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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Complex Soap TH18

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Street Address:	334 - 336 Illawarra Road MARRICKVILLE NSW 2204, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 9577 8888.
Website:	www.nicnas.gov.au

Director
Chemicals Notification and Assessment

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FULL PUBLIC REPORT

Complex Soap TH18

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Klüber Lubrication Australia Pty Ltd (ABN 77 005 809 852) of 3 Brand Drive Thomastown VIC 3074.

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 name, CAS number, molecular and structural formula, molecular weight, purity and spectral data.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: vapour pressure, water solubility, hydrolysis as function of pH, partition coefficient, adsorption/desorption, dissociation constant, particle size, flash point, explosive properties, reactivity, acute inhalation toxicity and chromosome damage (in vivo).

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None.

NOTIFICATION IN OTHER COUNTRIES
Austria, 2000.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Complex Soap TH18
Komplex Seife TH18
Isoflex NCA (formulated grease)
Klüberplex (formulated grease)
Klübersynth (formulated grease)
Duotemp (formulated grease).

3. COMPOSITION

DEGREE OF PURITY
High.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The ready-to-use grease containing the notified chemical will be imported by sea in 25 kg pails and 1 kg cans.

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

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

USE
The notified chemical is a component of a ready-to-use grease (at a concentration of less than 20%) used for long term and lifelong lubrication of rolling bearings, in automotive components, electrical control elements and small gears in sealed components throughout Australia.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Melbourne, Victoria

IDENTITY OF MANUFACTURER/RECIPIENTS
Various industrial sites throughout Australia

TRANSPORTATION AND PACKAGING
The notified chemical will be imported into Melbourne in plastic lined 25 kg pails and 1 kg steel cans by sea. From the notifier's site in Victoria the grease will be transported to various industrial sites throughout Australia.

5.2. Operation Description

More than half of the notified chemical will be used in the new automotive, machinery and equipment manufacturing sites. The greases containing the notified chemical will be added via automatic metering devices, dip feed devices or centralised lubrication devices in a closed system during the assembly of automotive components or machine and equipment parts.

Maintenance fitters and other mechanics at maintenance workshops will use less than half of the notified chemical. They will apply the greases manually by brush, spatula, grease gun or grease cartridge to existing machinery.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Importer	8-10	2-3 hour/day	3-6 day/year
Distributor		2-3 hour/day	<15 day/year
Manufacturing worker	<15		
Maintenance worker	<30	<1 hour/time	

Exposure Details
Inhalation exposure is expected to be negligible because the product containing the notified chemical is highly viscous and therefore has reduced potential to generate aerosols. In addition, the notified chemical has a very low vapour pressure, so vapour accumulation in the workplace air is unlikely. Eye contact is possible but also unlikely due to the high viscous nature of greases. Thus, dermal contact would be the main route for occupational exposure.

Importation and distribution
The formulated greases containing <20% notified chemical will be imported from overseas and distributed to end users including car and engine manufacturers, mining sites, engineering sites and maintenance workshops. Transport, storage and distribution of the lubricants should involve little exposure to the notified chemical, except in the case of an accidental spill.

End users
More than half of the notified chemical will be used in the automotive, machinery and equipment manufacturing sites. The greases containing the notified chemical will be added via automatic metering devices, dip feed devices or centralised lubrication devices in a closed system during the assembly of automotive components or machine and equipment parts. Occupational exposure during the automatic operation is expected to be negligible. Possible occupational exposure may occur when

opening the imported containers, adding the greases into storage containers, and during equipment cleaning up and maintenance. These operations generally will last for a short period of time, and dermal contamination would be the main route of occupational exposure.

Maintenance fitters and other mechanics at maintenance workshops will use less than half of the notified chemical. They will apply the greases manually by brush, spatula, grease gun or grease cartridge. Dermal exposure may occur during these manual operations. However, the exposure is expected to be infrequent (monthly or yearly) and has a short duration (<1 hour), as these products are designed to be long term lubricants.

The notifier indicated that workers will wear impermeable gloves, protective eyewear, protective clothing, and safety boots when using greases repeatedly or for prolonged periods.

5.4. Release

RELEASE OF CHEMICAL FROM USE

The notifier expects that the majority of the grease containing the notified chemical will be collected and disposed of by incineration. The notified chemical in wastes resulting from spillage and residual lubricant in import container and discarded machinery will be disposed of in landfill. Therefore, eventually the entire import volume is expected to need disposal.

5.5. Disposal

The notifier indicates that the majority of the grease containing the notified chemical will be collected and disposed of by incineration. Minor spills and residual lubricant in import drums and discarded machinery will be disposed of to landfill.

5.6. Public exposure

Significant public exposure to the notified chemical during importation, transportation and storage is unlikely, except in the event of an accidental spill. In the event of an accidental spillage, minor spills should be wiped up with cloth or paper towel and then collected in suitable containers and sealed for disposal. For major spills, keep public away and eliminate all sources of ignition. The spills should be scraped up with shovels and placed in suitable containers for disposal. All waste materials should be disposed of in accordance with State regulations for the disposal of oil and grease by licensed oil waste and registered waste drum companies where the product will be either recycled or incinerated. Some minor quantities, e.g. from minor spills or residual lubricant from the plastic liners, may be placed into landfill or they will be incinerated. Lubricants containing the notified chemical will not be available to the public for domestic use, and public exposure through the intended industrial use is expected to be negligible.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa	Colourless solid
Melting Point	200°C (decomposition)
Remarks	The melting point of the notified chemical was determined according to EC Directive 92/69/EEC A.1 Melting Freezing Temperature and OECD TG 102, Melting point/ Melting Range.
TEST FACILITY	Institut Für Biologische Analytik und Consulting IBACON GmbH (1999a).
Density	1070 kg/m^3 at 20°C
Remarks	The melting point of the notified chemical was determined according to EC Directive 92/69/EEC A.3 Relative Density and OECD TG 109, Density of liquids and Solids.
TEST FACILITY	Institut Für Biologische Analytik und Consulting IBACON GmbH (1999b).
Vapour Pressure	$< 8 \times 10^{-8}$ Pa at 25ºC.
METHOD	OECD TG 104 Vapour Pressure.

EC Directive 92/69/EEC A.4 Vapour Pressure.

Remarks: The vapour pressure was estimated using the lowest boiling point component of the notified chemical mixture. A boiling point of 331ºC was calculated for the free sebacic acid component utilising Meissner's method. The vapour pressure of this component was calculated to be 1×10^{-4} Pa. However, the corresponding dicalcium salt exhibited a lower vapour pressure than the free acid. The vapour pressure was estimated to be less than 8×10^{-8} Pa based on the calculated boiling point and using the Modified Watson Correlation.

TEST FACILITY: Institut Für Biologische Analytik und Consulting IBACON GmbH (1999c).

Water Solubility 363 DOC (Dissolved Organic Carbon) mg/L at 20ºC

METHOD: OECD TG 105 Water Solubility.

Remarks: The notifier indicates that the solubility of notified chemical was initially determined by visual assessment. The notified chemical (0.1 g) was added to deionised water in a 10 mL glass tube. After each addition the mixture was mixed vigorously and then checked for undissolved particles. The water solubility of the notified chemical determined by visual assessment was less than 1 g/L. The water solubility was also determined by a simplified flask method. Saturated solutions were prepared by mixing an excess of the notified chemical in dionised water for 24, 48 and 72 h at 30ºC followed by incubation for a further 24 h at 20ºC. The resulting suspensions were filtered and concentration of the notified chemical was determined by analysis for dissolved organic carbon. The result obtained above for the water solubility can presumably be attributed to Component I of the mixture.

TEST FACILITY: Institut Für Biologische Analytik und Consulting IBACON GmbH (1999d).

Hydrolysis as a Function of pH Not determined

Remarks: The notifier indicates that given its relatively low water solubility it was not possible to determine the notified chemical's propensity to hydrolyse. The notified chemical does contain amide groups that will not hydrolyse in the environmental pH range of 4-9 due to low solubilities of these components.

Partition Coefficient (n-octanol/water) log Pow = 0.9 (Component I)
log Pow = 9.2 (Component II)
log Pow = 18 (Component III)

Remarks: The notifier indicated that the notified chemical's solubilities in both water and octanol were so low that experimental determination of the partition coefficient was not possible. Therefore, the partition coefficient was determined by theoretical fragmentation of the molecule according to the Leo-Hansch method.

TEST FACILITY: Institut Für Biologische Analytik und Consulting IBACON GmbH (1999e).

Adsorption/Desorption log K_{oc} = 1.9 (Component I)
log K_{oc} = 6.3 (Component II)
log K_{oc} = 11.2 (Component III)

Remarks: Estimated through Quantitative Structure Activity Relationships (QSAR) using the relationships $\log_{10} K_{oc} = 0.544 \log P_{ow} + 1.377$ (based on partition coefficient). The adsorption/desorption coefficient indicates that components II and III of the notified chemical will be immobile in soil. However, Component I is expected to exhibit higher mobility in soil.

TEST FACILITY: RCC Ltd, Itingen, Switzerland (2001a).

Dissociation Constant pKa = 4.9 (Aliphatic carboxylic acid)
pKa = 22.7 (Amide)

Remarks: The dissociation constant was estimated based on applying a free energy relationship based on Taft and Hammett correlations. The carboxylic acid component of the notified chemical will remain fully dissociated while the amide

component is unlikely to dissociate in the environmental pH range of 4-9.

TEST FACILITY RCC Ltd, Itingen, Switzerland (2001b).

Particle Size Not determined.

Remarks The notified chemical is synthesised in situ in base oils and will not be isolated from the grease.

Flash Point Not determined.

Remarks The notified chemical is of a very low vapour pressure.

Flammability Limits Not highly flammable.

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids).

Remarks In contact with the ignition source, the notified chemical melted and coloured black. However, the test substance could not sustain a burning reaction.

TEST FACILITY Institut Für Biologische Analytik und Consulting IBACON GmbH (1999f).

Autoignition Temperature Not auto-flammable

METHOD 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.

Remarks The notified chemical shows three exothermic reactions. The starting temperatures for the three exothermic reactions were about 161, 217 and 293°C, respectively. A maximum temperature of about 351°C was measured in the sample cube. At the end of the run, the notified chemical showed a loss of mass of about 45% and coloured dark brown.

TEST FACILITY Institut Für Biologische Analytik und Consulting IBACON GmbH (1999g).

Explosive Properties Not determined.

Remarks The notified chemical does not contain any chemical unstable or highly energetic groups that might lead to an explosion.

Reactivity Not determined.

Remarks The notified chemical is incapable of causing fire or enhances the risk of fire when in contact with combustible material.

There is no incompatibility with other substances known.

Sunlight and temperature above 30°C may affect the substance.

Decomposition products arising from pyrolysis are carbon oxides and nitrogen oxides.

TEST FACILITY RCC Ltd, Itingen, Switzerland (2001c).

Surface Tension 70 mN/m at 20^{o}C

METHOD OECD TG 115 Surface Tension of Aqueous Solutions.
EC Directive 92/69/EEC A.5 Surface Tension.

Remarks The surface tension of the notified chemical was determined on a 90% saturation solution using a tensiometer. The notified chemical is not surface active.

TEST FACILITY Institut Für Biologische Analytik und Consulting IBACON GmbH (1999h).

Physical Properties of the grease products containing the notified chemical

The density of the formulated grease products containing <20% notified chemical is in the range of 800 to 990 kg/m^3. The base oil viscosity at 40°C may range from 20 to 130 mm^2/s, and the drop points are between 170 and >200°C.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50 > 2 000 mg/kg bw	low toxicity
Rat, acute dermal LD50 > 2 000 mg/kg bw	low toxicity
Rat, acute inhalation	No toxicity data were submitted
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation - adjuvant test.	no evidence of sensitisation.
Rat, oral repeat dose toxicity - 28 days.	NOAEL = 250 mg/kg/day
Genotoxicity - bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosome aberration	non genotoxic
Genotoxicity – in vivo	No toxicity data were submitted

7.1. Acute toxicity – oral

TEST SUBSTANCE Komplexseife TH18

METHOD OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain Rat/Wistar
Vehicle 1% carboxymethylcellulose
Remarks - Method GLP & QA.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3 males	2 000	0
2	3 females	2 000	0

LD50 > 2 000 mg/kg bw
Signs of Toxicity None.
Effects in Organs None.
Remarks - Results None.

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

TEST FACILITY Bioservice Scientific Laboratories GmbH (1999a).

7.2. Acute toxicity - dermal

TEST SUBSTANCE Komplexseife TH18

METHOD OECD TG 402 Acute Dermal Toxicity – Limit Test.
EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal) – Limit Test.
Species/Strain Rat/Wistar
Vehicle 1% carboxymethylcellulose
Type of dressing Semi-occlusive.
Remarks - Method GLP & QA.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	2 000	0

LD50	> 2 000 mg/kg bw
Signs of Toxicity - Local	None.
Signs of Toxicity - Systemic	None.
Effects in Organs	None.
Remarks - Results	No skin irritation observed.

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

TEST FACILITY Bioservice Scientific Laboratories GmbH (1999b).

7.3. Acute toxicity - inhalation

No toxicity data were submitted.

7.4. Irritation – skin

TEST SUBSTANCE Komplexseife TH18

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

Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	1% carboxymethylcellulose
Observation Period	72 hours
Type of Dressing	Semi-occlusive.
Remarks - Method	GLP & QA.

RESULTS The Draize scores for erythema/eschar and oedema were zero for all animals during 1 to 72 hours after treatment.

Remarks - Results No clinical signs of systemic toxicity were found.

CONCLUSION The notified chemical is non-irritating to skin.

TEST FACILITY Bioservice Scientific Laboratories GmbH (1999c).

7.5. Irritation - eye

TEST SUBSTANCE Komplexseife TH18

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

Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Observation Period	72 hours
Remarks - Method	GLP & QA.

RESULTS

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

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

Remarks - Results	Conjunctiva discharge was not observed. At one hour, the Draize scores of conjunctival redness for the three animals were 1, 1 and 0, respectively.
CONCLUSION	The notified chemical is slightly irritating to the eye.
TEST FACILITY	Bioservice Scientific Laboratories GmbH (1999d).

7.6. Skin sensitisation

TEST SUBSTANCE	Komplexseife TH18
METHOD	OECD TG 406 Skin Sensitisation - Adjuvant test. EC Directive 96/54/EC B.6 Skin Sensitisation - Adjuvant test.
Species/Strain	Guinea pig/DH
PRELIMINARY STUDY	Maximum Non-irritating Concentration: intradermal: not stated. topical: 100%
MAIN STUDY	
Number of Animals	Test Group: 10 Control Group: 5
induction phase	Induction Concentration: intradermal injection 25% (highest applicable concentration). topical application 100%
Signs of Irritation	None.
CHALLENGE PHASE	
1st challenge	topical application: 100%
Remarks - Method	GLP & QA.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after: 1st challenge*		
		24 h	*48 h*	*72 h*
Test Group	100%	0/10	0/10	0/10
Control Group	100%	0/5	0/5	0/5

Remarks - Results	Historic data of positive controls were provided in the report.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	Bioservice Scientific Laboratories GmbH (1999e).

7.7. Repeat dose toxicity

TEST SUBSTANCE	Komplexseife TH18
METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents. EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral).
Species/Strain	Rat/Wistar
Route of Administration	Oral – gavage.
Exposure Information	Total exposure days: 28 days; Dose regimen: 7 days per week;

Vehicle	1% carboxymethylcellulose
Remarks - Method	GLP & QA. Group I (control) data were shared by this study and another parallel study.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5/sex	0	0
II (low dose)	5/sex	50	0
III (mid dose)	5/sex	250	0
IV (high dose)	5/sex	1 000	0

Mortality and Time to Death
None.

Clinical Observations
In the group II, the bodyweight gains were lower in males and higher in females when compared with the controls. The control group data in this study were lower than the historic data.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
There were no treatment-related changes in clinical chemistry, haematology and urinalysis tests.

Pathology
No abnormal findings were observed.

Effects in Organs
The mean relative spleen value in females of the group IV was significantly lower than corresponding control group. There were no other treatment-related differences in relative and absolute organ weight for both sexes and any of the groups.

Histopathology
Histopathological examination showed that no differences in incidence or severity between control and treatment groups were considered to be of toxicological significance.

Remarks – Results
Decrease of the mean relative spleen weight in high-dose female rats could be considered to be treatment-related in the study. Some minor changes in biochemical, haematological, pathological and histopathological examinations were noted, however, they were not considered to be treatment-related.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as 250 mg/kg bw/day in this study, based on the decrease of the mean relative spleen value in high-dose female rats.

TEST FACILITY Bioservice Scientific Laboratories GmbH (1999f).

7.8. Genotoxicity - bacteria

TEST SUBSTANCE Komplexseife TH18

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

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100, TA102
Metabolic Activation System	S9-mix
Concentration Range in Main Test	a) With metabolic activation: 0 - 5 000 µg/plate. b) Without metabolic activation: 0 – 5 000 µg/plate.
Vehicle	DMSO
Remarks - Method	GLP & QA.

Experiment I was an incorporation test, and experiment II was a pre-incubation test.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in PreliminaryTest	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent	>5 000		≥1 000	
Test 1		Not seen	≥1 000	Not seen
Test 2		Not seen	≥1 000	Not seen
Present	>5 000		≥1 000	
Test 1		Not seen	≥1 000	Not seen
Test 2		Not seen	≥1 000	Not seen

Remarks - Results

No significant increases in revertant colony numbers of any tested strains were observed following treatment with the notified chemical either in the presence or absence of metabolic activation in both incorporation test and pre-incubation test.

The positive controls induced a distinct increase of induced revertant colonies.

CONCLUSION

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

TEST FACILITY

Bioservice Scientific Laboratories GmbH (1999g).

7.9. Genotoxicity – in vitro

TEST SUBSTANCE

Komplexseife TH18

METHOD

OECD TG 473 In vitro Mammalian Chromosomal Aberration Test.

Cell Type/Cell Line: Chinese hamster V79 cells

Metabolic Activation System: S-9 mix

Vehicle: DMSO

Remarks - Method: GLP & QA.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0, 5*, 50* and 100*	4 h	20 h
Test 2	0, 5*, 50* and 100*	20 h	20 h
Present			
Test 1	0, 5*, 50* and 100*	4 h	20 h

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in PreliminaryTest	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1		Not seen	≥5	Not seen
Test 2		Not seen	≥5	Not seen
Present				

Test 1	Not seen	≥5	Not seen

Remarks - Results

The notified chemical did not increase the frequency of aberration in Chinese V79 cells in the presence and absence of metabolic activation.

The positive controls induced a significant increase of cells with structural chromosome aberrations above test laboratory's historic control level.

The study was hampered by the low solubility of the test substance in DMSO and the culture medium.

CONCLUSION

The notified chemical was not clastogenic to Chinese hamster V79 treated in vitro under the conditions of the test.

TEST FACILITY

Bioservice Scientific Laboratories GmbH (1999h).

7.10. Genotoxicity – in vivo

No toxicity data were submitted.

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE

Complex Soap TH18

METHOD

OECD TG 301 F Ready Biodegradability: Manometric Respirometry Test.

Exposure Period

28 days

Remarks - Method

Activated sludge was mixed with the test substance to give final concentrations of 20 and 20.1 mg/L and with the standard material, aniline at a concentration of 25.3 mg/L. The study was carried out in darkness at 22 °C.

RESULTS

Test substance		*Aniline*	
Day	*Mean % degradation*	*Day*	*% degradation*
14	23.4	14	72.0
28	26.1	28	96.0

Remarks - Results

The aniline standard attained 96% biodegradation after 28 days, indicating the test conditions were valid. After 28 days, the mean biodegradation of the test substance based on $ThOD_{NH4}$ was 26.1% (24.7 and 27.5%) and based on $ThOD_{NO3}$ was 25.3% (23.9 and 26.6%). Results from the toxicity control indicate that the notified chemical does not have an inhibitory effect on activated sludge micro-organisms.

CONCLUSION

The notified chemical is not considered to be readily biodegradable under the conditions of OECD TG 301F.

TEST FACILITY

Institut Für Biologische Analytik und Consulting IBACON GmbH (1999i).

8.1.2. Bioaccumulation

Data on the bioaccumulation potential of the notified chemical were not provided for this notification. Due to low aquatic exposure the notified chemical it is unlikely to bioaccumulate (Connell 1990).

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE Complex Soap TH18

METHOD OECD TG 203 Fish, Acute Toxicity Test
- Species: Zebra Fish (*Brachydanio rerio*)
- Exposure Period: 96 h
- Water Hardness: 250 mg $CaCO_3$/L
- Analytical Monitoring: Test solutions were not measured.

RESULTS

Concentration mg/L *Nominal*	*Number of Fish*	*Mortality*				
		2 h	*24 h*	*48 h*	*72 h*	*96 h*
0	7	0	0	0	0	0
100	7	0	0	0	0	0

LC50 Not determined
NOEC (or LOEC) Not determined
Remarks – Results The definitive studies were conducted on the filtrate of a super saturated stock suspension of the notified chemical at a nominal concentration of 100 mg/L. The results of the definitive study showed that no mortalities were observed at this test substance concentration. A 96-hour EC_{50} for the notified chemical to *Brachydanio rerio* was not determined but the 96 h NOEC is expected to be greater than the limit of its solubility.

CONCLUSION The ecotoxicity data indicates the notified chemical is not toxic to fish up to the limit of its solubility.

TEST FACILITY Institut Für Biologische Analytik und Consulting IBACON GmbH (1999j).

8.2.2. Acute/chronic toxicity to aquatic invertebrates

TEST SUBSTANCE Complex Soap TH18

METHOD OECD TG 202 Daphnia sp. Acute Immobilisation Test
- Species: *Daphnia magna*
- Exposure Period: 48 hours
- Water Hardness: 250 mg $CaCO_3$/L
- Analytical Monitoring: Test solutions were not measured.

RESULTS

Concentration mg/L *Nominal*	*Number of D. magna*	*Number Immobilised*	
		24 h	*48 h*
0	20	0	0
100	20	0	0

LC50 Not determined
NOEC (or LOEC) Not determined

Remarks - Results	The definitive studies were conducted on the filtrate of a super saturated stock suspension of the notified chemical at a nominal concentration of 100 mg/L. The immobilisation tests with daphnia were performed in duplicate using 10 daphnids per flask with observations performed at 24 and 48 hours. A 48-hour EC_{50} for the notified chemical to *Daphnia magna* was not determined but the 48 h NOEC is expected to be greater than the limit of its solubility.
CONCLUSION	The ecotoxicity data indicates the notified chemical is not toxic to daphnia up to the limit of its solubility.
TEST FACILITY	Institut Für Biologische Analytik und Consulting IBACON GmbH (1999k).

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	Complex Soap TH18
METHOD	OECD TG 201 Alga, Growth Inhibition Test.
Species	*Scenedesmus suspicatus*
Exposure Period	72 hours
Concentration Range Nominal	6.25, 12.5, 25, 50 and 100 mg/L
Water Hardness	24 mg $CaCO_3$/L
Analytical Monitoring	Test solutions were not measured

RESULTS

Biomass		*Growth*	
E_bC50 (mg/L at 72 h)	*NOEC (mg/L)*	*E_rC50 (mg/L at 72 h)*	*NOEC (mg/L)*
75.4	6.25	> 100	25

Remarks - Results	Algae were exposed to the filtrate of a super saturated stock suspension of the notified chemical at a nominal concentration of 100 mg/L under constant illumination and shaking. After 72 h, there was no significant inhibition of algal growth and biomass at the nominal concentrations of 6.25, 12.5 and 25 mg/L. At a nominal concentration of 50 and 100 mg/L both algal growth and biomass were significantly reduced.
CONCLUSION	The ecotoxicity data indicates the notified chemical shows some toxicity to algae below the limit of its solubility.
TEST FACILITY	Institut Für Biologische Analytik und Consulting IBACON GmbH (1999l).

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Complex Soap TH18
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test.
Inoculum	Activated sludge
Exposure Period	3 hours
Concentration Range Nominal	10, 32, 100, 320, 1000 mg/L
RESULTS	The activated sludge study was conducted using sludge obtained from sewage treatment plant in Groβ-Zimmern, Germany. The definitive study was conducted on nominal concentrations of 10, 32, 100, 320 and 1000 mg/L. Amounts of test material (5, 16, 50, 160 and 500 mg) were

	added to water (284 mL) and sewerage (16 mL) and samples were stirred continuously. The reference material used in the study was 3,5-dichlorophenol. When compared to the control, activated sludge after 3 h experienced differences in respiration of between –3 to –10.2%. The 3-hour EC_{50} for the notified substance to activated sludge could not be quantified. However, the 3-hour EC_{50} for the notified substance to activated sludge is expected to be greater than 1000 mg/L. The EC50 of the reference substance was 7 mg/L, therefore confirming the suitability of the activated sludge.
EC50	> 1000 mg/L
NOEC	Not determined
CONCLUSION	The ecotoxicity data indicates the notified chemical is not toxic to activated sludge up to 1000 mg/L in suspension.
TEST FACILITY	Institut Für Biologische Analytik und Consulting IBACON GmbH (1999m).

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified chemical will be used as a component of ready-to-use grease used at industrial sites throughout Australia. As waste, the majority of the import volume will be collected and disposed of by incineration, which will result in the formation of water vapour and oxides of carbon and nitrogen and metal salts in the sludge. A small amount will be discarded in landfill through the disposal of plastic drum liners and machinery to which the grease containing the notified chemical has been applied.

Although it is not considered to be readily biodegradable, the notified chemical is expected to biodegrade to a certain extent in landfill. The high octanol-water partition coefficient calculated for Component's II and III of the notified chemical mixture and the expected low water solubilities indicate that they will partition to soil and sediment and be immobile in the environment. The third component of the mixture, Component I, is moderately soluble, has a low octanol-water partition coefficient and could potentially be mobile in soil. However, as a consequence of its anionic nature it is expected to associate with metal ions on the surface of soil and be immobile.

9.1.2. Environment – effects assessment

The notified chemical is not toxic to fish, daphnia and micro-organisms up to the limit of its solubility. However, it shows some toxicity to algae below this limit. Bioaccumulation is not expected due to the notified chemical's limited exposure to the aquatic compartment.

9.1.3. Environment – risk characterisation

The notified chemical will be used as a component of ready-to-use grease, and most if it is expected to eventually be collected and incinerated, which will result in the formation of water vapour and oxides of carbon and nitrogen and calcium salts in the sludge. A small amount will be discarded in landfill primarily through the disposal of import containers and machinery to which the grease has been applied. Here, given it is not readily biodegradable (< 30% over 28 days), has a relatively high partition and adsorption coefficients and low water solubility, the notified chemical would associate with soil and sediment and slowly degrade over time.

The above considerations indicate minimal hazard to the environment when the notified chemical is used in the manner and levels indicated by the notifier.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

The notified chemical will be imported in pails and drums as a component (<20%) of ready-to-use greases. The exposure for importation and distribution workers is expected to be negligible except in the event that the packaging is breached.

More than half of the notified chemical will be used at the manufacturing sites. Minimal exposure is expected because the systems for applying the greases are generally enclosed and automated. However, the possibility of exposure to drips and spills exists during the processes of preparation, cleaning and maintenance. Dermal exposure would be the predominant route of occupational exposure to workers during these activities.

Fitters or other mechanics at the maintenance sites will apply the greases manually to existing machinery by brush, spatula, grease gun or grease cartridge. Dermal exposure may occur. However, the exposure is considered to be of short duration and intermittent.

9.2.2. Public health – exposure assessment

Exposure of the general public to the notified chemical as a result of transport or through environmental release is assessed as being negligible.

9.2.3. Human health - effects assessment

Acute toxicity.
The notified chemical was of low oral and dermal toxicity in acute rat studies. No acute inhalation study data were submitted.

Irritation and Sensitisation.
In the eye irritation study, 2 of the 3 rabbits had Draize scores (redness) of one at 1 hour after treatment. All other Draize scores were zero. Thus, the notified chemical is considered to be a slight eye irritant. The notified chemical was non-irritant to rabbit skin and negative in a skin sensitisation adjuvant test in guinea-pigs.

Repeated Dose Toxicity (sub acute, sub chronic, chronic).
In the 28-day oral repeat study, decrease of the mean relative spleen value in high-dose female rats was considered to be treatment-related. No significant histopathological changes were observed. The No Observed Adverse Effect Level (NOAEL) was established as 250 mg/kg bw/day in this study.

Genotoxicity
The notified chemical was negative in an Ames test and found not to be clastogenic in a chromosomal aberration study in Chinese hamster V79 cells. However, the latter study was hampered by poor solubility, so the concentrations tested were lower than usual for this type of test. No in vivo genotoxicity study data were submitted.

Hazard classification for health effects.
Based on the available toxicological data, the notified chemical is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999b).

9.2.4. Occupational health and safety – risk characterisation

Dermal exposure would be the predominant route of occupational exposure to the notified chemical. Although the notified chemical is neither a skin irritant nor a skin sensitiser, repeated or prolonged skin contact with lubricant and grease products should be avoided since human experience has shown that prolonged skin contact with lubricant or grease products may cause skin irritation and/or dermatitis (oil acne or folliculitis).

The health risk for importation and distribution workers is expected to be negligible except in the event that the packaging is breached.

At sites manufacturing new machinery, minimal exposure is expected because the systems are enclosed and automated. However, gloves, eyewear and protective clothing should be worn

when the possibility of exposure to drips and spills exists during the processes of preparation, cleaning and maintenance. With the application of personal protective equipment, the risk of adverse health effects at the manufacturing sites is expected to be low.

Fitters or other mechanics at maintenance sites will apply the greases manually to existing machinery. Adverse skin effects may ensue if dermal contact is repeated or prolonged. It is recommended that the workers wear gloves, eyewear and protective clothing to minimise the risk of adverse skin effects from the greases.

In the case that any oil mist will be generated at workplaces, the NOHSC Exposure Standard for oil mist (5 mg/m^3, TWA) must be applied (NOHSC, 1995).

9.2.5. Public health – risk characterisation

Given that the notified chemical will be a component in grease intended for industrial use only and it has low acute oral and dermal toxicity, the risk to public health is considered to be minimal.

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 hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

10.2. Environmental risk assessment

On the basis of the available information, the overall environmental hazard of the notified chemical is expected to be low.

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 the product containing the chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994a). 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 products containing the chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994b). 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 safe work practices to minimise

occupational exposure during handling of products containing the notified chemical:
- avoid repeated or prolonged dermal exposure.
- avoid generation of any oil mist.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to products containing the notified chemical:
  - gloves
  - safety eyewear, 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 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.

Disposal

- The notified chemical should be disposed of by incineration.

Emergency procedures

- Spills/release of the notified chemical should be contained as described in the MSDS and the resulting waste disposed of by incineration.

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(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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