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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Urea 1

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Director
Chemicals Notification and Assessment

TABLE OF CONTENTS

FULL PUBLIC REPORT

Urea 1

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Klüber Lubrication Australia Pty Ltd (ABN 77 005 809 852), 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:

Part B: Chemical Name, Other Names, CAS Number, Molecular and Structural Formulae, Molecular Weight, Spectral Data, Purity, Impurities (Hazardous/Non-hazardous), Additives/Adjuvants.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:

Part B: Boiling Point, Vapour Pressure, Water Solubility, Hydrolysis as Function of pH, Partition Coefficient, Adrosption/Desorption, Dissociation Constant, Particle Size, Flash Point, Explosive Properties, Reactivity.

Part C: Acute Inhalation Toxicity, Chromosome Damage (In Vivo), Bioaccumulation.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
Not applicable.

NOTIFICATION IN OTHER COUNTRIES
EC, Spain (2000): 70-10-0200-00.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Urea 1 (notified chemical)
Stabutherm GH (<20% notified chemical)
Asonic GHY

3. COMPOSITION

DEGREE OF PURITY **Non-Confidential**
High

4. INTRODUCTION AND USE INFORMATION

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	≤18	≤18	≤18	≤18	≤18

USE

A thickening agent of mineral or synthetic oil-based greases for use in the mining industry to seal and lubricate slip rings on rotary kilns.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
Klüber Lubrication Australia Pty Ltd of 3 Brand Drive Thomastown VIC 3074.

TRANSPORTATION AND PACKAGING
The grease containing the notified chemical will be shipped and transported by road in robust and secure/sealed containers, such as in plastic lined 180 kg steel drums from dockside to the notifier for repackaging, and in 2000 kg bulk steel containers with bolted down lid from Melbourne to Western Australia for use in the mining industry. All transport between facilities is by licensed transport companies.

5.2. Operation Description

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

At the notifier site in Melbourne, the imported product will be repacked and this will involve pumping the grease from the 180 kg drums to bulk containers containing up to 2000 kg of the product. At one mining site in Western Australia where the grease is being used for sealing and lubrication of slip rings on rotary kilns, maintenance fitters will connect the bulk container to the central, automatic lubricating system. The notifier indicates that this will be done via quick couplings and only takes about five minutes.

The used and contaminated grease will be contained and collected in large drip trays. It is expected that the grease will be pumped from these trays to storage tanks by a mineral oil processing company for disposal by incineration.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Waterside, drivers and storage workers	8-10	1 h	Weekly
Repackaging workers	1-2	1 h	Weekly
Maintenance fitters	1-2	5 min	--
Disposal workers	1-2	<15	Fortnightly

Exposure Details
Waterside, transport and storage workers will be involved in transport and handling of the imported grease in robust and secure steel containers. Therefore direct exposure to the notified chemical is not expected, except in the case of an accident. However as the notified chemical is in the form of grease, accidental spills would be easily contained and collected in suitable containers either for recycling or incineration.

It is estimated that 1-2 workers will be potentially exposed to the grease for up to 1 hour a week while involved in repackaging of the imported grease. They will pump imported drums to bulk containers containing 2000 kg of the product via quick coupling, and thus skin contact may occur with possible ocular exposure due to spillages and splashes. The workers will wear protective clothing, impermeable gloves and safety goggles, and observe safe work practice.

At the mining site, 1-2 maintenance fitters may potentially be exposed to the notified chemical when connecting bulk containers to the lubricating system. However, exposure is predicted to be of short

duration (5 min) and the workers will wear industrial standard protective clothing, impermeable gloves and safety goggles.

Potential exposure of disposal workers to the notified chemical in transferring the used grease to the incinerating facility is anticipated to be less than 15 min for every two weeks. They are expected to wear adequate personal protective equipment and observe safe work procedures.

5.4. Release

RELEASE OF CHEMICAL AT SITE

The notifier estimates that, during the repackaging process, up to 18 kg per annum of the notified chemical will be released to landfill from the disposal of plastic drum liners. The empty steel drums will either be recycled or reused. Bulk containers (2000 kg) will be reused for subsequent batches without cleaning, as too will equipment used in the transfer of the grease.

RELEASE OF CHEMICAL FROM USE

The used grease containing the notified chemical will be collected in large drip trays and periodically disposed of by a mineral oil processing company. Eventually the entire import volume is expected to be collected for disposal in this manner.

5.5. Disposal

The notifier indicates that the grease containing the notified chemical will be incinerated by a mineral oil processing company. Minor spills and residuals in import drum liners will be disposed of in landfill.

5.6. Public exposure

The notified chemical will not be manufactured or reformulated in Australia, but will be imported as a component of grease (concentration <20%) in sealed freight containers. The imported product will be shipped to Melbourne and then transported by road to the notifier. The product will be repackaged into bulk containers and then transported by road to a mining site in Western Australia. Due to the notified chemical being used in mining industries, public exposure to the notified chemical will only occur in the event of a transport accident or spillage. 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, the public should be kept away and all sources of ignition eliminated. The spills should be scraped up with shovels and placed in suitable containers for disposal. Spills should be prevented from entering drains or watercourses. All waste materials should be disposed of in accordance with State/Territory regulations for the disposal of oil and grease by licensed oil waste and registered waste drum companies.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa white solid

Melting Point 217°C

METHOD	OECD TG 102 Melting Point/Melting Range – Capillary method. EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks	At about 340°C the melt turned to dark brown, indicating a reaction or decomposition of the substance.
TEST FACILITY	IBACON GmbH, Germany (1999a)

Boiling Point Not determined

Remarks	Urea 1 starts to react or decompose at about 340°C. This is within the vicinity of the melting temperature, therefore the boiling point test could not be performed.

Density 912 kg/m^3 at 20°C±1°C

METHOD	OECD TG 109 Density of Liquids and Solids – Gas comparison pycnometer. EC Directive 92/69/EEC A.3 Relative Density.

Remarks	Inert gas (Helium) was used.
TEST FACILITY	IBACON GmbH, Germany (1999b)

Vapour Pressure $<2x10^{-12}$ kPa at 25°C (calculated)

METHOD	OECD TG 104 Vapour Pressure. EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks	Estimation of the vapour pressure was based on the lowest calculated boiling point (576°C) of a component of Urea 1 using the Modified Watson Correlation. Calculation of the boiling point was based on Meissner's method.
TEST FACILITY	IBACON GmbH, Germany (1999c)

Water Solubility ≤1 mg/L at 20°C (calculated)

METHOD	OECD TG 105 Water Solubility. EC Directive 92/69/EEC A.6 Water Solubility.
Remarks	By a simplified flask method, the saturation concentration of Urea 1 was analytically estimated to be in the range of the quantification limit for the DOC measurements (1 mg DOC/L). The water solubility therefore was in the range of ≤1 mg/L (quantification limit) at room temperature (20°C).
TEST FACILITY	IBACON GmbH, Germany (1999d)

Hydrolysis as a Function of pH Not determined

Remarks	According the OECD TG 111 and the EC Directive 92/69/EEC C.7, the test of hydrolysis as a function of pH was impractical due to the low water solubility of Urea 1. In addition, the notified chemical does not contain any groups that can hydrolyse in the environmental pH range of 4-9.

Partition Coefficient (n-octanol/water) log Pow >6 at 20°C (calculated)

METHOD	OECD TG 117 Partition Coefficient (n-octanol/water), HPLC Method - Annex "Pow Calculation Methods". EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks	Calculation was based on the theoretical fragmentation of the molecule into suitable substructures for which reliable log Pow increments are known. The log Pow of Urea 1 components was determined to be 9.2, 19 and 14, and hence the log Pow of Urea 1 was estimated to be >6 using the Leo-Hansch method.
TEST FACILITY	IBACON GmbH, Germany (1999e)

Adsorption/Desorption log Koc = 6.4 ($Koc = 2.4x10^6$, calculated)

Remarks	Due to the low water solubility of ≤1 mg/L, the adsorption coefficient of Urea 1 was estimated using regression equations (Lyman, Reehl, Rosenblatt) in the Handbook of Chemical Property Estimation Methods and relating the Koc with the Pow. The high adsorption coefficient indicates the notified chemical will be immobile in soils.
TEST FACILITY	RCC Ltd, Switzerland (2001a)

Dissociation Constant pKa = 22.2 (calculated for amide)

Remarks	The dissociation constant was estimated using the Taft and Hammett correlation based on the linear free energy relationship assumption of separability of substituent constants and reaction constants. The notified chemical is unlikely to dissociate or protonate in the environmental pH range of 4-9.
TEST FACILITY	RCC Ltd, Switzerland (2001b)

Particle Size Not applicable

Remarks Urea 1 is synthesised in situ in different base oils (mineral or synthetic). It is not isolated but bound in grease and therefore unlikely to be in powder form.

Flash Point Not determined

Remarks Urea 1 is a solid substance with 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, Urea 1 melted. The melt could be ignited with the flame and burned. The burning time over a distance of 200 mm was determined to be 10 minutes.
TEST FACILITY IBACON GmbH, Germany (1999f)

Autoignition Temperature >240°C

METHOD 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Remarks Using a linear increase in temperature of 0.5 K/min, Urea 1 shows one exothermic reaction started at about 240°C. A maximum temperature of about 293°C was measured in the sample cube. At the end of the run, Urea 1 showed a loss of mass of about 72% and coloured black.
TEST FACILITY IBACON GmbH, Germany (1999g)

Explosive Properties Not explosive

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks Test was not conducted. Urea 1 does not contain any chemically unstable or highly energetic groups that might lead to an explosion.
TEST FACILITY SCC GmbH, Germany (1999a)

Reactivity/Oxidizing Properties Stable

Remarks Urea 1 does not have the functional groups associated with oxidizing activity. The oxygen balance is negative, i.e. there is a surplus of carbon atoms. Also, Urea 1 is incapable of causing fire or enhancing the risk of the fire when in contact with combustible material. There is also no incompatibility with other substances known. Sunlight and temperatures >30°C may affect the substance.
TEST FACILITY SCC GmbH, Germany (1999b) & RCC Ltd, Switzerland (2001c)

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50 >2000 mg/kg bw	low toxicity
Rat, acute dermal LD50 >2000 mg/kg bw	low toxicity
Rat, acute inhalation	no data available
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation - adjuvant test	no evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days.	NOAEL = 1000 mg/kg bw/day
Genotoxicity - bacterial reverse mutation	non mutagenic
Genotoxicity - in vitro mammalian chromosome aberration test	non genotoxic
Genotoxicity – in vivo	no data available

7.1. Acute toxicity – oral

TEST SUBSTANCE Notified chemical

METHOD — OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
EC Directive 96/54/EEC B.1tris Acute Toxicity (Oral) – Acute Toxic Class Method.

Species/Strain	Rat/Wistar
Vehicle	1% aqueous carboxymethyl cellulose
Remarks - Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	3/female	2000	0
II	3/male	2000	0

LD50	>2000 mg/kg bw
Signs of Toxicity	No clinical signs of toxicity. No weight loss was recorded throughout the 14 days observation period. The weight gain for the male animals was within the expected range. The female rats showed a slightly diminished weight gain.
Effects in Organs	Necropsy revealed an acute injection of blood vessels in all animals in the abdominal region. This is due to euthanasia with an overdose of pentobarbital injected intraperitoneally. No other macroscopic necropsy findings were recorded.
Remarks - Results	

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

TEST FACILITY — BSL GmbH, Germany (1999a)

7.2. Acute toxicity – dermal

TEST SUBSTANCE — Notified chemical

METHOD — OECD TG 402 Acute Dermal Toxicity – Limit Test.
EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal) – Limit Test.

Species/Strain	Rat/Wistar
Vehicle	1% aqueous carboxymethyl cellulose
Type of dressing	Semi-occlusive
Remarks - Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5/female	2000	0
II	5/male	2000	0

LD50	>2000 mg/kg bw
Signs of Toxicity - Local	Not reported
Signs of Toxicity - Systemic	No clinical signs of toxicity, except slightly diminished weight gain was observed. All animals showed reduced spontaneous activity throughout the contact period. Activity rose immediately after removal of the dressing.
Effects in Organs	Necropsy revealed an acute injection of blood vessels in all animals in the abdominal region. This is due to euthanasia with an overdose of pentobarbital injected intraperitoneally. No other macroscopic findings were recorded.
Remarks - Results	

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

TEST FACILITY BSL GmbH, Germany (1999b)

7.3. Acute toxicity – inhalation

Remarks Test not conducted.

7.4. Irritation – skin

TEST SUBSTANCE Notified chemical

METHOD OEC D 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 females
Vehicle	1% aqueous carboxymethyl cellulose
Observation Period	72 hours
Type of Dressing	Semi-occlusive
Remarks - Method	No significant protocol deviations.

RESULTS

Remarks - Results There were no irritant effects on the intact skin after a contact time of 4 hours (Draize scores zero at all observation times). There were no significant body weight changes during the contact and observation period.

CONCLUSION The notified chemical is non-irritating to skin.

TEST FACILITY BSL GmbH, Germany (1999c)

7.5. Irritation – eye

TEST SUBSTANCE Notified chemical

METHOD OEC D 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 females
Observation Period	72 hours
Remarks - Method	No significant protocol deviations.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	0	0	0	1	1 h	0
Conjunctiva: chemosis	0	0	0	0	0	0
Conjunctiva: discharge	Not reported.			--	--	--
Corneal opacity	0	0	0	0	0	0
Iridial inflammation	0	0	0	0	0	0

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

Remarks - Results Urea 1 at a dose of 0.1 g caused minimal blepharospasm in all animals immediately after application. A slight erythema of the conjunctivae was visible in all animals after 1-hour application.

CONCLUSION	The notified chemical is slightly irritating to the eye.
TEST FACILITY	BSL GmbH, Germany (1999d)

7.6. Skin sensitisation

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 406 Skin Sensitisation – Maximisation Test. EC Directive 96/54/EC B.6 Skin Sensitisation - Maximisation Test.
Species/Strain	Guinea pig/Hsd Poc:DH
PRELIMINARY STUDY	Maximum Non-Irritating Concentration: intradermal: 2000 mg in 8 mL saline solution topical: 2000 mg moistened with 1% aqueous carboxymethyl cellulose (CMC 1%)
MAIN STUDY	
Number of Animals	Test Group: 10 Control Group: 5
INDUCTION PHASE	Induction Concentration: intradermal: 2000 mg/8 mL saline solution topical: 2000 mg moistened with CMC 1% (100%)
Signs of Irritation	The test sites were pre-treated with 10% sodium lauryl sulphate 24 hours before topical induction. No signs of irritation were observed in test and control animals following topical induction.
CHALLENGE PHASE	
1st challenge	topical: 2000 mg moistened with CMC 1% (100%)
Remarks - Method	No significant protocol deviations.

RESULTS

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

Remarks - Results	The maximum percentage of animals sensitised was 0%. Animals of the test and control groups survived throughout the test period and showed normal food intake and weight gain.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	BSL GmbH, Germany (1999e)

7.7. Repeat dose toxicity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents. EC Directive 96/54/EEC B.7 Repeated Dose (28 Days) Toxicity (Oral).
Species/Strain	Wistar rats/Hsd Brl:WH
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days; Dose regimen: 7 days per week; Post-exposure observation period: 0 day
Vehicle	1% aqueous carboxymethyl cellulose
Remarks - Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5/female, 5/male	0	0
II (high dose)	5/female, 5/male	1000	0

Mortality and Time to Death
All animals (test and control groups) survived throughout the test period and were sacrificed on day 28.

Clinical Observations
No differences were observed concerning functional and behaviour examination prior to application and during the last week of dosing. There were no significant differences in weight gain and food intake between the test and control groups. There was a slightly diminished weight gain in the female high dose group as compared to the control group, however it was not statistically significant.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
No significant changes were found in the haematology values (haemoglobin, haematocrit, red and white blood counts, platelet, clotting and differential blood count). It was noted that with the exception of few individual values, all mean and individual values obtained from the analyses of haematology, urine and clinical biochemistry were within the expected ranges. None were considered of toxicological significance and occurred both in the test and control groups.

Effects in Organs
No treatment-related changes (including changes in absolute and relative organ weights) were recorded upon necropsy. Few morphological changes reported from the histopathological assessment were those commonly observed in laboratory maintained rats of the age and strain employed, and there were no significant differences between the treatment and control groups.

Remarks – Results
Few individual borderline deviations were found, but none were compound-related.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as 1000 mg/kg bw/day in this study, the highest dose tested.

TEST FACILITY — BSL GmbH, Germany (1999f)

7.8. Genotoxicity – bacteria

TEST SUBSTANCE — Notified chemical

METHOD — OECD TG 471 Bacterial Reverse Mutation Test.
EC Directive 92/69/EEC L383 A, Annex V, B.14 Mutagenicity – Reverse Mutation Test using Bacteria.
Plate-incorporation procedure/Pre-incubation procedure

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100, TA102.
Metabolic Activation System	S9 fraction from Phenobarbital and β-Naphtoflavone induced rat liver
Concentration Range in Main Test	a) With metabolic activation: 31.6, 100, 316.2, 1000, 2500, 5000 µg/plate. b) Without metabolic activation: 31.6, 100, 316.2, 1000, 2500, 5000 µg/plate.
Vehicle	Dimethyl sulphoxide (DMSO)
Remarks - Method	10 µg/plate 2-aminoanthracene was used as positive control for TA102 instead of 2.5. However, it is claimed this did not influence the quality and integrity of the study.

RESULTS

Remarks - Results	Precipitation of the test substance was observed at a concentration of

≥1000 μg/plate. Toxic effects, as indicated by a dose-dependent reduction of revertant yield per plate, were noted with strain TA1537 in the pre-incubation test with S9 activation. This reduction was not accompanied by a reduction of the background lawn. There were no substantial increases in revertant colony numbers of any of the five test strains following treatment with Urea 1 at any concentration level in either plate-incorporate or pre-incubation tests with or without metabolic activation. Negative controls were within historical limits. Positive controls confirmed the sensitivity of the test system.

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

TEST FACILITY — BSL GmbH, Germany (1999g)

7.9. Genotoxicity – in vitro

TEST SUBSTANCE — Notified chemical

METHOD — OECD TG 473 In vitro Mammalian Chromosomal Aberration Test.
EC Directive 92/69/EEC L383 A, Annex V, B.10 Mutagenicity - In vitro Mammalian Cell Gene Mutation Test.

Cell Type/Cell Line	Chinese hamster V79 cells
Metabolic Activation System	S9 fraction from Phenobarbital and β-Naphtoflavone induced rat liver
Vehicle	Dimethyl sulphoxide (DMSO)
Remarks - Method	No significant protocol deviations.

Metabolic Activation	*Test Substance Concentration (μg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	25*, 250*, 500*	4 h	20 h
Test 2	10*, 25*, 50*	20 h	20 h
Present			
Test 1	25*, 250*, 500*	4 h	20 h

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (μg/mL) Resulting in:*		
	Cytotoxicity in Main Test	*Precipitation*	*Genotoxic Effect*
Absent			
Test 1	>500	>25	Negative
Test 2	>50	>50	Negative
Present			
Test 1	>500	>25	Negative

Remarks - Results — No relevant reduction in the mitotic index and cell density was observed at any test concentrations with and without metabolic activation. The aberration rates of the cells after treatment with the test substance were within the historical range (0%-4.5%) and no concentration relationship was found. Positive controls confirmed the sensitivity of the test system.

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

TEST FACILITY — BSL GmbH, Germany (1999h)

7.10. Genotoxicity – in vivo

Remarks — Test not conducted.

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	Urea 1
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 test concentrations of 19.9 and 20.2 mg/L and with the standard material, aniline at a concentration of 25 mg/L. The study was carried out in darkness at 22 °C.

RESULTS

Test substance		*Aniline*	
Day	*Mean % degradation*	*Day*	*% degradation*
14	-	14	73.9
28	8.25	28	94.1

Remarks - Results	The aniline standard attained 94% 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 9.85% (8.6 and 11.1%) and based on $ThOD_{NO3}$ was 8.25% (7.2 and 9.3%). 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	IBACON GmbH, Germany (1999h)

8.1.2. Bioaccumulation

Data regarding the bioaccumulation potential of the notified chemical were not provided. The notified chemical's high partition coefficient and low water solubility suggest a potential for bioaccumulation. However, due to low aquatic exposure the notified chemical is unlikely to bioaccumulate.

8.2. Environmental Effects

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Urea 1
METHOD	OECD TG 203 Fish, Acute Toxicity Test, 96 h Static
Species	Zebra fish (*Branchydanio rerio*)
Exposure Period	96 h
Water Hardness	2.5 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 *Branchydanio rerio* was not determined but the 96 h NOEC is expected to be greater than the limit of it solubility.
CONCLUSION	The ecotoxicity data indicates the notified chemical is not toxic to fish up to the limit of its solubility.
TEST FACILITY	IBACON GmbH, Germany (1999i)

8.2.2. Acute/chronic toxicity to aquatic invertebrates

TEST SUBSTANCE	Urea 1
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test
Species	*Daphnia magna*
Exposure Period	48 hours
Water Hardness	2.5 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	10	0	0
100 mg/L	10	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 *D. magna* 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 *D. magna* was not determined but the 48 h NOEC is expected to be greater than the limit of it solubility.
CONCLUSION	The ecotoxicity data indicates the notified chemical is not toxic to daphnia up to the limit of its solubility.
TEST FACILITY	IBACON GmbH, Germany (1999j)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	Urea 1
METHOD	OECD TG 201 Alga, Growth Inhibition Test.
Species	*Scenedesmus suspicatus*
Exposure Period	72 hours

Concentration Range Nominal	100 mg/L (Filtered)
Water Hardness	24 mg $CaCO_3$/L
Analytical Monitoring	Test solutions were not measured

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 or biomass at the nominal concentration of 100 mg/L.

CONCLUSION

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

TEST FACILITY

IBACON GmbH, Germany (1999k)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE

Urea 1

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 –6.6 to 5.7%. The 3-hour EC50 for the notified substance to activated sludge could not be quantified. However, the 3-hour EC50 for the notified substance to activated sludge is expected to be greater than 1000 mg/L. The EC50 of the reference substance was 9 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 suspension.

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9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The new chemical will be used as a component of a ready-to-use grease at one mining site in Western Australia. The majority of the import volume will be collected and disposed of by incineration which results in the formation of water vapour and oxides of carbon and nitrogen. A small amount will be discarded in landfill through the disposal of plastic drum liners.

Although Urea 1 is not considered to be readily biodegradable, biodegradation of the notified

chemical is expected to occur in landfill. The high octanol-water partition coefficient and low water solubility indicates the notified chemical will partition to soil and sediment and be immobile in the environment.

9.1.2. Environment – effects assessment

The notified chemical is not toxic to fish, daphnia, algae and micro-organisms up to the limit of its solubility. In addition, bioaccumulation is not expected due to the limited exposure of the chemical to the aquatic compartment.

9.1.3. Environment – risk characterisation

The notified chemical will eventually be collected and incinerated with a small amount discarded in landfill through the disposal of plastic drum liners. Given it is not readily biodegradable (< 10% over 28 days), has a high partition and adsorption coefficients and low water solubility, the notified chemical would associate with soil and sediment and slowly degrade over time.

Taking all into considerations there would be minimal risk 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

Waterside, transport and storage workers will be involved in transport of the imported grease in robust and secure steel containers. Therefore, they would not be exposed to the notified chemical under normal conditions. In the case of an accident involving damage to the containers, spills would be easily contained and collected because the notified chemical remains in the form of grease.

Repackaging workers will be potentially exposed to the grease containing the notified chemical for up to 1 hour a week mainly via dermal contact and possibly some ocular exposure due to spillages and splashes. However, considering the personal protective equipment (PPE) they wear, the implementation of safe work practice and hygiene measures at the industrial plant, their occupational exposure is determined to be low.

Maintenance fitters will be potentially exposed to the notified chemical only for a short period of 5 minutes while connecting bulk containers to the lubricating system at the mining site. They will also wear industrial standard protective clothing, impermeable gloves and safety goggles during the operation to minimise occupation exposure.

Disposal workers are expected to wear adequate PPE and observe safe work procedures while transferring the used grease to the incinerating facility for disposal in accordance with regulations. The process of waste collection will take approximately 15 minutes for every two weeks.

9.2.2. Public health – exposure assessment

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

9.2.3. Human health - effects assessment

Based on the assessment of toxicological data, the notified chemical has low acute oral and dermal toxicity in rats (LD50 >2000 mg/kg bw). It is not irritating to the skin but slightly irritating to the eyes of rabbits. The notified chemical is not a skin sensitiser in an adjuvant study in guinea pigs.

In a 28-day repeat dose oral study in rats, the NOAEL was established to be 1000 mg/kg bw/day. No toxicological relevant effects were observed in any of the test animals at this highest tested dose.

In bacterial reverse mutation assay, the notified chemical was not mutagenic. In an in vitro chromosome aberration assay with Chinese hamster V79 cells, the notified chemical did not

show any clastogenic activity either in the presence or absence of S9 metabolic activation.

Based on the available data, the notified chemical would not be classified as hazardous in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

9.2.4. Occupational health and safety – risk characterisation

Exposure of waterside, transport and storage workers to the notified chemical is expected to be negligible as they will be involved in transport of the imported grease in robust and secure steel containers. In the case of an accident, spills will be contained and collected in suitable containers for recycling or incineration in accordance with State/Territory regulations. As a consequence, these workers would not experience a significant health risk.

Repackaging workers will be involved in pumping the grease from the 180-kg imported drums to bulk containers containing 2000 kg of the product. Although the process is not expected to take more than 1 hour every week and the notified chemical will not be a skin irritant nor a sensitiser based on the available toxicological data, human experience has shown that prolonged or repeated skin contact with mineral oils in lubricants and greases may cause skin irritation and/or dermatitis (oil acne or folliculitis) (NZDermNet, 2002). Given that these workers will wear appropriate PPE and observe industrial hygiene and safe work practice during the operation, dermal and ocular exposure to notified chemical if any would be minimal. Hence, no significant occupational health risk is likely.

At the mining site, the maintenance fitters and disposal workers from a professional waste disposal company will also wear adequate PPE during their work duty. Considering a short period of exposure, the low toxicity of the chemical, the PPE worn and their experience of safe work procedures, it is determined that the occupational risk posed by the chemical to these workers will not be of concern.

9.2.5. Public health – risk characterisation

Given the notified chemical will only be used in the mining industry and has low acute oral and dermal toxicity, the risk to public health is considered 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 risk posed by 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 lubricating grease product containing <20% notified chemical (Stabutherm GH 461) 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 Stabutherm GH 461 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

No specific measures are required for Urea 1. However, in the interest of good occupational health and safety, the following guidelines and precautions should be observed for use of the import grease product containing less than 20% notified chemical.

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the grease product:
  - Adequate training in safe work practices for repackaging and maintenance fitter staff.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the grease product:
  - Impermeable gloves;
  - Industrial standard protective clothing;
  - Safety goggles;

  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 and in landfill (residues in import containers only).

Emergency procedures

- Spills/release of the notified chemical should be handled as outlined in the MSDS.
- Personnel involved in the clean up procedure should wear protective clothing and impermeable gloves to avoid skin contact.

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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