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May 2009

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Chemical in Vanlube 887 and Vanlube 887E

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health and Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment, Water, Heritage and the Arts.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at 334-336 Illawarra Road, Marrickville NSW 2204.

This Full Public Report is also available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

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Director
NICNAS

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This notification has been carried out under the approved foreign scheme provisions (Canada) of Section 44 of the Act. The health and environment hazard assessment of the Canadian report was provided to NICNAS and where appropriate used in this assessment report. The other elements of the risk assessment and recommendations on safe use of the notified polymer were carried out by NICNAS.

Chemical in Vanlube 887 and Vanlube 887E

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Ciba (Australia) Pty Ltd (ABN 97 005 061 469)
235 Settlement Rd
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, CAS Number, Molecular Formula, Structural Formula, Molecular Weight, Spectral Data, Purity, Identity of Impurities, Identity and Weight of Additives/Adjuvats, Import Volumes, Identitiy of Recipients, and Details of Use.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA, Canada, Europe, China, Japan (in progress)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Vanlube 8877 (product containing the notified chemical)
Vanlube 887E (product containing the notified chemical)

OTHER NAME(S)
Tolutriazole compound

MOLECULAR WEIGHT
>500 Da

ANALYTICAL DATA
Reference NMR and UV/Vis spectra were provided.

3. COMPOSITION

DEGREE OF PURITY >90%

4. PHYSICAL AND CHEMICAL PROPERTIES

All physico-chemical tests were performed on the test substance, Vanlube 887, which contained 100% of the notified chemical and did not contain any diluent.

APPEARANCE AT 20°C AND 101.3 kPa: Brown or black solid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	34-64°C	Measured
Boiling Point	167°C (decomposes)	Measured
Relative Density	1.0278 g/m^3 at 21°C	Measured
Vapour Pressure	1.5 x 10^{-13} KPa at 25°C	Measured
Water Solubility	<1 x 10^{-3} g/L at 20°C	Measured. The notified chemical is expected to be insoluble (< 0.1 mg/L) in water based on its hydrophobic structure.
Hydrolysis as a Function of pH	Half-life not calculated.	Measured. Hydrolysis was detected at a higher rate under more acidic conditions.
Partition Coefficient (n-octanol/water)	log K_{OW} > 6.2	Measured. Predicted values include log Kow = 12.22 (EPI), 12.58 (CLOGP), and 11.31 (PALLAS). Based on this information, the notified substance is expected to have a log Kow > 5.
Adsorption/Desorption	log K_{OC} > 4.29	Measured. EPI predicted a log K_{OC} = 9.52. Based on this information, very strong sorption to soils is expected.
Dissociation Constant	Not determined	PALLAS predicts that there are no acidic or basic groups present in the substance that may dissociate or associate at environmental pH.
Particle Size	Not determined	Products will be only sold in solution. In its pure form, the notified chemical is a massed solid.
Flash Point	Not determined	The notified chemical is solid.
Flammability	Not highly flammable	Measured
Autoignition Temperature	None below 400°C	Measured
Explosive Properties	Not explosive	Measured
Oxidizing Properties	Non-oxidising	Measured

DISCUSSION OF PROPERTIES

Full details of tests on physical and chemical properties are in Appendix A.

Reactivity

There are no known conditions that contribute to the notified chemical's instability, and no substances are that are incompatible with the notified chemical. The likely decomposition products are expected to be water, oxides of carbon and oxides of nitrogen.

Dangerous Goods classification

Based on the available data, the notified chemical is not classified as a Dangerous Goods according to the Australian Dangerous Goods Code (NTC, 2007).

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
Vanlbe 887 and Vanlube 887E containing 30-60% of the notified chemical will be imported by sea.

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

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

PORT OF ENTRY
Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
The notified chemical will not be manufactured in Australia. However, formulation and packaging of lubricating oils (automotive & hydraulic oils) containing the notified chemical will occur at different sites in Australia. The general purpose greases containing the notified chemical will be imported into Australia and will not be formulated in Australia.

TRANSPORTATION AND PACKAGING
Vanlube 887 and Vanlube 887E products containing the notified chemical will be imported by sea in containers (0.95 L, 3.8 L & 18.9 L), drums (208 L & 1040 L), and in 1250 L IBCs and will be initially stored at the notifier's warehouse for further distribution to other companies for formulation and packaging of lubricating oils containing the notified chemical. Greases will be imported as finished products and distributed to customers.

USE
The notified chemical will be used as an antioxidant synergist in lubricating oils (automotive, hydraulic and gear oils) and general purpose greases. The product containing the notified chemical and other additives are blended with petroleum based or synthetic base stock oils to form finished products. The predominant use (>80%) of the notified chemical in finished products will be in industrial lubricating oils.

Vanlube 887 and Vanlube 887E will be used in the formulated lubricating oils at a maximum concentration of 5%, depending on the application. Since these products contain notified chemical at a concentration of 30-60%, the maximum concentration of the notified chemical in the finished products will be 3%.

The general purposes greases will be imported as finished products and distributed to customers as such and will contain Vanlube 887 or Vanlube 887E at levels less than 3% (< 2% notified chemical).

OPERATION DESCRIPTION
The notified chemical will not be manufactured in Australia. In the main application in lubricating oils, the notified chemical will be imported as a component of the products, Vanlube 887 and Vanlube 887E, at a concentration of 30-60% and reformulated into finished lubricant products (at different sites across Australia) that will be then distributed for use.

During formulation, the notified chemical in the imported products is pumped from the containers in which they are imported, to a closed system blend tank. Typically, base oils and other additive, are pumped to the tank and after slow mixing, the final lubricants are transferred to holding tanks for packing off by automated processes and enclosed filling systems into final packages of various size and container types for distribution to customers. There may also be direct transfer from bulk tanks to bulk containers for transport to customers.

Greases will be imported as finished products and distributed to customers as such.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

Category of Worker	*Number*	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and storage	5-10	1 hour/day	30-60 days/year
Blending operators	10-20	2 hours/day	50-100 days/year
Quality technicians	10-20	1 hour/day	50-100 days/year
Packaging workers	10-20	2 hours/day	50-100 days/year
End use of lubricants	>100	1 hour/day	100-200 days/year
End use of greases	>100	2 hours/day	10-20 days/year

EXPOSURE DETAILS

Transport and storage

Transport and storage workers are not likely to be exposed to the notified chemical except in the case of an accident involving damage to the packaging.

Formulation

The blending operation lasts approximately 2 hours, 50-100 blending operations are performed in each year, and are supervised by 1-2 workers per site. The blending operation is an automated process using dedicated tanks and transfer lines, if it is feasible. Therefore, exposure will mostly be limited to transfer operations in mixing vessels, residues in lines, and on coupling and occasionally from leaks and spills. Dermal contamination would be the main route of occupational exposure. Some inhalation exposure could occur if mists are generated during formulation processes. Workers are likely to wear aprons, gloves and safety glasses.

One quality control worker will take a sample for quality analysis at the formulation site and it takes about one hour to conduct each quality analysis. The sample will be recycled into the batch and the quality control worker will wear safety glasses. The packaging process is an automated process and enclosed filling system is used for final packages of various size and container types for distribution to customers. One packaging worker will run the packaging process and duration for each packaging run will be around 2 hours. Dermal contact would be the main route of occupational exposure and the packaging workers will wear aprons, gloves and safety glasses.

End use

Exposure to engine oils, hydraulic fluids or gear oils can be high during addition or replacement, but exposure to the notified chemical will be low, given its low concentration (maximum of 3%) in the oils. Dermal exposure of the hands may be significant as it is uncommon for gloves to be worn during addition of these products to automotive or hydraulic equipment.

The general purpose greases will be used in the automotive, machinery and equipment manufacturing sites. Occupational exposure may occur when opening the containers, adding the greases into storage containers, manual application by brush, spatula, grease gun, grease cartridge, and during equipment cleaning up and maintenance. These operations will generally last for a short period of time (<1 hour) and dermal exposure may occur during these manual operations. However, exposure is expected to be infrequent (monthly or yearly). Workers will wear impermeable gloves, protective eyewear, protective clothing and safety boots when using greases repeatedly or for prolonged periods.

6.1.2. Public exposure

As the predominant use (>80%) of the notified chemical will be in industrial lubricating oils contained in closed systems, public exposure to the notified chemical through the intended industrial use is expected to be low, except in the event of a spill. Automotive engine oil containing the notified chemical may be used to replace spent crankcase oil. In this case, when members of the public change the engine oil, dermal exposure to the oil may occur. However, given the low concentration (3%) of the notified chemical in the oil and the fact that the engine oil is changed infrequently, potential for exposure to the notified chemical is low.

As general purposes greases would be predominantly used in industrial situations and their physical form makes them less susceptible to spillage, public exposure to the notified chemical in greases is not expected to be occur.

6.2. Human health effects assessment

6.2.1. Toxicology studies on the notified chemical

The results from toxicological investigations conducted on the notified chemical are summarised in the table below. The test substance used in the toxicity studies was identified either as OD 887, OD 887 (without oil) or Vanlube 887. These test substances (except OD 887 in some cases, see below) contain 100% of the notified chemical and did not contain any diluents.
The test substance OD 887 used in acute oral study, acute dermal study, dermal irritation study (one study), and eye irritation study contains notified chemical in 50% of petroleum process oil.

Endpoint	*Material tested*	Result and Assessment Conclusion
Rat, acute oral toxicity	OD 887: contains the notified chemical at 50% in petroleum process oil	oral LD50 >5000 mg/kg bw low toxicity
Rabbit, acute dermal toxicity	OD 887: contains the notified chemical at 50% in petroleum process oil	LD50 >2000 mg/kg bw low toxicity
Rat, acute inhalation toxicity	-	Not submitted
Rabbit, skin irritation	OD 887: contains the notified chemical in 50% of petroleum process oil	slightly irritating
Rabbit, skin irritation	Notified chemical	mildly irritating
Rabbit, eye irritation	OD 887: contains the notified chemical at 50% in petroleum process oil	slightly irritating
Guinea pig, skin sensitisation–adjuvant test	Notified chemical	no evidence of sensitisation
Rat, repeat dose oral toxicity–28 days (Vanlube 887*)*	Notified chemical	NOEL: 150 mg/kg bw/day NOAEL: 1000 mg/kg bw/day
Mutagenicity–bacterial reverse mutation	Notified chemical	non mutagenic
Genotoxicity–in vitro chromosomal aberration test in human lymphocytes	Notified chemical	non genotoxic
Genotoxicity–in vivo mouse bone marrow micronucleus test	Notified chemical	non genotoxic

6.2.2. Summaries of the toxicology studies

Systemic Toxicology

Acute Toxicity:
The test substance (OD 887 containing 50% of the notified chemical in petroleum process oil) was found have low acute oral and dermal toxicity in rats and rabbits, with estimated LD_{50} of >5000 mg/kg bw and > 2,000 mg/kg bw, respectively.
Following a dose-range finding component, the test substance (OD 887) was administered via a single oral dose by gavage to five male and five female Sprague-Dawley rats at 5000 mg/kg bw. Decreased activity was noted in one male and one female rat and was resolved by Day 1 in the female and Day 5 in the male. There were no effects on body weight gain, mean and absolute liver and kidney weights as compared to the control group and there were no toxicologically significant pathological findings.

OD 887 (containing 50% of the notified chemical in petroleum process oil) was applied at the limit dose of 2,000 mg/kg bw to the clipped skin of male and female (5/sex) New Zealand White albino rabbits. After application the treatment area was covered under occlusive dressing for 24 hours. The treatment did not result in any deaths or treatment related body weight changes. Clinical signs were limited to one male and one female and included soft stools and anorexia or reduced food consumption. These clinical signs are considered non-treatment related as they were spontaneous in nature and noted in the latter part of the observation periods (Day 8 through 15). All animals exhibited moderate to severe erythema and edema at the test site after removal of the dressing, resolving by study termination.

Primary Irritation:
Two primary dermal irritation studies were conducted; one study applied the notified substance at 50% in an oil-based vehicle (OD887) and the other used the notified substance without the oil component OD 887 (without oil).

The first study was conducted on six New Zealand White rabbits (4F/2M) with OD887 in oil (0.5 mL) applied topically on a clipped test site. The site was semi-occluded for four hours after test article administration, subsequently wiped to remove excess test material and observed for 7 days at the following intervals: 0.5, 24, 48 and 72 hours and 4 and 7 days after patch removal. The test substance initiated very slight to very well defined erythema and very slight to moderate edema. Dermal irritation indices subsided by Day 7 in all animals. The mean primary dermal irritation score (using the Draize method, 24-72h scores) was determined to be 1.61, indicating a mild irritant. Including the 0.5 h scores in the calculation (0.5-48 h scores), a primary dermal irritation score of 1.92 was obtained, also indicating a mild irritant.

In the second study conducted with the notified substance, 0.5 g of OD-887 (without oil*)* was wetted with 0.5 ml of distilled water and applied topically on a clipped test site of New Zealand White rabbits (3M). The site was semi-occluded for four hours after test article administration, subsequently wiped to remove excess test material and observed for 7 days at the following intervals: 1, 24, 48 and 72 hours and at 7 days after patch removal. Under the study protocol, scores for erythema and edema at the 24 and 72 hour observations were used to obtain the primary irritation index of 2.0. Well defined erythema and very slight edema were noted during the observation periods indicating mild irritancy. No indication of corrosive effects was noted and skin irritation was generally resolved by Day 7.

The test substance OD 887 (containing 50% of the notified chemical in petroleum process oil) was found to be minimally irritating following rabbit eye exposure with rinsing (3 animals) and without rinsing (6 animals) after test substance application. The Maximum Mean Score for non-rinsed animals was 6.0 at 1 hour and 1.0 at 24 hours. The Maximum Mean Score was slightly lower following eye irrigation after test substance application with a value of 5.3 at 1 hour and 1.3 at 24 hours. No signs of irritation were noted at the 48 hour observation period. Adverse effects were localized to the conjunctivae where diffuse crimson redness (grade 2) was occasionally accompanied by minimal swelling (grade 1).

Skin Sensitization:
The potential of the notified substance to induce skin sensitization was assessed in a Magnusson & Kligman Maximisation Study in male Dunkin Hartley albino guinea pigs with Vanlube 887 (notified substance). Following a preliminary dose range finding component, ten guinea pigs were intra-dermally injected at three different sites with Freund=s Complete Adjuvant in distilled water, 25% w/v formulation of the test substance in Arachis oil, and 25% w/v formulation of the test substance in Freund=s Complete Adjuvant in distilled water. The vehicle control animals (5M) were injected with Freund=s Complete Adjuvant in distilled water, Arachis oil, and with 50% Arachis oil in Freund=s Complete Adjuvant in distilled water. One week later, the same sites were topically administered a 75% formulation of the notified substance in Arachis oil via a saturated filter paper.

Two weeks after the topical administration, a challenge dose (75% and 50% in Arachis oil) was applied topically via a saturated filter paper for 24 hours. Skin reactions were monitored after each dose application. During the induction phase, skin effects were evident and included reactions of well defined erythema after the intradermal injection and very slight erythema after the topical application. Following the challenge dose, there were no reactions to the administration of the notified substance or vehicle control articles. Historical positive control data was provided to confirm the sensitivity of the test system. The notified substance was not considered to be a skin sensitizer.

Repeat Dose Toxicity:
A 28 day repeated dose oral toxicity study was conducted with Sprague Dawley rats. Five animals per sex/group were administered the notified substance (Vanlube 887*)* in Arachis oil once daily by oral gavage at doses of 0, 15, 150 or 1000 mg/kg bw/day. The number of animals per group is relatively low with respect to similar studies of the same duration, however as there were no overt indications of toxicity in the study, this deviation is considered minor and would not change the overall conclusions of the study. No unscheduled deaths occurred during the study period and there were no overt treatment related changes in blood chemistry parameters, no treatment-related organ weight changes or gross and histopathological findings as compared to the control at any dose level. Clinical signs were limited to high dose animals (1000 mg/kg bw/day) which exhibited salivation post dose, and is normally associated with test article palatability and not systemic toxicity. Body weight gain and corresponding food consumption were reduced during Week 1 of the study in high dose males (1000 mg/kg bw/day) as compared to control animals, resulting in overall slightly decreased body weights in high dose males at study end. The NOEL, based on the slight body weight reductions in high dose males, was considered to be at 150 mg/kg.bw/day. However, a NOAEL of 1000 mg/kg.bw/day is concluded as the body weight differences in high dose males were relatively minor and were not seen in female rats at any dose level.

Genotoxicity:
A Salmonella reverse-mutation assay was conducted with the notified substance (Vanlube 887) following the plate incorporation technique both in the presence and absence of metabolic activation and using dose levels of 50, 150, 500, 1500, or 5 000 µg/plate. The test substance did not induce point mutations in *S. typhimurim* strains TA 98, 100, 1535, 1537 or 1538 in any of the doses tested in two independent assays. An oily, globular precipitate was observed at 1500 Φg/plate and above, which did not interfere with the scoring of revertant colonies. Positive controls were used to validate the assay and showed an acceptable response. The substance did not cause gene mutations *in vitro* under the conditions of this assay.

A chromosomal aberration assay was conducted with the notified substance (Vanlube 887) using human lymphocytes, in the presence (+S9) and absence (-S9) of metabolic activation at dose levels ranging from 0 to 5000 µg/mL. In the absence of metabolic activation, cell cultures were exposed continuously to the test substance for either 20 or 44 hours, whereas in the presence of metabolic activation cell cultures were exposed to the test substance for 4 hours followed by 16 or 40 hour expression periods. Dose levels selected for metaphase analysis were 1250, 2500 and 5000 µg/mL. There were no significant increases in the incidence of chromosomal aberrations after treatment at any dose or sampling time. Positive controls were used to validate the assay and showed an acceptable response. The tested substance did not cause chromosomal aberrations *in vitro* under the conditions tested.

The notified substance was concluded to be not clastogenic to mouse bone marrow following an *in vivo* mouse micronucleus test. Following a range finding study which determined that there were no sex differences and no indication of overt toxicity at the highest tested dose level, male mice (7 males/test and control groups, 5 males/positive control group) were administered doses of 0 (Arachis oil) or 2000 mg/kg.bw, by intraperitoneal injection. The animals were sacrificed 24 and 48 hours after administration. The notified substance was well tolerated by all of the treatment animals. There were no clinical signs indicating toxicity. Following sacrifice, there was no significant differences in the PCE/NCE ratio of the treatment animals as compared to the control animals and there were no significant increases in the number of micronucleated PCEs in any of the treatment animals. The test article was considered non-genotoxic under the conditions of the study.

Structural Alerts:
The notified substance does not contain any structural features known to be associated with adverse human health effects

6.2.3. Summary of Human Health Effects

Toxicokinetics, metabolism and distribution:
Information on toxicokinetics, metabolism and distribution of the notified chemical was not submitted.

Acute toxicity:
The product containing 50% of the notified chemical was found to have low acute oral and dermal toxicity in rats and rabbits, with estimated LD_{50}s of >5000 mg/kg.bw and > 2,000 mg/kg.bw, respectively. Acute dermal toxicity was tested only up to 1000 mg/kg bw (based on the notified chemical itself). No mortality was seen at this dose, however dermal toxicity at higher doses cannot be ruled out. Information on inhalation toxicity is not available.

.Irritation and Sensitisation.
Skin irritation studies were conducted on the two formulations of the notified chemical: one without oil and one in oil. The formulation without oil was solid and contains 100% of the notified chemical while the formulation in oil was liquid and contains the notified chemical at 50% in petroleum process oil.

Based on the results of these studies, the notified chemical would not be classified as a skin irritant but is expected to have potential for irritation. This is supported by the effects seen in the dermal toxicity study.

No eye irritation studies were provided on the notified chemical itself. Based on the slight irritation seen in testing at a concentration of 50%, the notified chemical is likely to be a mild eye irritant.

The notified chemical was not a skin sensitiser in a guinea pig maximisation study.

Repeated Dose Toxicity:
The 28-day study indicated that the notified chemical has low toxicity by repeated oral administration. The NOEL, based on the slight body weight reductions in high dose males, was considered to be at 150 mg/kg.bw/day. However, a NOAEL of 1000 mg/kg.bw/day is concluded as the body weight differences in high dose males were relatively minor and were not seen in female rats at any dose level.

Mutagenicity:
The notified chemical was found to be non-mutagenic in a bacterial reverse mutation test and also showed no evidence of clastogenicity to human lymphocytes *in vitro* and in mouse bone marrow micronucleus test *in vivo*. Based on these results, the notified chemical is not suspected to be genotoxic.

Carcinogenicity:
Information is not available to assess the carcinogenic potential of the notified chemical.

Toxicity for reproduction:
Information is not available to assess the potentials for toxicity for reproduction of the notified chemical.

Health hazard classification
Based on the available data the notified chemical is not classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

Based on available studies, the notified chemical is expected to have low acute oral and dermal toxicity and low toxicity after repeated exposure. It is not a skin sensitiser and is not suspected to be genotoxic. It is expected to be mildly irritating to the skin and eyes. The notifier has also stated that 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 product may cause skin irritation and/or dermatitis (oil acne or folliculitis).

There is potential for occupational exposure to the notified chemical at concentrations up to 30-60% during importation, loading/unloading, transfer and formulation, and concentrations up to 3% during sampling and analysis, packaging, transportation and use of the finished end-use products (engine oils, hydraulic fluids or gear oils, greases). The main routes of occupational exposure are *via* dermal, ocular and inhalation.

During transport and storage, worker exposure will be minimal and workers will only be exposed to the notified chemical in the case of an accident involving damage to the packaging.

The formulation of products is an automated blending process using dedicated tanks and transfer lines and exposure will mostly be limited to transfer operations in mixing vessels, residues in lines, and on coupling and occasionally from leaks and spills. Although dermal /ocular contamination would be the main route of occupational exposure, some inhalation exposure could occur if mists are generated during formulation processes. Workers carrying out formulation, sampling and quality assurance testing are likely to wear aprons, gloves and safety glasses.

The packaging process is automated and an enclosed filling system is used. Dermal and ocular contact would be the main route of occupational exposure for packaging workers, who will wear aprons, gloves and safety glasses.

Worker exposure to end-use products (engine oils, hydraulic fluids or gear oils) containing the notified chemical is likely to occur, particularly during addition or replacement of lubricant oils. Furthermore, dermal exposure of the hands may be significant as it is uncommon for gloves to be worn during addition of these products to automotive or hydraulic equipment. However, the notified chemical is present at maximum concentration of 3% in the finished end-use products.

The imported greases containing the notified chemical will be used in automotive, machinery and equipment manufacturing sites and dermal exposure would be the predominant route of occupational exposure. However, exposure is expected to be infrequent (monthly or yearly) and the chemical is present at low concentrations. Workers will wear impermeable gloves, protective eyewear, protective clothing and safety boots when using greases repeatedly or for prolonged periods.

Skin and eye irritation effects can be prevented if controls are in place to minimise skin and eye contact with the notified chemical, especially as introduced and during formulation. Compliance with the exposure standard for oil mist of 5 mg/m^3 (TWA) established by NOHSC (NOHSC 1995) at any worksites where mist could be generated would minimise inhalation exposure to workers.

Considering the proposed use of engineering controls and PPE, and the low concentration of the notified chemical in products during packaging and end-use, the exposure and risk to workers is considered low.

6.3.2. Public health

Automotive engine oil containing the notified chemical may be used to replace spent crankcase oil. In this case, when members of the public change the engine oil, there is potential for dermal exposure to the oil. However, given the low concentration (<3%) of the notified chemical in the oil and the fact that the engine oil is changed infrequently, potential for exposure to the notified chemical is low and the risk to public health is considered acceptable.

As general purposes greases would be predominantly used in industrial situations, public exposure to the notified chemical is not expected to occur through the use of general purposes grease. Therefore, the risk of the general public from this use is considered to be very low.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical will be imported as a component of imported products in Australia for further reformulation into final lubricating oil products at different sites across Australia.

The reformulation process will be automated and take place in an enclosed system. The imported product will be blended with base oil and other additives. When cleaning the blend tank, base oil is used to flush the tank/drum/container/IBC and the flushings are added to the blend. Therefore, release will be from accidental spills only, and is expected to be less than 1% of the import volume.

RELEASE OF CHEMICAL FROM USE

Waste residual lubricant oils in empty containers are expected to be < 0.1%, and will be washed and recycled by drum reconditioners.

RELEASE OF CHEMICAL FROM DISPOSAL

The applicant indicates that about 10% of the notified chemical will be used for formulation of grease, which will be mainly disposed of by incineration or to landfill. Limited spills and residues in containers and discarded machinery will also be disposed of to landfill.

Assuming all the rest of the notified chemical will be used for production of lubricant oils (90%), it is suggested that at least 60% of used oil generated are collected for recycling to be resold mainly as fuel oil. The fate of the remaining 40% of used oil (corresponding to 36% of the imported notified chemical) was not certain but not collected for recycling.

A survey by the Australian Institute of Petroleum (AIP 1995) indicates that of the annual sales of automotive engine oils in Australia, some 60% are potentially recoverable (i.e. not burnt in the engines during use). This report also indicates that around 86% of oil changes take place in specialised automotive service centres, where old oil drained from crankcases is disposed of responsibly (e.g. oil recycling or incineration). Assuming this is the case, negligible release of the notified chemical should result from these professional activities. The remaining 14% of oil is removed by "do it yourself" (DIY) enthusiasts. In these cases, some of the used oil would be either incinerated, left at transfer stations where it is again likely to be recycled, or deposited into landfill. Meinhardt (2002) estimated that DIY activities account for 7-10% of the unaccounted used oil.

According to a survey tracing the fate of used lubricating oil in Australia (Snow 1997), only approximately 20% of used oil removed by DIY enthusiasts is collected for recycling, approximately 25% is buried or disposed of in landfill, 5% is disposed of into stormwater drains and the remaining 50% is used in treating fence posts, killing grass and weeds or disposed of in other ways. In a worst case scenario involving the 14% of used oil removed by DIY enthusiasts, the notified chemical could be collected for recycling (≤ 2.8%), buried or disposed of in landfill (≤ 3.5%), disposed of in stormwater drains (≤ 0.7%) and used in treating fence posts, to kill weeds or disposed of in other ways (≤ 7%). A proportion of the latter may potentially be disposed of to sewer. Therefore, about 0.7% of the total import volume of the notified chemical could potentially enter the aquatic environment via disposal into the stormwater system. In addition to this, considering the unknown fate of some of the oil used by DIY operators, up to 7% may also be sent to the sewer for disposal. Since the use of the lubricating oils will occur throughout Australia, all releases resulting from use or disposal of used oil will be very diffuse, and release of the notified chemical in neat concentrations is very unlikely except as a result of transport accidents. Any releases to water will adsorb strongly to sediment based on the very low water solubility.

7.1.2 Environmental fate

The biodegradation calculated as percentage of measured amount of inorganic carbon over the theoretical amount was 0% in 28 days. Based on the data provided, the notified substance will not be degradable in the aquatic environment and have a half-life in water ≥ 182 days.

The low water solubility makes the potential for bioaccumulation of the notified chemical low to the aquatic life.

The majority of the notified chemical will be either sent to landfill or incinerated to recover the calorific value. In landfill, the notified chemical is not expected to leach due to the low water solubility, and will undergo slow degradation processes via biotic and abiotic pathways. In either way, the notified chemical will finally be decomposed into small molecules of water and oxides of carbon and nitrogen.

7.1.3 Predicted Environmental Concentration (PEC)

The calculation of PEC is not necessary given the low import volume and the estimated percentage of release of the notified chemical.

7.2. Environmental effects assessment

The results from ecotoxicological investigations conducted on the notified chemical are summarised in the table below. These results have been taken from the Canadian report for the notified chemical.

Organism	Endpoint	Value (mg/L)	Method
Fish (rainbow trout)	96h LC50	> 5 mg/L	OECD 203
	96h NOEC	5 mg/L	
Daphnia	48h EC50	> 5 mg/L	OECD 202
	48h NOEC	5 mg/L	
Green Algae	72h EC50(b)	> 5 mg/L	OECD 201
	72h EC50(r)	> 5 mg/L	
	72h NOEC	5 mg/L	

Considering the low water solubility (< 1 x 10^{-3} g/L), the notified chemical is considered not toxic to the aquatic life up to the limit of the solubility.

7.2.1 Predicted No-Effect Concentration

The PNEC has not been calculated given the low imported volume and limited release of the notified chemical to the aquatic environment. In addition, the low water solubility of the notified chemical in water makes the bioavailability low to the aquatic life, which makes the calculation of PNEC unnecessary.

7.3. Environmental risk assessment

In the worst case scenario, less than 7.7% of the notified chemical is expected to enter the aquatic environment via disposal into the stormwater and sewage. Most of these released chemical is expected to be separated out from water via absorption to sediment based on the hydrophobic nature. Combining with the low import volume, the release of the notified chemical to the aquatic environment is expected to be low.

Given the low release of the notified chemical to the aquatic compartment and the lack of toxicity to aquatic life at saturation, the risk of the notified chemical to the aquatic environment is expected to be acceptable.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available data the notified chemical is not classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

As a comparison only, the notified chemical was not classified as Hazardous using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations, 2003). This system is not mandated in Australia and carries no legal status but is presented for information purposes.

Human health risk assessment
Under the conditions of the occupational settings described, the notified chemical is not considered to pose an unacceptable risk to the health of workers.

When used in the proposed manner, the notified chemical is not considered to pose an unacceptable risk to public health.

Environmental risk assessment
On the basis of the reported use pattern, the notified chemical is not considered to pose a risk to the environment.

Recommendations

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced and during formulation:
  - Avoid contact with the skin and eyes
  - If there is any possibility of oil mist being generated, observe an exposure standard for oil mist of 5 mg/m^3 (TWA) (NOHSC 1995).

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced and during formulation:
  - Safety glasses if splashing may occur
  - Gloves
  - Coveralls

  Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- A copy of the MSDS should be easily accessible to employees.

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified chemical should be disposed of to landfill.

Storage

- There are no special requirements regarding the storage of this product. However, the containers should be kept dry and stored in a cool, well-ventilated place. All equipment should be earthed.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by physical containment, collection and subsequent safe disposal.

Regulatory Obligations

Secondary Notification
This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from as an anti-oxidant synergist for lubricating oils and general purpose greases, or is likely to change significantly;
- the amount of chemical being introduced has increased from 3 tonnes/year, or is likely to increase, significantly;
- the chemical has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

No additional secondary notification conditions are stipulated.

Material Safety Data Sheet
The MSDS of the product containing the notified chemical provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

All physico-chemical tests were performed on the test substance, Vanlube 887, which contains 100% of the notified chemical and did not contain any diluent.

Melting Point/Freezing Point 34-64°C (307-337±0.5 K)

Method EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Test Facility SafePharm Laboratories Ltd (1996a)

Boiling Point 167°C (decomposes) at 101.3 kPa

Method EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks Vanlube 887 was found to decompose from 440±0.5K (167°C) but failed to boil up to 629±0.5K (356°C).
Test Facility SafePharm Laboratories Ltd (1996a)

Relative Density 1.0278 g/cm^3 at 21°C

Method EC Directive 92/69/EEC A.3 Relative Density.
Remarks The relative density of Vanlube 887 has been determined to be 1.0278 g/cm^3 at 21.0±0.5°C.
Test Facility SafePharm Laboratories Ltd (1996a)

Vapour Pressure 1.5 x 10^{-13} KPa at 25°C

Method EC Directive 92/69/EEC A.4 Vapour Pressure.
Test Facility Safepharm Laboratories (1996b)

Water Solubility <1 x 10^{-3} g/L at 20±0.5°C

Method EC Directive 92/69/EEC A.6 Water Solubility.
Remarks The standard method was not applicable to this material as it hydrolyses rapidly in aqueous solution. It was deemed more appropriate to estimate the water solubility by visual estimation.
Test Facility SafePharm Laboratories Ltd (1996a)

Hydrolysis as a Function of pH

Method OECD TG 111 Hydrolysis as a Function of pH.

Medium	pH	% Remaining
Acetonitrile:Buffer (50:50)	4	0
Acetonitrile:Buffer (50:50)	7	113*
Methanol:Buffer (50:50)	7	55.6
Methanol:Buffer (50:50)	9	84.7

* Odd % remaining value reported in the study, there were signs of degradation in the HPLC spectrum.

Remarks The substance tested has low water solubility and therefore was dispersed with help of acetonitrile and methanol. The test was conducted at room temperature for a period of ~ 1 hour. The results of the hydrolysis study indicate that the parent chemical is not found at pH 4 and slight hydrolysis at higher pH values.

The benzotriazole moiety itself is not susceptible to hydrolysis. However, the structure of the notified chemical suggests a mechanism for hydrolysis which is likely to occur in a substituent of the benzotriazole moiety. Further the suggested mechanism is likely to proceed more rapidly under acidic conditions, which is consistent with the test results. Further assessment of the chromatography for the sample acetonitrile/pH 7 buffer, instead of 113% as reported in the study, obvious decline in the remaining percentage value was noted, which is consistent with the claim of "there were signs of degradation in the HPLC spectrum" and suggesting that the hydrolysis occurred at pH 7.

	Consequently, we conclude that the notified chemical hydrolysis in the environmental pH range of 4 – 9.
Test Facility	SafePharm Laboratories Ltd (1996d)

Flammability Not highly inflammable

Method	EC Directive 92/69/EEC A.10 Flammability (Solids).
Remarks	The test substance has been determined to be not highly inflammable, as it did not propagate combustion over 200 mm of the preliminary screening test.
Test Facility	SafePharm Laboratories Ltd (1996c)

Autoignition Temperature None below 400ºC

Method	EC Directive 92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases).
Remarks	Vanlube 887 has been determined not have an auto-ignition temperature below 400 ºC.
Test Facility	SafePharm Laboratories Ltd (1996c)

Explosive Properties Determined not to have explosive properties.

Method	EC Directive 92/69/EEC A.14 Explosive Properties.
Test Facility	SafePharm Laboratories Ltd (1996c)

Oxidizing Properties Non-oxidising

Method	EC Directive 92/69/EEC A.17 Oxidizing Properties (Solids).
Remarks	Vanlube 887 has been determined not to have oxidising properties as the test material/cellulose mixture failed to propagate combustion at a rate greater than or equal to that of the barium nitrate/cellulose mixures.
Test Facility	SafePharm Laboratories Ltd (1996c)

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