so, confine spill using boom and skim from water's surface.

12.1. Secondary notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(1) of the Act; if
- the notified chemical is included in grease at concentrations $\geq$ 5%

or

(2) 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.

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