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March 2010

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Chemical in Vanlube 289

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 chemical were carried out by NICNAS.

Chemical in Vanlube 289

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Ciba (Australia) Pty Ltd (ABN 97 005 061 469)
Level 12, 28 Freshwater Place
Southbank VIC 3006

NOTIFICATION CATEGORY
Standard: Chemical other than polymer (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical Name, CAS Number, Molecular Formula, Structural Formula, Molecular Weight, Spectral Data, Purity, Identity and Weight of Impurities and Additives/Adjuvants, Import Volumes, Identitiy of Manufacturer, 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
Canada (2008), UK (2008)
USA, China, Korea, Japan (in progress)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Vanlube 289 (product containing the notified chemical)

OTHER NAME(S)
Amide-borate complex

MOLECULAR WEIGHT
< 700 Da

ANALYTICAL DATA
Reference NMR, IR, HPLC and UV spectra were provided.

3. COMPOSITION

DEGREE OF PURITY 45-60%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: clear gold to amber liquid

Property	Value	Data Source/Justification
Melting Point	-24.3°C	Measured
Boiling Point	> 350°C	Measured
Density	985 kg/m^3 at 20°C	Measured
Vapour Pressure	1.96-14.0 × 10^{-10} kPa at 25°C	Calculated based on representative structures
Water Solubility	< 10.9 mg/L	Estimated. For more information, refer to the Discussion of Properties following this table.
Hydrolysis as a Function of pH	Not determined	Measurement impossible. For more information, refer to Discussion of Properties following this table.
Partition Coefficient (n-octanol/water)	log P_{OW} > 4.69	Estimated based on the solubilities in water and n-octanol.
Adsorption/Desorption	Log K_{OC} < 1.25 to 3.8 with the main peak: Log K_{OC} = 2.1	Measured. For more information, refer to the Discussion of Properties following this table.
Dissociation Constant	Not determined	The components of the notified chemical are not expected to be ionised in the environmental pH range of 4-9.
Particle Size	Not determined	Liquid
Flash Point	175.2°C at 101.3kPa	Measured (closed cup)
Flammability	Not determined	Not considered to be flammable.
Autoignition Temperature	375°C	Measured
Explosive Properties	Not expected to be explosive	The structural formula contains no explosophores.
Oxidising Properties	Not oxidising	Based on structure

DISCUSSION OF PROPERTIES

The experimental water solubility of the notified chemical (present in Vanlube 289) was determined to be < 10.9 µg/ml (10.9 mg/L) using OECD TG 105. The results were based on visual inspection. The test substance forms persistent emulsions in water.

The notified chemical has very low water solubility so that the hydrolysis test is not feasible. In addition, the notified chemical is a mixture of several components, and it is therefore practically impossible to identify the individual and the degradation products.

The notifier submitted experimental data for the log K_{OC} ranging between < 1.25 and 3.8 with the main peak indicating a log KOC of 2.1 (K_{OC} = 132). This indicates that the chemical will be moderately to strongly adsorbed to organic carbon in soil and sediments.

Reactivity

The substance is stable under normal conditions.

5. INTRODUCTION AND USE INFORMATION

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

Vanlube 289 containing the notified chemical at up to 60% will be imported into Australia by sea.

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

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

PORT OF ENTRY

Melbourne

TRANSPORTATION AND PACKAGING
Vanlube 289 containing the notified chemical will be imported by sea in containers (0.9 L, 3.8 L & 18.9 L), drums (208 L), and in intermediate bulk containers (IBCs) (1040 L & 1250 L), and will be initially stored at the 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 primarily as an antiwear additive for engine oils and general purpose lubricants at < 1%.

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 (at up to 60%) of the product Vanlube 289 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 will be pumped from the containers in which they are imported, to a closed system blend tank. Typically, base oils and other additives, will be pumped to the tank and after slow mixing, the final lubricants will be 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	30-60
Blending operators	10-20	2	50-100
Quality technicians	10-20	1	50-100
Packaging workers	10-20	2	50-100
End use of lubricants	> 100	1	100-200
End use of greases	> 100	2	10-20

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 (< 1%) 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
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 (< 1%) 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 occur.

6.2. Human health effects assessment

6.2.1. Toxicology studies on the notified chemical
The results from toxicological investigations conducted on Vanlube 289 (containing 45-60% notified chemical) are summarised in the table below.

Endpoint	Result and Assessment Conclusion
Rat, acute oral toxicity	LD50 > 2000 mg/kg bw, low toxicity
Rat, acute dermal toxicity	LD50 > 2000 mg/kg bw, low toxicity
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Mouse, skin sensitisation – local lymph node assay	no evidence of sensitisation (up to 5% concentration)
Rat, repeat dose oral toxicity–28 days	NOEL = 200 mg/kg bw/day
Mutagenicity–bacterial reverse mutation	non mutagenic
Genotoxicity–in vitro chromosomal aberration test in Chinese Hamster Ovary V79 cells	weakly clastogenic
Genotoxicity–in vivo mouse bone marrow micronucleus test	non mutagenic/none clastogenic

6.2.2. Summaries of the toxicology studies

Acute Toxicity:

An acute oral toxicity study was performed using three HanRcc:WIST(SPF) rats. The rats were dosed once only at 2000 mg/kg bw by oral gavage. There were no mortalities during the 14-day observation period. Clinical signs included hunched posture in all animals at 3 hours post-dosing, which persisted in three animals until the 5-hour reading. The bodyweights of the animals were within the range commonly recorded for this strain and age. No macroscopic findings were recorded at necropsy. After a single oral administration of the test article to female rats, the LD50 was found to be > 2000 mg/kg bw indicating low acute oral toxicity.

An acute dermal toxicity study was performed using HanRcc:WIST(SPF) rats (5/sex) using the test substance at a dose of 2000 mg/kg bw. The test substance was applied to the shaved backs of the animals and covered by a semi-occlusive patch for a period of 24 hours. There were no mortalities. Slight erythema was observed in all animals on day 2 and persisted in three males and three females until day 3, days 4-7, respectively. Scaling was noted in three females on day 4 and persisted in two animals until day 7, and in three males from days 4-7, persisting in two animals until day 10 and 11, respectively. Slight crusts were noted in one animal between days 8-10. The bodyweight of the animals was within the range commonly recorded for this strain and age. No macroscopic findings were observed at necropsy. It was concluded that the notified chemical has low acute dermal toxicity in rats (LD50 > 2000 mg/kg bw).

Primary Irritation:

A primary skin irritation study in New Zealand White rabbits was performed using two females and one male. Four days before treatment, the left flank was clipped, exposing an approximately 10 cm × 10 cm area. The undiluted test article (0.5 ml) was placed on a surgical gauze patch and applied to the intact skin of the clipped area. The patch was covered with a semi-occlusive dressing for a period of four hours. No clinical signs of systemic toxicity were observed in the animals during the study and no mortality occurred. The mean score for irritation was calculated across three scoring times (24, 48 and 72 hours after patch removal) for each animal for erythema/eschar grades and for oedema grades, separately. The mean erythema/eschar score (the skin reaction was assessed according to numerical scoring system listed in the Commission Directive 2004/73 EC) of the three animals were 1.33, 1.00, and 1.00, respectively and the mean oedema score was 0.33 for each of the three animals. Very slight to well-defined erythema was present in all of the animals at the 1-hour observation period, and persisted in two animals until the 72-hour observation period, and in one animal until day 7. Very slight oedema was noted in two animals at the 1-hour observation and in three animals at the 24-hour observation. In addition, scaling was present in one animal from 72 hours to 10 days post-treatment. No abnormal findings were observed on the treated skin of any animal 14 days post-treatment. No corrosive effects were seen. The bodyweights of all rabbits were considered to be within the normal range of variability. The PII was found to be 1.58 which indicates that the notified chemical is slightly irritating to rabbit skin.

An acute eye irritation assay was performed using New Zealand White rabbits with the application of 0.1 ml of the test substance into the left conjunctival sac of one male and two female rabbits. The right eye of each animal served as the control. The treated eyes were not rinsed after instillation. No clinical signs of systemic toxicity were observed in the animals during the study, and no mortality occurred. The mean score was calculated across three scoring times (24, 48 and 72 hours after instillation) for each animal for corneal opacity, iris, redness and chemosis of the conjunctivae, separately. The individual mean scores for corneal opacity and iris were 0.00, 0.33 and 0.33 for reddening and 0.00 for chemosis for all animals. No abnormal findings were observed in the cornea or iris of any animals at any of the measurement intervals. Slight reddening of the conjunctivae was noted in all animals at 1-hour and persisted in two animals until 24-hours. Slight swelling of the conjunctivae was observed in all animals at 1-hour. Slight reddening of the sclerae was present at 1-hour post treatment in all animals. One animal showed a slight ocular discharge at 1-hour. No abnormal findings were observed in the treated eye of any animals at 48-hours post-treatment. No staining of the treated eyes was observed, and no corrosion of the cornea was observed. The bodyweights of all rabbits were considered to be within the normal range of variability. It was concluded that the notified chemical was slightly irritating to rabbit eyes with a maximum average score of 0.33.

Skin Sensitisation:
A skin sensitisation test was submitted using the Local Lymph Node Assay in mouse. Three groups each of four female mice were treated daily with the test substance at concentrations of 1%, 2.5% and 5% (w/v) in N, N-dimethylformamide (DMF) by a topical application of 25 µl to the dorsum of each ear lobe (left and right) for three consecutive days. A control group of four female mice was treated with the vehicle DMF only. On day 6, all mice were injected via the tail vein with 250 µl of radio-labelled thymidine (^{3}H-methyl thymidine, ^{3}HTdR) giving a total of 19.7 µCi to each mouse. Approximately five hours later, all mice were sacrificed, the draining auricular lymph nodes excised and pooled per group. There were no mortalities. Neither clinical/local signs nor other findings were observed in any animals of the control group, group 2 (1%), or group 3 (2.5%). One day after the first topical application, slight ear swelling and ear erythema were observed at both dosing sites in all mice of group 4 (5%), persisting for a total of four or three days. Individual bodyweight changes of the test animals between day 1 and day 6 were comparable to those observed in the corresponding control group animals over the same period. A test substance is considered a sensitiser in the LLNA if the exposure to one or more test concentrations results in 3-fold or greater increase in incorporation of ^{3}HTdR compared with concurrent controls, as indicated by the Stimulation Index (SI). The SI results were 1.3, 1.2 and 1.1 for group 2, 3 and 4, respectively. No positive dose-response was observed. The sensitivity and reliability of the assay was assessed in a separate experiment using a known skin sensitiser in CBA/Ca mice, α-hexylcinnamaldehyde (α-HCA). SI values of 2.4, 2.5 and 9.0 were determined with α –HCA at concentrations of 5%, 10% and 25%, respectively, in acetone:olive oil, 4:1 (v/v), and an EC3 value of 11.2% was derived. Calculation of the EC3 value for the test substance was not performed as no test concentrations produced a SI ≥ 3. Based on the test results, the test substance is not a sensitiser when tested up to the concentration of 5% (w/v) in DMF.

Repeat Dose Toxicity:
A sub-chronic 28-day repeated dose toxicity study was performed in Wistar rats (5/sex/dose, 10/sex/dose for control and high dose groups) at doses of 0, 50, 200 and 1000 mg/kg bw/day by oral gavage. A control group was treated similarly with the vehicle, PEG 300, only. Five animals per sex in the control and high dose groups were allowed to recover for 14 days prior to necropsy. There were no mortalities. No test item-related clinical signs were noted during the treatment period and no late effects were noted during the recovery period. No test-substance related clinical signs were noted during the detailed clinical observations performed during the treatment period (weeks 1-3). No test substance-related clinical signs were noted during the functional observational battery performed during the treatment period (week 4), and no test substance-related effects upon mean fore- or hind-limb grip strength or locomotor activity were noted at any dose level.

The mean daily food consumption of the test substance-treated animals was generally similar to that of the controls during the treatment and recovery periods, and no test substance-related changes were noted in the mean bodyweights or mean bodyweight gain were seen.

Haematology changes included test substance-related changes noted in rats treated with 1000 mg/kg bw/day. In males, a significantly reduced mean cell haemoglobin concentration ($p < 0.05$) was noted, and in females, a significantly reduced hematocrit ($p < 0.01$) was noted after 4 weeks. After 4 weeks, in both males and females at 1000 mg/kg bw/day, clinical biochemistry changes included elevated protein and elevated albumin (both $p < 0.01$) which exceeded the ranges of the historical control data.

Test substance-related changes in organ weights were noted in the livers of males and females and kidneys of males treated with 1000 mg/kg bw/day. Slightly elevated mean absolute and relative liver and/or kidney weights were considered to potentially be indications of metabolic adaptation. No test substance-related changes in the organ weights were noted after the recovery period.

No macroscopic changes were noted. Microscopic findings showed that the livers of five males and three females treated with 1000 mg/kg bw/day displayed an increased incidence of minimal to slight hepatocellular hypertrophy. In addition the kidneys of five males and one female treated with 1000 mg/kg bw/day showed minimal to moderate tubular cell swelling, however this finding was not seen in rats sacrificed after the recovery period.

Test substance-related findings were confined to slight differences in haematology and clinical biochemistry parameters in rats treated with 1000 mg/kg bw/day. The histopathological changes in livers and kidneys correlated with the organ weights and ratios that were recorded in the animals treated for 4 weeks. Similar changes were not seen after recovery. Based on the results of the study, the NOEL was established at 200 mg/kg bw/day, with the only potentially significant finding being the noted histopathology in the kidneys in the high dose group.

Genotoxicity:
A bacterial reverse mutation assay was performed using the Salmonella typhimurium strains TA98, TA100, TA1535, TA1537 and Escherichia coli strain WPuvrA. The bacteria were exposed to a concentration range of 3-5000 µg/plate in both the presence and absence of metabolic activation for 48 hours using the plate incorporation method. Appropriate reference mutagens were used as positive controls and a distinct increase of induced revertant colonies in both the presence and absence of metabolic activation was observed. No substantial increase in revertant colony numbers of any of the five tester strains was observed following treatment with the test substance at any dose level, neither in the presence nor absence of metabolic activation. It was concluded that under the conditions of the experiment, the test substance did not induce either gene mutations by base pair changes or frameshifts in Salmonella typhimurium strains TA98, TA100, TA1535, TA1537 or Escherichia coli strain WPuvrA in both the presence and absence of metabolic activation.

A chromosomal aberration assay was performed using Chinese Hamster Ovary V79 cells in both the presence and absence of metabolic activation in three independent experiments, IA, IB, and II. Doses were chosen based on a preliminary cytotoxicity study. In the absence of S9, in experiments IA, IB, and II, at preparation interval 18 hrs, cytotoxicity was observed at the highest evaluated concentrations. In experiment IA, in the presence of S9 at preparation interval 18 hrs and in experiment II, in the absence of S9 at preparation interval 28 hrs, concentrations showing clear cytotoxity were not scorable for cytogenetic damage. In experiment IA, in the absence of S9, a statistically significant increase in the number of aberrant cells, excluding gaps (6.5%) was observed at the highest scored concentration. In a repeat experiment (IB), the observations found in IA in the absence of S9 could not be confirmed. Therefore, it was concluded that they were biologically irrelevant. In the presence of S9, at the highest scored concentration, 4.8% aberrant cells, excluding gaps were observed. Although this value exceeded the laboratory's historical control range (0.0-4.0% aberrant cells, exclusive of gaps), it was not statistically significant compared to the corresponding control (3.0%) and was considered biologically irrelevant.

In Experiment II, in the absence of S9, no clastogenicity was observed up to the highest scorable concentration. In the presence of S9, the values of the two highest scored concentrations were increased in both in a statistically significant and biologically significant manner, however the evidence for clastogenic potential may be considered equivocal due to cell toxicity and the presence of precipitation.

In Experiment IA, the number of endomitotic cells, in both the presence and absence of S9, and polyploidy cells, in the presence of S9, was statistically significantly increased. In the repeat experiment, IB, in the absence of S9, the observations could not be confirmed and were considered biologically irrelevant. In all other experimental parts, no relevant increase in the frequencies of polyploidy metaphases was found after treatment with the test substance as compared to the frequencies of the controls. Appropriate mutagens were used as positive controls which induced statistically significant increases ($p < 0.05\%$) in cells with structural chromosome aberrations. Based on the equivocal results, the notified chemical is considered to be weakly clastogenic in the chromosome aberration test in the presence of S9.

An in vivo micro nucleus assay was performed with the test substance to determine mutagenic potential. NMRI mice were administered the test substance once intraperitoneally at doses of 250, 500 or 1000 mg/kg bw. Five animals per sex from each dose group were sacrifice 24 hours post-exposure and an additional five animals per sex from the high dose group were sacrificed 48 hours post-exposure. Clinical signs during treatment included reduction of spontaneous activity (all doses), abdominal position (mid and high dose group), eyelid closure (all doses), ruffled fur (all doses) and at the highest dose, death (1 male at 48 hrs). The mean number of polychromatic erythrocytes was slightly decreased after treatment as compared to the mean value of PCEs in the negative control indicating that the test substance had cytotoxic properties in the bone marrow. In comparison to the corresponding vehicle controls there was no statistically significant or biologically relevant enhancement in the frequency of the detected micronuclei at any preparation interval and dose level of test substance. The mean values of micronuclei observed after treatment with the test article were near to the value of the vehicle control

group and within the historical control range. The positive control substance (CPA: 40 mg/kg bw) induced clear increases in the frequency of micronucleated polychromatic erythrocytes, confirming the sensitivity of the test system to a known clastogen. In conclusion, the test substance did not produce any toxicologically significant increases in the frequency of micronucleated polychromatic erythrocytes at doses up to 1000 mg/kg bw, following 24 or 48 hours exposure, therefore the notified chemical was not clastogenic under the conditions of this in vivo test.

6.2.3. Summary of human health effects

Toxicokinetics
As the notified chemical is highly lipophilic (log P_{OW} > 4.69) uptake into the stratum corneum is likely. Given the relatively low molecular weight (< 700 Da) and slight water solubility there is also potential for transfer to epidermis. Hence there is some potential for dermal absorption of the notified chemical. Based on a log P_{OW} higher than 4.69, it is likely the notified chemical will distribute into the cells, and particularly in fatty tissues.

Acute toxicity
The notified chemical is expected to have a low acute oral and dermal toxicity based on studies conducted in rats (LD50 > 2000 mg/kg bw).

Irritation and Sensitisation
The notified chemical is expected to be a slight skin and eye irritant based on studies conducted in rabbits. The notified chemical is not expected to be a sensitiser up to 5% concentration based on the results of a Local Lymph Node Assay in mice.

Repeated Dose Toxicity
A NOEL of 200 mg/kg bw/day was established for the test substance containing 45-60% notified chemical in a 28-day repeated dose oral toxicity test in rats based on statistically significant haematological effects seen at 1000 mg/kg bw/day.

Mutagenicity
The notified chemical was not mutagenic in the Ames test both in the presence and absence of metabolic activation, but was weakly clastogenic in the Chromosome Aberration Assay in the presence of S9. In the *in vivo* micronucleus assay, the notified chemical was not mutagenic, or clastogenic.

Health hazard classification
Based on the available data the notified chemical is not classified as hazardous according to 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 expected to be genotoxic. It is expected to be slightly irritating to the skin and eyes.

There is potential for dermal and ocular exposure to the notified chemical at concentrations up to 60% during importation, loading/unloading, transfer and formulation, and concentrations up to 1% during sampling and analysis, packaging, transportation and use of the finished end-use products (engine oils, hydraulic fluids or gear oils, greases).

Workers handling the notified chemical as introduced and during formulation with the notified chemical at concentrations up to 60% will be most at risk of slight skin and eye irritation. However, the expected use of PPE (gloves, safety glasses and overalls) and engineering controls (largely automated and enclosed systems) should minimise this risk. Inhalation exposure may occur if mists are generated during formulation processes. 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.
Overall, 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 risk to workers from use of the notified chemical is not considered unacceptable.

6.3.2. Public health

Given the notified chemical is only expected to pose slight skin and eye irritation and the public will only be exposed to low concentrations (< 1%), the risk to public health from use of the notified chemical is not considered unacceptable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical will be manufactured and blended overseas into additive packages, and will be imported into Australia in drums and isotainers for use in engine oils and lubricants. Further blending with other ingredients may be required at customer's blending facilities. At the blending facilities (if it is applicable), release during the highly automated blending process is not expected. The equipment used will typically be cleaned with oil, with these washings used in the formulation of the next batch or another oil blend. In these situations release would occur through accidental spills, which would be recycled or collected for proper disposal which will most likely be landfill. Any of the notified chemical remaining in the import containers, expected to be < 1% of the contents, would be washed out and recycled or collected for proper disposal which will most likely be landfill.

RELEASE OF CHEMICAL FROM USE

The notified chemical will be primarily used as an antiwear additive for engine oils and general purpose lubricants. The following summary regarding the potential releases is based on usage in automotive engine oil, which represents the greatest potential for environment exposure among the common industrial application areas for engine oils and lubricants. Any industrial applications other than automotive engine oil will be carried out by professional operators, and therefore, no significant release of the notified chemical to the environment is expected.

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, no significant release of the notified chemical should result from these professional activities. The remaining 14% of oil is removed by "do-it-yourself" (DIY) enthusiasts.

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% of the imported quantity), 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%). Therefore, assuming for the worst case that 100% of the notified chemical will be used for automotive engine oils only, about 0.7% of the total import volume of the notified chemical could potentially enter the aquatic environment through inappropriate disposal into the stormwater system.

Release to air is not expected due to the low vapour pressure of the substance. Release of residues in containers to water is not expected - drums will be reconditioned by commercial operators who do not release to water; totes will be reclaimed, returned and refilled. Small plastic pails or drums may end up in a landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

Iso-containers and drums should be sent for cleaning and reconditioning by a licensed company. The resultant washings from such companies are typically passed to an on-site waste treatment facility and any waste sludge may be sent to landfill.

Used oil drained from crankcases at specialised automotive service centres is expected to be disposed of to oil recycling centres.

7.1.2 Environmental fate

The notifier submitted biodegradability test for the notified chemical using OECD TG 301F "Ready Biodegradability; Maniometric Respirametry Test" in accordance with GLP. The test material Vanlube 289 attained 81% degradation after 28 days, indicating that the notified chemical can biodegrade quickly.

Most of the notified chemical will be thermally decomposed during usage in engine oils or through re-use as an energy source into water and oxides of carbon, boron and nitrogen. No data for bioaccumulation is available for the notified chemical. The molecular weight and the estimated log P_{OW} of > 4.69 indicate that the notified chemical has some potential for bioaccumulation. However, the ready biodegradation test shows that the notified chemical can biodegrade quickly and there is limited potential for aquatic exposure based on the current use pattern. Therefore, the risk of bioaccumulation in aquatic organisms is not considered high.

7.1.3 Predicted Environmental Concentration (PEC)

A worst case PEC can be calculated if it is assumed that 0.7% of the notified chemical (maximum 35 kg/year) is released into stormwater drains in a single metropolitan area with a geographical footprint of 500 km^2 and an average annual rainfall of 500 mm, all of which drains to stormwater. With a maximum annual release into this localised stormwater system of 35 kg and the annual volume of water drained from this region estimated to be approximately 250 x 10^6 m^3, the resultant PEC is approximately 0.14 µg/L. It should be stressed that this result reflects a worst case scenario, as in reality releases of the notified chemical would be more diffuse and at lower levels.

7.2. Environmental effects assessment

The results from ecotoxicological investigations conducted on Vanlube 289 (containing 45-60% the notified chemical) are summarised in the table below. Details for the study for the inhibition of microbial activity can be found in Appendix C.

Endpoint	*Result*	*Test Method*	*Assessment Conclusion*
Fish Toxicity (Zebra fish)	96h-LL_{50} = 42mg/L* NOEL = 10 mg/L*	OECD TG 203	Acutely harmful to fish
Daphnia Toxicity (*Daphnia magna*)	48h-EL_{50} = 56 mg/L* 24h-ELC_{50} = 87 mg/L*	OECD TG 202	Acutely harmful to invertebrates
Algal Toxicity (Desmodesmus subspicatus)	72h-EL_{50} > 100 mg/L* NOEL = 32 mg/L*	OECD TG 201 Growth inhibition	Not harmful to alga
Inhibition of Bacterial Respiration	IC50 > 1000 mg/L		Not harmful to sludge microorganisms

* Filtered water accommodated fractions (WAFs)

The notified chemical is considered to be acutely harmful to aquatic life.

7.2.1 Predicted No-Effect Concentration

The PNEC has been calculated using the endpoint for the most sensitive species (fish, LL50) and an assessment factor of 100 given experimental endpoints for species from three trophic levels are available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
LL50 (Fish)	42.00	mg/L
Assessment Factor	100.00	
PNEC:	420.00	µg/L

7.3. Environmental risk assessment

The risk quotient (RQ = PEC/PNEC) for aquatic exposure is calculated to be « 0.01 based on the above calculated PEC and PNEC. The RQ value of « 1 indicates that the notified chemical is not expected to pose an unacceptable risk to the aquatic environment from the proposed use in engine oils and general purpose lubricants.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

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

The environmental classification of the notified polymer using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2009) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

	Hazard category	*Hazard statement*
Environment	Acute Category 3	Harmful to aquatic life
	Chronic Category 3	Harmful to aquatic life with long lasting effects

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 PEC/PNEC ratio and 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 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).

- 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.

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

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 an antiwear additive for engine oils and general purpose lubricants, or is likely to change significantly;
  - the amount of chemical being introduced has increased from 5 tonnes per 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

Flammability Not considered to be flammable.

Method	EC Directive 92/69/EEC A.12 Flammability (Contact with Water).
Remarks	The assessment was performed based on the chemical structure and the test item properties. The appraisal of the molecular structure indicates no risk with respect to pyrophoric properties or the potential of evolving flammable gases in contact with water or humid air. It can be concluded beyond reasonable doubt that the test item does not ignite spontaneously when in contact with water or humid air.
Test Facility	RCC Ltd (2007b)

Autoignition Temperature 375°C

Method	EC Directive 92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases).
Test Facility	RCC Ltd (2007c)

Explosive Properties Not explosive

Remarks	There are no chemical groups that would imply explosive properties, therefore the result has been predicted negative.
Test Facility	RCC Ltd (2007d)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Ecotoxicological Investigations

C.1.1 Inhibition of microbial activity

TEST SUBSTANCE	Vanlube 289 (containing 45-60% the notified chemical)
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test. EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test
Inoculum	Activated sewage sludge
Exposure Period	3 hours
Concentration Range	Nominal: 1000 mg/L
Remarks – Method	A single limit test was conducted by exposing activated sewage sludge to 1000 mg/L (nominal) dispersion of the test substance for 3 hours. To prepare the test sample, the test material was directly mixed into tap water followed by ultrasonic treatment for 15 minutes and intense stirring for 24 hours at room temperature in the dark. The reference substance 3,5-dichlorophenol was tested in parallel under identical conditions at nominal concentrations of 5, 16 and 50 mg/L, and functioned as a positive control. Additionally, a control containing only tap water, synthetic wastewater and inoculum was conducted in duplicates.
RESULTS	
IC50	> 1000 mg/L
NOEC	1000 mg/L
Remarks – Results	No significant inhibitory effect on the respiration rate of activated sludge was observed after 3 hour exposure to 1000 mg/L of the test substance. The 3 h IC50 of the reference item was calculated to be 20 mg/L (95% confidence limits were not calculable), which is within the guideline recommended range of 5-30 mg/L.
CONCLUSION	The notified chemical is not considered to be harmful to sewage sludge microorganisms.
TEST FACILITY	RCC Ltd (2007e)

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