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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Lithium complex grease soap

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Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Harrison Manufacturing Co Pty Ltd (ABN: 50 000 080 946)
75 Old Pittwater Rd
BROOKVALE NSW 2100

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: Spectral data, manufacture volume and identity of sites.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: Toxicological investigations, ecotoxicity data, biodegradability and bioaccumulation data.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None.

NOTIFICATION IN OTHER COUNTRIES
None.

2. IDENTITY OF CHEMICAL

OTHER NAME(S)
Lithium complex grease soap.

MARKETING NAME(S)
Component in Lithium Complex Grease.

MOLECULAR WEIGHT
824.944

SPECTRAL DATA

METHOD	Infrared (IR) Spectroscopy
Remarks	A reference spectrum was provided.

METHODS OF DETECTION AND DETERMINATION

METHOD	IR spectroscopy

3. COMPOSITION

DEGREE OF PURITY
High

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

No impurities greater than 1%.

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight)

No impurities greater than 1%.

ADDITIVES/ADJUVANTS
None.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical is manufactured at a single site in NSW.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	100 - 1000	100 - 1000	100 - 1000	100 - 1000	100 - 1000

USE
Component of grease for use as a lubricant in industrial and automotive applications.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Manufactured in NSW.

IDENTITY OF MANUFACTURER/RECIPIENTS
75 Old Pittwater Rd
Brookvale NSW

TRANSPORTATION AND PACKAGING
The grease containing the notified chemical is manufactured and packed into containers which are typical of grease products ranging from 180 kg drums to 450 g cartridges for road transport.

5.2. Operation description
The notified chemical is manufactured as a component of grease by addition of various constituents together with base oil to a "kettle". Various QC checks are conducted and additions made. The final grease is packed off automatically into a range of commercial containers.

5.3. Occupational exposure
Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Grease blenders	4	0.25 hours/day	200 days/year
Laboratory staff	4	0.5 hours/day	150 days/year
Grease packers	5	1.5 hours/day	200 days/year
End users	Several hundred		

Exposure Details
Components of the notified chemical are added to mineral oil in a grease kettle. The grease is sampled (50 g) and transferred to a sample tin by a metal spatula and carried to the laboratory. The mixing

vessel is connected to extraction equipment and the grease blender wears a face shield, chemical and heat resistant gloves and long sleeved overalls to limit exposure which should be mainly dermal. The temperature of the grease is 150°C at the time of sampling.

Laboratory staff wearing chemically resistant disposable gloves, safety goggles and a long sleeved laboratory coat use a metal spatula to transfer 10 g of grease to a beaker containing solvent to measure acidity/alkalinity. Exposure to laboratory staff will most likely be dermal with potential for secondary transfer to eyes.

Once a batch of grease is completed it is automatically transferred to containers via fixed piping. Workers position an empty container on the pack off scale and place a lid on the container when filled. Workers wear chemical resistant gloves, safety glasses and long sleeved overalls to prevent possible dermal and ocular exposure.

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

5.4. Release

RELEASE OF CHEMICAL AT SITE

The chemical is manufactured as part of a component of grease in a grease kettle. A maximum of 15 tonnes per annum of waste grease containing 1.8 tonnes of the notified chemical will be disposed of from the manufacturing process. A further amount of approximately 20 kg per annum of the neat chemical is required for quality control testing and is disposed of after the test. This disposal of the notified chemical is performed by licensed contractor to authorised landfill.

Occasional rinsing of equipment with mineral oil for operational and maintenance reasons will not result in any significant release of the chemical as it is recycled.

It is highly unlikely that there will be any significant environmental release resulting from spills during manufacture or transportation as the product is very viscous and will be easily contained for either re-use or disposal.

RELEASE OF CHEMICAL FROM USE

The notified chemical is used as thickener for grease for industrial and automotive applications such as wheel bearings. There is a growing tendency for automotive components such as wheel bearings to be fully sealed components. The release of the notified chemical will therefore be intrinsically linked to the fate of the sealed components. Such components are likely to be landfilled or used in recycled metal at the end of the useful life of the component.

Over time unsealed bearings require repacking and/or lubrication due to degradation, contamination or loss of the grease. Due to the viscosity of the grease it is expected that the majority will adhere to the components, which are likely to be landfilled or used as recycled metal. However, it is expected that some grease may be spilled, dissolved in organic solvents or require disposal during repacking and lubricating of unsealed bearings. Due to its viscosity the grease may be physically recovered by simply collecting the material with rags or paper. The collected material would be disposed of as ordinary domestic waste. For the particular case of wheel bearings, clean up will likewise be with rags or paper, with automotive repairers likely to dispose of the product using an oil recycler or landfill, whilst DIY enthusiasts are likely to dispose of the material as household waste which will go to landfill. Any residue due to its viscosity and water insolubility will eventually undergo in situ degradation by abiotic and biotic processes.

Minor quantities are expected to be lost to the environment from unsealed bearings during use. In automotive applications the losses are expected to occur over a large area. The losses will undergo the same fate as that of the aforementioned residue.

5.5. Disposal

The majority of the chemical will be disposed of at the end of the useful life of the component to which the grease is applied. The component will be landfilled or used as recycled metal. Approximately 1.8 tonnes per annum will be disposed of as waste from the manufacturing site to landfill by licensed

contractor.

5.6. Public exposure

DIY enthusiasts may be exposed to grease containing the notified chemical at 12% (w/w) and will not normally be wearing gloves.

6. PHYSICAL AND CHEMICAL PROPERTIES

The notified chemical is manufactured as a component at 12% (w/w) in the final grease and is not isolated. Therefore, the physicochemical properties either have been estimated or measured as a concentrate in baseoil (22% (w/w)) as indicated below. Some information is available in a Robust Summary prepared by the American Petroleum Institute listed on the US EPA web site ().

The following chemical properties were estimated using EPI Suite: log Kow, boiling point, melting point, vapour pressure, soil adsorption, ready biodegradation,

Appearance at 20°C and 101.3 kPa Light yellow paste (as a concentrate)

Melting Point 250 - 280°C

METHOD ASTM D2265 Dropping Point.
Remarks Baseoil concentrate.

Density 940 kg/m^3

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

Vapour Pressure 1.5×10^{-24} kPa at 25°C (estimated)

Remarks Estimated with modified Grain method.

Water Solubility 3.382×10^{-4} g/L at 20°C

METHOD Water solubility estimate from log Kow (WSKOW)

Hydrolysis as a Function of pH Not determined.

Remarks No functional groups expected to undergo hydrolysis. This was confirmed by a preliminary laboratory experiment, wherein the pH was raised from 3 - 9 and conductivity measured. There was no noticeable difference between the test sample and the control. Water may disrupt hydrogen bonding of complex.

Partition Coefficient (n-octanol/water) log Pow = 5.13 at 20 °C

Remarks Estimated from KOWWIN v 1.67

Adsorption/Desorption – screening test log K_{oc} = 7.277

Remarks Estimate Using PCKOCWIN v 1.66

Dissociation Constant Not determined.

Remarks The notified chemical is intimately mixed with the grease which may impede measurement of the dissociation constant. The chemical is a salt of an organic molecule and is expected to be fully dissociated, whilst it remains in the grease.

Particle Size Not applicable.

Flash Point	>240 °C
Remarks	Grease product containing the notified chemical.
Flammability Limits	Not flammable in use.
Autoignition Temperature	400°C (estimate).
Explosive Properties	Not explosive in use.
Reactivity	Highly stable under normal environmental conditions. May react with strong oxidising agents.

7. TOXICOLOGICAL INVESTIGATIONS

The notified chemical is a member of a category of chemicals, Fatty Acids, Lithium and Calcium Salts used as Grease Thickeners submitted to US EPA for consideration under the High Production Volume (HPV) Chemical Challenge Program. A robust summary prepared by the American Petroleum Institute dated 11 January 2005 is available on the US EPA web site http://www.epa.gov/chemrtk/lbgrease/c15019rr.pdf. A summary of the toxicological data in this document is presented below.

7.1. Acute toxicity – oral, lithium salts

TEST SUBSTANCE	Lithium complex grease (65% (w/w) base oil, lithium 12-hydroxy stearate (13.1%), dilithium azelate (2.6%)
METHOD	Not stated but done to GLP standard.
Species/Strain	Rat/Sprague-Dawley.
Vehicle	Undiluted.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	5000	None.

LD50	> 5000 mg/kg bw
Signs of Toxicity	None.
Effects in Organs	None.

CONCLUSION The test substance is of low toxicity via the oral route.

7.2. Acute toxicity – oral, magnesium stearate

TEST SUBSTANCE	Magnesium stearate
METHOD	Not stated.
Species/Strain	Rat/Albino.
Vehicle	Corn oil.
LD50	> 10000 mg/kg bw
Remarks	Animals administered doses of 50 to 10000 mg/kg. Animals given the top dose had mild diarrhoea. Information taken from a Cosmetic Ingredient Review (CIR) report.

CONCLUSION The test substance is of low toxicity via the oral route.

7.3. Acute toxicity – oral, lithium stearate

TEST SUBSTANCE	Lithium stearate
METHOD	Not stated.
Species/Strain	Rat/Albino.
Vehicle	Propylene glycol.
LD50	5000 – 15000 mg/kg bw
Remarks	The test substance was administered to 30 rats (sex unspecified) at 50 to 15000 mg/kg. All animals administered 15000 mg/kg died within 16 hours having exhibited unkempt coats, impaired locomotion and lethargy prior to death.

Information taken from a Cosmetic Ingredient Review (CIR) report.

CONCLUSION The test substance is of low toxicity via the oral route.

7.4. Acute toxicity – dermal

TEST SUBSTANCE Lithium complex grease (65% (w/w) base oil, lithium 12-hydroxy stearate (13.1%), dilithium azelate (2.6%).

METHOD Similar to OECD TG 402 Acute Dermal Toxicity – Limit Test.
Species/Strain Rabbit/New Zealand White.
Vehicle None.
Type of dressing Occlusive.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	3000	0

LD50 > 3000 mg/kg bw
Signs of Toxicity - Local Erythema and oedema were observed at the treated skin site when the occlusive covering was removed. All skin responses had cleared by Day 6.
Signs of Toxicity - Systemic None.
Effects in Organs None.

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

7.5. Acute toxicity – inhalation

No data available.

7.6. Irritation – skin

TEST SUBSTANCE Lithium complex grease (65% (w/w) base oil, lithium 12-hydroxy stearate (13.1%), dilithium azelate (2.6%).

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 6
Vehicle None.
Observation Period 6 days.
Type of Dressing Semi-occlusive.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Erythema/Eschar	0.2		72 hours	0
Oedema	0.13		48 hours	0

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

Remarks Individual scores were not provided. Moderate to severe erythema with well defined to severe oedema were reported. Skin reponses had cleared by Day 6.
CONCLUSION The notified chemical is slightly irritating to the skin.

7.7. Irritation – skin

TEST SUBSTANCE	Magnesium stearate.
METHOD	According to the procedures described in 49 CFR 173.420 (a) (1).
Species/Strain	Rabbit/New Zealand White
Number of Animals	6
Vehicle	None.
Observation Period	Not known.
Type of Dressing	Occlusive.
RESULTS	Primary irritation index of 0.
Remarks	Information taken from a Cosmetic Ingredient Review (CIR) report.
CONCLUSION	The notified chemical is not irritating to the skin.

7.8. Irritation – eye

TEST SUBSTANCE	Lithium complex grease (65% (w/w) base oil, lithium 12-hydroxy stearate (13.1%), dilithium azelate (2.6%).
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	6
Observation Period	7 days.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	2.4[a]		72 hours	0
Conjunctiva: chemosis				
Conjunctiva: discharge				
Corneal opacity	0.8		48 hours	0
Iridial inflammation	0.8		24 hours	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for ALL animals. [a] Scores were not separated into the various conjunctival effects.

Remarks - Results	No indication of whether the conjunctival effects were restricted to erythema but corneal opacity suggests moderate irritancy. All eyes were normal after 7 days.
CONCLUSION	The notified chemical is slightly to moderately irritating to the eye.

7.9. Irritation – eye

TEST SUBSTANCE	Magnesium stearate.
METHOD	Not stated.
Species/Strain	Rabbit
Number of Animals	6
Observation Period	7 days.

RESULTS

Remarks - Results	The scores were zero on days 1,2 and 3. Information taken from a Cosmetic Ingredient Review (CIR) report.
CONCLUSION	The notified chemical is not irritating to the eye.

7.10. Skin sensitisation

TEST SUBSTANCE	Lithium complex grease (80% (w/w) base oil, lithium 12-hydroxy stearate (8.8%), dilithium azelate (1.8%).
METHOD	Similar to OECD TG 406 Skin Sensitisation – Buehler test.
Species/Strain	Guinea pig
PRELIMINARY STUDY	Maximum Concentration: topical: undiluted
MAIN STUDY	
Number of Animals	Test Group: 10 Control Group: 10
INDUCTION PHASE	Induction Concentration: topical: undiluted
Signs of Irritation	None
CHALLENGE PHASE	
Challenge	topical: undiluted
Remarks - Method	The test substance applied under a Hilltop chamber.

RESULTS

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

Remarks - Results	None.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.

7.11. Repeat dose toxicity

TEST SUBSTANCE	Magnesium stearate
METHOD	Feeding study.
Species/Strain	Rat/Wistar
Route of Administration	Oral – diet
Exposure Information	Total exposure days: 90 days Dose regimen: 7 days per week
Vehicle	None
Remarks - Method	The diets were semi-synthetic in which sodium caseinate replaced casein and magnesium sulfate substituted for carbohydrates due to the calorific value of stearate. Acidified water (pH 3.5) was available *ad libitum*.

RESULTS

Group	*Number and Sex of Animals*	*Dose % in diet*	*Mortality*
I (control)	20/sex	0	0
II (low dose)	"	5	0

III (mid dose)	"	10	0
IV (high dose)	"	20	4/20 males

Mortality and Time to Death
Four males in the high dose group died due to stone formation in the lower urinary pathways.

Clinical Observations
Lower weight gain in the high dose group was observed during the first 8 weeks of the study. One high dose surviving male was incontinent.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
Nephrocalcinosis seen in all females and 12/20 control males and with less severity in the high dose group was attributed to the semi-synthetic diet. Deposition of iron was found in various amounts in high dose animals in the kidney and liver. Decreased liver glycogen was observed in high dose males.

Effects in Organs
Stone formation in the lower urinary pathways has previously been associated with high magnesium content in the diet.

A dose related low relative liver weight was found in males and solely in high dose females. Lower relative kidney weights were seen in females.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as 2500 mg/kg bw/day (5% in the diet) in this study, based on liver weights.

7.11. Repeat dose toxicity

TEST SUBSTANCE	Lithium complex grease (80% (w/w) base oil, lithium 12-hydroxy stearate (8.8%), dilithium azelate (1.8%).
METHOD	Similar to OECD TG 408 Repeated Dose 90-Day Oral Toxicity Study in Rodents.
Species/Strain	Rat/Sprague Dawley
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 90 days Dose regimen: 7 days per week
Vehicle	Corn oil

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	10/sex	0	None
II (low dose)	"	250	"
III (mid dose)	"	500	"
IV (high dose)	"	1000	"

Mortality and Time to Death
None.

Clinical Observations
None.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
There was a 9% increase in phosphate levels in mid dose females.

Prothrombin time was elevated in mid and high dose males and activated partial thromboplastin time was

elevated in low and high dose animals.

All effects were within the historical range and were considered to have occurred by chance.

Effects in Organs
No effects on organ weights and neither macroscopic nor microscopic findings.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as 1000 mg/kg bw/day in this study, based on the lack of identifiable systemic effects at any dose level.

7.12. Repeat dose toxicity

TEST SUBSTANCE	Lithium complex grease (80% (w/w) base oil, lithium 12-hydroxy stearate (8.8%), dilithium azelate (1.8%).
METHOD	Similar to OECD TG 410 Repeated Dose Dermal Toxicity: 21/28-day Study.
Species/Strain	Rat/Sprague Dawley
Route of Administration	Dermal – occluded
Exposure Information	Total exposure days: 28 days Dose regimen: 5 days per week, 6 hours per day
Vehicle	Mineral oil

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	10/sex	0	None
II (low dose)	"	525	"
III (mid dose)	"	1050	"
IV (high dose)	"	2100	"

Mortality and Time to Death
None.

Clinical Observations
None.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
None.

Effects in Organs
No effects on organ weights and neither macroscopic nor microscopic findings.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as 2100 mg/kg bw/day in this study, based on the lack of identifiable systemic effects at any dose level.

7.13. Repeat dose toxicity

TEST SUBSTANCE	Lithium complex grease (80% (w/w) base oil, lithium 12-hydroxy stearate (8.8%), dilithium azelate (1.8%).
METHOD	Similar to OECD TG 411 Subchronic Dermal Toxicity: 90-day Study.

Species/Strain	Rat/Sprague Dawley
Route of Administration	Dermal – occluded
Exposure Information	Total exposure days: 90 days Dose regimen: 5 days per week, 6 hours per day
Vehicle	Mineral oil

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	10/sex	0	None
II (low dose)	"	525	"
III (mid dose)	"	1050	"
IV (high dose)	"	2100	"

Mortality and Time to Death
None.

Clinical Observations
Slightly lower body weights in mid dose males throughout the study were not considered to be biologically significant.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
None.

Effects in Organs
No effects on organ weights and neither macroscopic nor microscopic findings.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as 2100 mg/kg bw/day in this study, based on the lack of identifiable systemic effects at any dose level.

7.14. Genotoxicity – bacteria

A cosmetic ingredients review panel concluded that magnesium stearate was not a mutagen in *Salmonella typhimurium* TA 1535, TA 1537, TA 1538 and *Saccharomyces cerevisiae* D4 with or with metabolic activation by liver and lung preparations from rats, mice and monkeys.

7.15. Chronic toxicity/carcinogenicity

TEST SUBSTANCE	Lithium complex grease (80% (w/w) base oil, lithium 12-hydroxy stearate (7.5%), other additives (12%).
METHOD	Fifty mg of test material was applied twice weekly to the shorn interscapular region of C3H mice (50/sex). Positive controls were treated with 50 mg of a 0.05% solution of BaP in toluene and negative controls received toluene or were untreated. Applications were continued for 104 weeks or until a horny lesion on the surface of the skin grew to 1 mm^3. Potential tumours were examined histologically.
Species/Strain	Mouse/C3H
Route of Administration	Dermal – non-occluded.
Exposure Information	Total exposure: 104 weeks Dose regimen: 2 days per week.
Vehicle	None.

RESULTS

Group	*Number of mice with malignant tumours*	*Number of mice with benign tumours*	*Latent period (weeks)*
Untreated controls			
46 males	0	0	
50 females	1	2	
Toluene controls			
48 males	3	3	87
50 females	5	2	72
Test substance			
47 males	0	2	67
50 females	1	0	82
BaP			
46 males	21	5	48
49 females	45	2	49

CONCLUSION
The test substance was not a skin carcinogen.

7.16. Developmental toxicity/teratogenicity

The teratogenic effect of lithium compounds has been reviewed by Leonard *et al.* (1995). A number of studies in various animal species have produced mixed results. Lithium carbonate given to mice over several days to produce serum levels comparable to those achieved in patients with manic depressive disorders did not result in any effects but dosages at a 6 times higher level caused malformations in the offspring.

Many authors have reported that lithium given to women in the first trimester of pregnancy causes congenital defects, especially of the cardiovascular system. As a result registers of "lithium babies" have been set up.

8. ENVIRONMENT

8.1. Environmental fate

No environmental fate data were submitted.

8.1.1. Ready biodegradability Not determined.

Remarks - Results The grease matrix is not expected to be readily biodegradable. However once this has been degraded to expose the lithium soap this is expected to be biodegradable.

8.1.2. Bioaccumulation Not determined.

Remarks - Results The chemical is not soluble in water and is further bound in a grease matrix. It is not expected to be bioavailable and therefore is unlikely to bioaccumulate.

8.2. Ecotoxicological investigations

No ecotoxicity data were submitted. No testing is planned as the notified chemical is entrained within the grease and no aquatic exposure is likely.

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified chemical is produced as a thickener during the manufacture of grease in a grease kettle and is bound in the grease matrix. Approximately 15 tonnes of waste grease containing 1.8 tonnes of the chemical will be released from the manufacturing site with an additional 20 kg per annum of the neat chemical released. This will be collected and disposed of to landfill where it is expected to be immobile due to its high viscosity and low water solubility. The grease and the notified chemical will undergo eventual abiotic and biotic degradation to landfill gases namely, oxides of carbon and methane as well as water vapour and lithium oxide. Components containing the grease will be disposed of at the end of their useful life. Landfilled components will eventually corrode exposing the grease which will undergo eventual abiotic and biotic degradation. Grease contained in components used for recycled metal, will be combusted during metal recycling to form oxides of carbon and water vapour, with the lithium oxide formed reporting to the slag. Spills, residues and losses from unsealed components are expected to be immobile and will eventually undergo in situ abiotic and biotic degradation to oxides of carbon, water vapour and lithium oxide.

9.1.2. Environment – effects assessment

No environmental data were submitted. However, the aquatic toxicity of fatty acid soaps is very variable and seems to be highly dependent on both the species and the specific fatty acid tested. Many soaps exhibit slight toxicity to aquatic life (Cetox, 2001).

The water insolubility of the notified chemical and the matrix to which it's bound is likely to reduce the toxicity of the chemical. The grease matrix is expected to be persistent in the aquatic environment; however, once the lithium soap is exposed to the environment it expected to biodegrade. The notified chemical is water insoluble and is bound in a grease matrix; it is unlikely to be bioavailable and therefore is unlikely to bioaccumulate.

9.1.3. Environment – risk characterisation

The notified chemical may exhibit toxicity to aquatic life. However, the vast majority of the notified chemical will be disposed to authorised landfill either as waste grease or contained in components in which, the grease is used. It is very viscous and water insoluble and therefore will be immobile and highly unlikely to leach to the aquatic environment. Spills, residues and losses from components will likewise be immobile and highly unlikely to leach to the aquatic environment.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

The notified chemical is manufactured as a component of grease in a mixing vessel, which is connected to extraction equipment. The grease blender wears a face shield, chemical and heat resistant gloves and long sleeved overalls to limit (mainly dermal) exposure. The concentration of notified chemical to which blenders are exposed is limited to 12% (w/w). The extraction system should limit exposure to fumes in the workplace although the notified chemical has a low vapour pressure which should limit its concentration in the fumes in any case.

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.

Once a batch is completed it is automatically transferred to containers via fixed piping. The limited opportunity for dermal and/or ocular exposure is further reduced by workers wearing chemical resistant gloves, safety glasses and long sleeved overalls.

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.

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

As noted in the chapter on toxicological data, the notified chemical is a member of a category of chemicals being considered by the US HPV Chemical Challenge Program. The toxicological profile of the notified chemical or analogues or greases containing the notified chemical is as follows:

Lithium stearate and a grease containing lithium 12-hydroxy stearate (13.1%) and dilithium azelate (2.6%) were of low toxicity via the oral and dermal routes in rats.

A grease containing lithium 12-hydroxy stearate (13.1%) and dilithium azelate (2.6%) was a slight skin irritant and a slight to moderate eye irritant in rabbits. Magnesium stearate was not a skin irritant in rabbits but was a slight to moderate eye irritant.

A grease containing lithium 12-hydroxy stearate (8.8%) and dilithium azelate (1.8%) was not a skin sensitiser in guinea pigs.

A number of repeat dose studies were conducted. Magnesium stearate at 2500 mg/kg bw/day in the diet for 90 days caused lower liver weights, mainly in male rats. A grease containing lithium 12-hydroxy stearate (8.8%) and dilithium azelate (1.8%) administered to rats for 90 days by gavage had a NOAEL of 1000 mg/kg bw/day with no identifiable organ toxicity. The same grease administered under dermal occlusion for 28 or 90 days had a NOAEL of 2100 mg/kg bw/day.

Magnesium stearate was not mutagenic in bacteria and a grease containing lithium 12-hydroxy stearate (7.5%) and other additives (12%) was not carcinogenic to the skin of mice in twice weekly treatment. Lithium carbonate administered to mice at 6 times the therapeutic dose for manic depressive disorders caused malformations in the offspring and lithium given to women in the first trimester of pregnancy causes congenital defects, especially of the cardiovascular system.

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

9.2.4. Occupational health and safety – risk characterisation

The maximum concentration of notified chemical in grease is 12% (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. Therefore, the risk to workers involved in manufacture, use, transport and storage 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 benign toxicological profile 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 not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

10.2. Environmental risk assessment

The notified 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 Low Concern to public health when used as described.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of a 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 a product 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

CONTROL MEASURES

Occupational Health and Safety

- 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 authorised landfill.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by physical collection such as scooping or wiping with paper or rags, followed by authorised landfill.

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.

13. BIBLIOGRAPHY

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