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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

OLOA 247Z

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

OLOA 247Z

1. APPLICANT

Chevron Chemical Company (A Division of Chevron Exploration Corporation) of State Bank Building, Level 22, 385 Bourke Street, Melbourne Vic 3000, has applied for the standard notification of the new chemical in OLOA 247Z.

2. IDENTITY OF THE CHEMICAL

Based on the nature of the chemical and the data provided, the notified chemical is considered to be non-hazardous. Therefore, the chemical name, CAS number, molecular formula, structural formula, molecular weight and spectral data have been exempted from publication in the Full Public Report and the Summary Report.

Other names: Long chain alkaryl sulfonic acid, calcium salt

Alkyl benzene sulfonic acid salt

Trade names: OLOA 247Z (50% notified chemical in lube oil)

Method of detection and determination: The chemical can be identified by infrared spectroscopy. The following elements and compounds can also be used to characterise the substance: sulphur, calcium, sulphated ash and basic calcium.

3. PHYSICAL AND CHEMICAL PROPERTIES

Physico-chemical data were provided for OLOA 247Z: containing 50% notified chemical; lube oil (43.8%); benzene, C_{20-24} alkyl derivatives (5%), calcium chloride (1%); calcium hydroxide (0.5%) and calcium sulfate (0.3%).

Appearance: dark brown viscous liquid

Melting Point: not applicable

Specific Gravity: 1.125 g/ml

Vapour Pressure: non-detectable at 100°C (Reid Vapour pressure)

Water Solubility: 0.05 g/L

Partition Co-efficient (n-octanol/water) log P_{ow}: >6.0

Hydrolysis: not applicable

Adsorption/Desorption: not provided

Dissociation Constant: not known

Flash Point: 160°C (typical)

Comments on physico-chemical properties:

No melting point or boiling point data were supplied. The omission of melting point data is acceptable, given that the substance is a liquid. Similarly the lack of boiling point data is accepted as the substance is a salt mixture which is likely to decompose on the application of heat prior to boiling.

The solubility data were obtained using OECD method 105, with tests not run according to GLP standards. A test report was not submitted. It is likely that the notified substance will be surface active, as it forms reverse micelles (ie. water soluble end on inside). The water solubility results should therefore be treated with caution.

Hydrolysis data were not submitted on the grounds that as a salt the substance will not hydrolyse in water. Examination of the provided structures of the various components reveal no readily hydrolysable groups, therefore omission of this data is acceptable.

A test report was not submitted for partition co-efficient results. The test was apparently made using HPLC procedures, as described in Chromatographica (1989) Volume 27 : 118-122, and was not conducted according to GLP standards. Again, the tendency of this surface active substance to form micelles will affect the validity of partition coefficient test result.

The omission of adsorption/desorption data were justified by the notifier on the grounds that due to the low water solubility, OLOA 247Z will tend to partition from water to solids or organic matter. This is acceptable, although on grounds of the surface activity and micelle formation, rather than low solubility.

4. PURITY OF THE CHEMICAL

The notified chemical contains no hazardous impurities at levels necessary to classify it as as a hazardous substance (1). Therefore, information on the purity of the polymer has been exempted from publication in the Full Public Report and the Summary Report.

5. INDUSTRIAL USE

OLOA 247Z is a detergent that is used in automotive and industrial oils.

OLOA 247Z will be manufacted in France and the USA. It will be imported into Australia as a component of lubricating oil additives (typically 5-10%). These additive packages will be blended in Australia with petroleum lubricating oil base stocks to produce crankcase engine oils for passenger cars, heavy duty diesel trucks and marine diesel engines. The final engine oils will contain 0.25 to 0.5% of notified chemical. Approximatey 20-30% of the finished oils will be sold to firms requiring bulk transport in trucks (likely users are trucking fleets and owners of large ocean going diesel powered vessels). The remaining product will be sold pre-packaged to lubrication outlets, truck stops, hardware and large chains of stores.

Approximately 40 tonnes of OLOA 247Z (20 tonnes of notified chemical) will be imported per annum for the first five years.

6. OCCUPATIONAL EXPOSURE

Approximately 5 lubricant additive packages containing 5-10% OLOA 247Z will be imported into Australia. The additive package will be unloaded into bulk storage tanks or tank trucks or drums. Smaller volumes will be shipped in drums. Additive packages will be transported from the marine storage terminal via tank trucks or drums to approximately 4 customers.

At a typical customer site, the additive package will be transferred to a storage tank via a 10 cm hose. The procedure will involve one worker to couple the hose end to the tank truck and one worker to uncouple it when the transfer is complete. Workers are expected to take 10 mins for each of these tasks and will wear gloves, coveralls and eye protection during to minimise exposure. Spillages during the transfer will be minimised by the use of special air back flush systems.

From the storage tanks, additive package, along with lubricating oil blend stocks and other ingredients, will be pumped into a blending tank. This process is conducted by computer controlled valves and no worker exposure is expected during the transfer or the blending process. Worker exposure will, however, be possible during sampling and analysis procedures. Approximately 2 workers will sample from the blending vessel and 1-2 personnel will conduct the laboratory analysis. During sampling, workers will be required to wear gloves, coveralls and eye protection. Exposure of laboratory personnel should be low as the analysis is expected to take only a few minutes and the sample volumes are expected to be small.

Blended fuel additives will be packaged into 1 or 4 L jugs, 200 L drums or bulk tank trucks. Worker exposure should be minimal during the packaging into jugs as the packaging line is highly automated. The drumming fascility is not as automated. Operators will be required to check, from a distance of ~3 m, that the drum filling mechanism properly enters the drums. After filling the drums, bungs and labels will be attached by the operators. Worker exposure during the loading of bulk lubricant in bulk tank trucks, will depend on the type of delivery system employed by the customer. The bulk lubricant loading will involve the connection of 10 cm line to the truck, and disconnection from the filled tank. Each of these procedures should take only a few minutes and exposure will be reduced by the wearing of personal protective equipment. If closed delivery systems are used, exposure should be minimal. An estimated 20-30 personnel Australia-wide will be involved in the transportation and drumming of finished lubricant containing OLOA 247Z.

The finished lubricant will be sold to trucking fleets and owners of large ocean going diesel vessels (20-30%), as well as through retail outlets (70-80%). The lubricant will be used during oil changes or as makeup add oil. Mechanics may be exposed to the notified chemical during servicing. However, vehicles in large fleets will typically be serviced by pheumatic delivery systems. Operators of these delivery systems (1 or 2) will wear gloves and overalls during the servicing.

7. PUBLIC EXPOSURE

Imported additives containing the notified chemical will be transported by road tanker to about 4 blending plants, where blending will be performed in closed tanks. The tanks will be later cleaned with lube oil which will either be recycled into future blends or incinerated. The public is not expected to be exposed to the notified chemical during these operations.

The public may be exposed to the notified chemical when changing engine oils.

8. ENVIRONMENTAL EXPOSURE

. Release

· Formulation and handling

At the customer sites there is the potential for spills to occur during the transfer of additive packages to the storage tanks. Such spills will be minimised by the use of air back flush systems, and are expected to be minor. The hose end is kept in an oily drain when not in use. The contents of the drain are to be sent periodically to an incinerator or sold to used oil recyclers. No estimates of the amounts of waste have been supplied.

The tank trucks are generally steam cleaned with waste water being passed to on-site waste water treatment plants which are said to include an API separator and biological oxidation features, induced air flotation and sand filtration. Water thus cleaned is then sent to sewers. The hydrocarbon fraction reclaimed by these procedures will again be sent to an incinerator or sold to used oil recyclers.

Lubricating oil stocks and the additive packages are blended together when they are pumped from their respective storage tanks through computer controlled valves into a blending tank, where blending takes place at about 140^{o}C. Various other additives (such as viscosity index improvers, pour point depressants and foam inhibitors) are also added to meet various specifications (according to the desired final product). There is the potential for release to occur when these blends are sampled for analysis, but again such release would be expected to be minor, and would be contained by bunding. Blending equipment is cleaned with lube oil, which is recycled to future blends.

The drumming off procedures are automated, and checks are made to prevent spills. Packing lines are cleaned with lube oil that is recycled into future batches or incinerated. Truck bulk loading procedures follow similar methods to unloading, in that delivery lines are again attached to oily drains when not in use. Again, there is potential for spillage to occur during loading.

The notifier estimates that approximately 3 kg/day of the additive packages may be released as a result of analyses sampling and cleaning of equipment. As it is estimated that the notified substance will be used on 220 days per year, a maximum of 660 kg per year will be released. Although the company has stated that these releases will be treated as waste water, it is reasonable to assume that most will eventually pass to sewers. Taken over an entire year, approximately 1.8 kg per day will be discharged to waterways.

· Use

Lubricant will be added to engines during oil changes, or to “top-up” crankcase oil. In the case of fleet operators, pneumatic delivery systems are said to be used to service vehicles. Used oils in these cases is sent to oil recyclers. Drums at fleet operation sites are also cleaned before being sent to recyclers (although the methods used, and amounts of wastes generated have not been included in the submission). Individual car owners, and truck owners doing their own oil changes are believed to be the main source of release of the oil and additives. Some of these people may utilise oil recycling facilities, but waste oils may also be incinerated, used in dust suppression or landfarming, dumped to landfill, or dumped in other areas such as onto soils, fencing or down drains (2).

. Fate

The environmental fate of the notified substance will be closely aligned with the environmental fate of the used engine oil.

Around 40% of engine oil sold within Australia is consumed by burning during use or lost from engine leaks. Much of the oil sold is bought either by industry, garages or other service centres, where used oils are collected and/or disposed of correctly. ANZEC (2) reported that in Australia, 96% of the waste engine oil is either used as a fuel or incinerated, with very little being recycled. Use of waste oils as a means of dust suppressant is currently being phased out (2).

Approximately 7% of the market for oils in Australia is used by the DIY market, with 83% approximately of that being used for oil changes in motors. In 1990, only 12.5% of these sales were recovered for recycling or disposal, with the remainder being disposed of in a variety of ways (as above). Assuming that 40% of the oil sold is consumed, and only 12.5% is collected, approximately 55% of oils sold may enter the environment in a variety of ways (mostly through sewers or from landfill sites where used oil in containers is often dumped).

The notified substance is moderately soluble, but has a relatively high log Kow value (> 6.0). The formation of reverse micelles by the substance should ensure that it is surface active. Hydrolysis is not expected. Although adsorption/desorption data were not supplied, the substance is not expected to leach easily from landfill sites. Behaviour in waterways is more difficult to predict, due to lack of data, and the substance may be expected to spread through waterways.

· Biodegradation

Ready biodegradability of AS 702 (chemistry described in Section 9) was conducted following the closed bottle test procedures outlined by the OECD Guideline 301D, EEC directive 79/831 and EEC Directive 67/548 Annex V C.6 as published in 84/449/EEC.

Over 28 days, and at 20 ± 1^{o}C, the test substance at a concentration of 2 mg/L showed only 8% biodegradation. The reference substances sodium benzoate and aniline attained 97 and 61% degradation, respectively, over the same test period. Thus, the degree of inherent biodegradation is unclear from the data supplied.

· Bioaccumulation

No bioaccumulation tests were conducted. Given the high partition co-efficient of the notified substance and its low biodegradation potential, the notified substance would have the potential to bioaccumulate should the substance be spilt to waterways or onto soils. However, the proposed method of use of the substance, resulting in minor amounts released in a dispersed manner should prevent bioaccumulation occurring to any great degree.

9. EVALUATION OF TOXICOLOGICAL DATA

Skin irritation and skin sensitisation data were provided for OLOA 247Z. All other toxicological data were provided for AS 702 calcium sulfonate, OLOA 247E, OLOA 246B and OLOA 246S, all of which contain complex mixtures similar to the notified chemical.

AS 702 calcium sulfonate

AS 702 calcium sulfonate contains a complex mixture of calcium salts of:

mono C_{20-24} derivatives of benzenesulfonic acid } major
mono C_{20-24} derivatives and mono C_{4-9} alkyl derivatives of benzenesulfonic acid } major products
di C_{20-24} derivatives of benzenesulfonic acid } minor
di C_{20-24} derivatives and mono C_{4-9} alkyl derivatives of benzenesulfonic acid } minor products

plus a mixture of various calcium salt cross products.

This complex mixture forms 50% of the test substances. Other components of the test substance include: lube oil (44.2%); benzene, C_{20-24} alkyl derivatives and C_{4-9} alkyl derivatives and benzene, C_{20-24} derivatives (4%); calcium chloride (1%); calcium hydroxide (0.5%) and calcium sulfate (0.3%).

OLOA 247E

OLOA 247E contains a complex mixture of sulfonic acid, petroleum, calcium salts, overbased (CAS No: 68783-96-0) plus calcium carbonate. This complex mixture forms 45% of the test substances. Other components of the test substance include: lube oil (53.3%); calcium chloride (0.6%); calcium hydroxide (0.8%) and calcium sulfate (0.3%).

OLOA 246B

OLOA 246B contains a complex mixture of sulfonic acid, petroleum, calcium salts, overbased (CAS No: 68783-96-0). This complex mixture forms 50% of the test substances. Other components of the test substance include: lube oil (47.2%); calcium chloride (1%); calcium hydroxide (0.5%) and calcium sulfate (0.3%).

OLOA 246S

OLOA 246S contains a complex mixture of benzene sulfonic acid, C_{20-24} alkyl derivatives plus benzene sulfonic acid mono C_{14-24} branched alkyl derivatives and di C_{10-14} branched alkyl derivatives, distillation residues, calcium salts. This complex mixture forms 50% of the test substances. Other components of the test substance include: lube oil (43.8%); benzene, C_{20-24} alkyl derivatives (5.0%), calcium chloride (1%); calcium hydroxide (0.5%) and calcium sulfate (0.3%).

9.1 Acute Toxicity

Table 1 Summary of the acute toxicity

Test	Test Substance	Species	Outcome	Reference
Oral	AS 702 calcium sulfonate	rat	LD_{50} > 5000 mg/kg	3,4
	OLOA 247E	rat	LD_{50} > 5000 mg/kg	5
	OLOA 246B	rat	LD_{50} > 5000 mg/kg	6
Dermal	AS 702 calcium sulfonate	rat	LD_{50} > 2000 mg/kg	7
	OLOA 247E	rabbit	LD_{50} > 2000 mg/kg	8
	OLOA 246B	rabbit	LD_{50} > 5000 mg/kg	9
Skin irritation	AS 702 calcium sulfonate	rabbit	slight to moderate irritant	10
	OLOA 247E	rabbit	non-irritant	11
	OLOA 246B	rabbit	non-irritant	12
Eye irritation	AS 702 calcium sulfonate	rabbit	non to slight irritant	13
	OLOA 247E	rabbit	slight to moderate irritant	14
	OLOA 246B	rabbit	non-irritant	15
Skin sensitisation	**OLOA 247Z**	human	non-sensitising	16
		guinea pig	sensitising	17
	OLOA 246S	guinea pig	sensitising	18

9.1.1 Oral Toxicity

Oral toxicity studies were provided for 702 calcium sulfonate, OLOA 247E and OLOA 246B. All studies were conducted in accordance with OECD guideline No: 401 (19).

AS 702 calcium sulfonate

Two acute oral toxicity studies were conducted using AS 702 calcium sulfonate. Study 1 was conducted using 2000 mg/kg of the test compound (3), study 2 with 5000 mg/kg (4).

In Study 1, undiluted AS 702 calcium sulfonate was administered intragastrically to 10 Sprague-Dawley Bkl:(SD) rats (5/sex), at a single dose of 2000 mg/kg (average dosing volume: 0.4 g). Clinical observations were made each day after dosing for 14 days. An equal number of undosed animals (controls) were observed for the same period. All animals were necropsied at the termination of the study. No mortalities occurred during the study. Mean bodyweights of the treated animals were no different from controls. No clinical signs of toxicity were observed.

The same protocol was followed in study 2, except that the dosing volumes were 1.3 g for males and 1.1 g for females. No mortalities occurred and there were no bodyweight effects. Clinical signs were observed in one treated animal only: female, day 1, diarrhoea and reduced food intake. No other signs of toxicity were reported.
The results of these studies indicate an acute oral LD_{50} of >5000 mg/kg in rats of both sexes for AS 702 calcium sulfonate.

OLOA 247E (5)

Undiluted OLOA 247E was administered intragastrically to 10 Sprague-Dawley® Crl:CD® rats (5/sex), at a single dose of 5000 mg/kg (average dosing volumes: 1.5 g for males and 1.0 g for females). Ten untreated animals (5/sex) served as controls. Clinical observations were made each day after dosing for 14 days. All animals were necropsied at the termination of the study.

There were no deaths or bodyweight effects during the study. Reduced food consumption was observed in two treated animals (male at day 2 and female at day 1). Gross pathology revealed no treatment related effects.

The results of this study indicate an acute oral LD_{50} of >5000 mg/kg in rats of both sexes for OLOA 247E.

OLOA 246B (6)

OLOA 246E in peanut oil was administered intragastrically to 10 Sprague-Dawley® Crl:CD® (CD) BR rats (5/sex), at a single dose of 5000 mg/kg (714 mg/m; 2.8 ml for males and 1.7 ml for females). Ten animals (5/sex) were given vehicle alone and served as controls. Clinical observations were made each day after dosing for 14 days. All animals were necropsied at the termination of the study.

There were no deaths, bodyweight effects or treatment-related clinical signs observed during the study. Gross pathology revealed no treatment-related effects.

The results of this study indicate an acute oral LD_{50} of >5000 mg/kg in rats of both sexes for OLOA 246B.

9.1.2 Dermal Toxicity

Dermal toxicity studies were provided for 702 calcium sulfonate, OLOA 247E and OLOA 246B. All studies were conducted in accordance with OECD guideline No: 402 (20).

AS 702 calcium sulfonate (7)

A single dose of undiluted AS 702 calcium sulfonate was applied at a conentration of 2000 mg/kg (~0.7 g for males and 0.5 g for females) to the clipped backs of 10 Sprague-Dawley Bkl:(SD) rats (5/sex) and covered with an occlusive dressing for 24 hours. An equal number control animals (5/sex) were clipped and wrapped for 24 hours without the application of test agent. Clinical observations were made daily for 14 days after treatment. All rats were sacrificed on day 14 and necropsy performed.

No deaths occurred during the observation period. The mean bodyweights of treated males were significantly lower than control males (measurements made on days 2, 7 and 14). Necropsy on sacrificed animals revealed multiple pinpoint scabs on the treated sites of 3 males and 1 female. Skin irritation was observed in all treated animals.

The results of this study indicate an acute dermal LD_{50} of >2000 kg/mg in rats of both sexes for AS 702 calcium sulfonate.

OLOA 247E (8)

A single dose of undiluted OLOA 247E was applied at a conentration of 5000 mg/kg to the clipped and abraded skin of 10 New Zealand white rabbits (5/sex) and covered with an occlusive dressing for 24 hours. At the end of the exposure period the test sites were wiped with sterile gauge. An equal number control animals (5/sex) were clipped, abraded and wrapped without the application of test agent. Clinical observations were made daily for 14 days after treatment. Treatment sites were scored for irritation on days 1, 7 and 14 after treatment. All animals were sacrificed on day 14 and necropsy performed.

No deaths occurred during the observation period. There were no treatment-related clinical signs of toxicity or bodyweights effects during the study. Necropsy on sacrificed animals revealed no treatment-related gross pathological or histopathological findings.

The study reported skin irritation in treated animals only (day 1: all animals with well-defined to moderate erythema and slight oedema; day 7: all animals with slight to moderate erythema and no to slight oedema; day 14: one animal with slight erythema and no oedema). Individual data were not provided.

The results of this study indicate an acute dermal LD_{50} of >5000 kg/mg in rabbits of both sexes for OLOA 247E.

OLOA 246B (9)

A single dose of undiluted OLOA 246B was applied at a conentration of 5000 mg/kg to the clipped (non-abraded) skin of 10 New Zealand white rabbits (5/sex) following a protocol similar to the previous study.

There were no mortalities, treatment-related clinical signs of toxicity or bodyweights effects during the study. Gross pathology showed dry and flaky skin on the treatment sites of all treated animals. Histopathology on the treated skin revealed trace (7/10) to mild (3/10) hyperkeratosis.

The study reported skin irritation in treated animals only (day 1: all animals with slight to moderate erythema and oedema; day 7: three animals with slight erythema, all animals with dry and flaky skin; day 14: all animals with dry and flaky skin). Individual data were not included in the study.

The results of this study indicate an acute dermal LD_{50} of >5000 kg/mg in rabbits of both sexes for OLOA 246B.

9.1.3 Inhalation Toxicity

Inhalation toxicity data are not required for the notified chemical as the chemical will only be available in liquid form with negligible vapour pressure.

9.1.4 Skin Irritation

Studies were provided for 702 calcium sulfonate, OLOA 247E and OLOA 246B. All studies were conducted in accordance with OECD guideline No: 404 (21).

AS 702 calcium sulfonate (10)

Undiluted AS 702 calcium sulfonate (0.5 ml) was applied by semi-occlusive application to 3 sites on the clipped dorsa of 6 New Zealand white rabbits (both sexes, numbers not specified). Four hours later the dressings were removed and the test site wiped with gause pad soaked with mineral oil. Skin reactions were assessed 1, 24, 48 and 72 hours as well as 7 and 14 days after dressing removal.

Slight to moderate erythema was observed in all animals at the 1 hour observation. By 24 hours severe erythema had developed in one of these animals. These effects remained in all animals through to 72 hours (at which stage 2 animals showed severe erythema) and to day 7 in two of these animals (slight to well-defined erythema).

Slight to well-defined oedema was present in two animals at 1 hr persisting to 72 hours in one animal. No corrosive effects were reported during the study. The results of this study indicate that AS 702 calcium sulfonate is a slight to moderate skin irritant in rabbits.

OLOA 247E (11)

In a similar method to that described above, undiluted OLOA 247E (0.5 ml) was applied to 4 sites (2 intact, 2 abraded) on the clipped dorsa of 6 New Zealand white rabbits (female) and observations made at 1, 24, 48 and 72 hours as well as 7 days.

Slight erythema was observed in 2 animals at 1 hour. At 24 hours no erythema was observed on any animal. Oedema was absent from all sites throughout the study.

The results of this study suggest OLOA 247E is not a skin irritant in rabbits.

OLOA 246B (12)

Undiluted OLOA 246B was tested using a protocol as described for OLOA 247E.

Slight erythema was observed at 1 hour through to 72 hours (2, 5, 3 and 3 animals at 1, 24, 48 and 72 hours respectively). No oedema was observed.

The results of this study suggest OLOA 246B is not a skin irritant in rabbits.

9.1.5 Eye Irritation

Studies were provided for 702 calcium sulfonate, OLOA 247E and OLOA 246B. All studies were conducted in accordance with OECD guideline No: 405 (22).

AS 702 calcium sulfonate (13)

Undiluted AS 702 calcium sulfonate (0.1 ml) was instilled in the conjuctival sac of one eye of each of 9 New Zealand white rabbits. The other eye served as the control. The eyes of 3 animals were rinsed with distilled water after 30 seconds exposure. The eyes were examined 1, 24, 48 and 72 hours after treatment.

No corneal opacity or iritis was observed during the study. Conjunctival reddness (moderate to severe in all animals), chemosis (slight in all animals) and discharge (moderate to severe in unrinsed, slight to moderate in rinsed) was present at 1 hour only. A brown stain on the fur around the eye was observed at every time point.

The results of this study suggest that AS 702 calcium sulfonate is a non- to slight eye irritant in rabbits.

OLOA 247E (14)

Undiluted OLOA 247E (0.1 ml) was instilled in the conjuctival sac of one eye of each of 9 New Zealand white rabbits. The other eye served as the control. The eyes of 3 animals were rinsed with distilled water after 30 seconds exposure. The eyes were examined 1, 24, 48, 72 and 96 hours as well as 7, 10, 14, 17 and 21 days after treatment.

No corneal opacity or iritis was observed during the study. Conjunctival reddness was observed at 1 hour (moderate to severe in unrinsed animals, severe in rinsed). These effects persisted until 24 hours in all animals (slight to severe in unrinsed and slight to moderate in rinsed) but had subsided by day 14 (unrinsed) and 17 (rinsed). Slight chemosis was present in all animals at 1 hour subsiding by 72 hours (unrinsed) and 48 (rinsed). No conjunctival discharge was observed during the study.
The results of this study suggest that OLOA 247E is a slight to moderate eye irritant in rabbits.

OLOA 246B (15)

Undiluted OLOA 246B (0.1 ml) was instilled in the conjuctival sac of one eye of each of 9 New Zealand white rabbits. The other eye served as the control. The eyes of 3 animals were rinsed with distilled water after 30 seconds exposure. The eyes were examined 1, 24, 48 and 72 hours after treatment.

No corneal opacity or iritis was observed during the study. Slight to moderate conjunctival reddness was present at 1 hour (unrinsed: 5 slight, 1 moderate: rinsed 2 slight, 1 no reaction) persisting through 24 hours (unrinsed: 3 slight; rinsed 1 slight). Conjunctival discharge was observed in 2 animals at 1 hour only (unrinsed: slight). No conjunctival chemosis was observed during the study.

The results of this study suggest that OLOA 247E is not an eye irritant in rabbits.

9.1.6 Skin Sensitisation

Skin sensitisation data were provided for OLOA 247Z (containing 50% notified chemical) and OLOA 246S.

OLOA 247Z: Repeated insult patch test (16)

Induction

Undiluted OLOA 247Z was applied topically to 109 human subjects three times a week for a period of 3 weeks. Application sites (infrascapular area of the back) were occluded for 24 hours. Skin reactions were evaluated 24 hours after patch removal. Applications made on Fridays were evaluated 48 hours after patch removal (ie after the weekend). At the end of the induction stage, all subjects underwent a 2 week rest period.

Challenge

Patches were applied to previously unexposed sites and occluded for 24 hours. Skin reactions were assessed 24 and 48 hours after patch removal.

Results

Four subjects exhibited barely perceptible erythema during the induction phase. No skin reactions were observed during the rest period or after challenge. The results of this study suggest that OLOA 247Z is not a skin sensitiser in humans.

OLOA 247Z: Delayed contact sensitivity study in guinea pigs (17)

Hartley albino guinea pigs, equal numbers of each sex, were used in a delayed contact hypersensitivity study using the Buehler technique. Twenty test animals and 10 control animals were utilised. The study was conducted in accordance with OECD guideline No: 406 (23)

Pretest

The test substance was tested topically in 8 animals for irritancy at concentrations ranging from 0.5 to 100 %. Dilutions were made w/v in Spectrum Mineral Oil Light. Test sites were occluded for 6 hours. Skin reactions were assessed 24 and 48 hours after treatment. Based on the irritancy results an induction dose of 100% OLOA 247Z and a challenge dose of 50% OLOA 247Z (both producing slight to well-defined irritation) were chosen for the main study.

Induction and Challenge

Test animals were treated topically once a week for three weeks with 100% OLOA 247Z. Two weeks after the last induction dose, the test and control animals were treated with 50% OLOA 247Z to previously untreated sites. All applications were made to clipped sites and occluded for 6 hours. Sensitisation reactions were assessed 24 and 48 hours after patch removal.

Results

One test animal was found dead at the 24 hour observation. The test substance caused moderate erythema (grade 2) in 4/19 of the test animals at 24 hours and 7/19 test animals at 48 hours. The control group showed slight to well-defined erythema (grades $\underline{+}$ and 1) at 24 and 48 hours. Oedema was reported in one test animals at 24 hours. The results of this study suggest that OLOA 247Z is a skin sensitiser in guinea pigs.

OLOA 246S: Delayed contact sensitivity study in guinea pigs (18)

Hartley albino guinea pigs, equal numbers of each sex, were used in a delayed contact hypersensitivity study using the Buehler technique. Twenty test animals and 10 control animals were utilised. The study was conducted in accordance with OECD guideline No: 406 (23)

Pretest

The test substance was tested topically in 8 animals for irritancy at concentrations ranging from 0.5 to 100 %. Dilutions were made w/v in Spectrum Mineral Oil Light. Test sites were occluded for 6 hours. Skin reactions were assessed 24 and 48 hours after treatment. Based on the irritancy results an induction dose of 50% OLOA 246S (mild to moderately irritating) and a challenge dose of 5% (non to slightly irritating) were chosen for the main study.

Induction and Challenge

Test animals were treated topically once a week for three weeks with 50% OLOA 246S. Two weeks after the last induction dose, the test and control animals were treated with 5% OLOA 246S to previously untreated sites. All applications were made to clipped sites and occluded for 6 hours. Sensitisation reactions were assessed 24 and 48 hours after patch removal.

Results

One test animal was found dead at the 24 hour observation. The test substance caused moderate to severe erythema (grade 2 or higher) in 14/19 of the test animals at 24 hours and 17/19 test animals at 48 hours. The control group showed well-defined erythema in 5/10 animals at 24 hours and 7/10 animals at 48 hours. Oedema was reported in five test animals at both observation times. The results of this study suggest that OLOA 246S is a skin sensitiser in guinea pigs.

9.2 Repeated Dose Toxicity

Repeated dose toxicity studies were provided for 702 calcium sulfonate and OLOA 247E.

AS 702 calcium sulfonate (24)

This study was conducted in accordance with OECD guideline No: 407 (25). AS 702 calcium sulfonate was given orally for 29 consecutive days to Sprague-Dawley rats at dose levels of 0 (control), 100 (low dose), 500 (mid dose) or 1000 (high dose) mg/kg. Six animals of each sex were used in each dose group. An additional 2 groups of animals (recovery animals) were given 0 or 1000 mg/kg of the test substance and observed for 2 weeks after treatment.

One animal (male) died on day 9 due to probable dosing error. All other animals survived to scheduled necropsy. There were no statistically significant effects on body weight during the study. No treatment-related changes in food consumption, haematology, urinalysis or pathology were observed during the study.

Animals treated with the high dose (both sexes) showed a significant decrease in serum cholesterol at the end of the treatment period. This effect persisted in females to the end of the recovery period. There were no other treatment-related effects on serum chemistry.

OLOA 247E (26)

This study was conducted in accordance with OECD guideline No: 410 (27). Groups of Sprague-Dawley rats (12/sex/dose) were given mineral oil (control), 10% OLOA 247E (low dose), 50% OLOA 247E (mid dose) or 100% OLOA 247E (high dose) topically for 6 hours/day, 5 days/week, for 4 consecutive weeks. The low and mid dose were prepared w/w in mineral oil. Dosing volumes were 1.0 ml/kg.

Skin effects were observed in treated and control animals throughout the study. The severity of the reactions was slightly greater in the treated males as compared to control males (no to well-defined erythema and no to slight erythema respectively). Treated and control females showed no to well-defined erythema. Oedema was observed on day 2 in all male groups (no to slight in controls, no to well-defined in low and mid dose, slight in high dose). Control and high dose females showed no oedema (low dose: no to slight, day 2; mid dose no to well-defined days 2 and 23). Scabs were observed in all groups from day 9. The incidence was least in the high dose animals. These results suggest that the skin reactions may be due to the mineral oil.

No deaths or clinical signs of toxicity were observed during the study. There were no significant effects on body weight, food consumption or haematology during the study. No treatment-related effects on serum chemistry or organ weights were observed. Gross pathology and histopathology revealed no treatment-related effects.

9.3 Genotoxicity

9.3.1 Salmonella typhimurium and E coli Reverse Mutation Assays

Studies were provided for 702 calcium sulfonate and OLOA 247E. Both were conducted in accordance with OECD guidelines No: 471 (28) and No: 472 (29).

AS 702 calcium sulfonate (30)

AS 702 calcium sulfonate diluted with 25% Pluronic F127 (w/w in ethanol) was tested in the *Salmonella typhimurium* test strains TA 98, TA 100, TA 1535 and TA 1537, and *Escherichia coli* strain WP2 uvrA, with or without metabolic activation. Two separate experiments were conducted, each in triplicate. The test doses were 100, 333, 1000, 3333 and 10000 µg/plate. The positive controls were 2-aminoanthracene (all strains; + S9), 2-nitrofluorene (TA 98; - S9), sodium azide (TA 100, TA 1535; - S9) and ICR-191 (TA 1537, WP2 uvrA; - S9). The negative control was 25% Pluronic F127.

Statistically significant increases in revertant colonies were seen in TA 100 in the absence of S9 (100 µg/plate: 1.2 x negative control) and in WP2 uvrA in the presence of S9 (1000 µg/plate: 1.3 x negative control; 10000 µg/plate 1.4 x negative control). These effects were not reproducable and were not dose-dependent. The positive control gave the expected results. Based on the above results AS 702 calcium sulfonate is not mutagenic.

OLOA 247E (31)

OLOA 247E was tested in the *Salmonella typhimurium* test strains TA 98, TA 100 and TA 102, and *Escherichia coli* strain WP2 uvrA, with or without metabolic activation. One experiment was conducted using 3 plates per treatment. The positive controls were 2-aminoanthracene (TA 98, TA 100, WP2 uvrA; + S9), Dantron (TA 102; + S9), 2-nitrofluorene (TA 98; - S9), sodium azide (TA 100; - S9), Mitomycin C (TA 102; - S9) and 1-ethyl 2-nitro 3-nitrosoguanidine (WP2 uvrA; - S9). The negative control was DMSO.

There were no increases in the number of histidine or tryptophan revertants with any of the test doses or the solvent control. The positive controls gave the expected increases in revertant colonies. Under the conditions of this study OLOA 247E is not mutagenic.

9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse (32)

The following study was conducted with AS 702 calcium sulfonate. The protocol was in accordance with OECD guideline No: 474 (33).

Swiss Albino Crl:LCD®-1 mice were dosed intraperitoneally with AS 702 calcium sulfonate in peanut oil at doses of 100, 200, 400 or 500 mg/kg and sacrificed 24, 48 or 72 hours later (5 mice/sex/dose/treatment time). Negative control animals were given vehicle alone. Positive control animals were given triethylenemelamine (0.25 mg/kg) and sacrificed at 24 hours only. Upon sacrifice, bone marrow cells were collected and examined for micronuclei.

One thousand polychromatic erythrocytes (PCE) were scored per animal, and the number of micronucleated PCEs recorded. The frequency of micronucleated cells was expressed per 1000 PCEs. Cytotoxic effects were described by the ratio of PCE to normochromatic erythrocytes (NCE) for each animal.

Deaths occurred in animals treated with doses of 500 mg/kg (4/15 males and 4/15 females) and 400 mg/kg (1/18 females). Clinical signs were reported as palpebral closure, decreased motor activity and weakness.

Elevated PCE/NCE ratios were observed in animals treated with 400 and 500 mg/kg AS 702 calcium sulfonate. A statistically significant increase was only seen in males treated with 500 mg/kg and sacrificed at 24 hours.

After treatment with AS 702 calcium sulfonate, there was no significant enhancement of micronuclei frequency observed at any time point. The positive control produced a significant increase in the micronuclei frequency validating the test. The results of this study indicate that AS 702 calcium sulfonate does not cause chromosomal damage *in vivo*.

9.3.3 Mouse Lymphoma Mutagenicity Test (34)

The following study was conducted with OLOA 247E in accordance with OECD guideline No: 476 (35).

OLOA 247E was tested for its potential to induce point mutations at the *Tk* locus (5-trifluorothymidine) in cultured mouse lymphoma L5178Y cells, both in the presence and absence of S9 mix prepared from Aroclor-induced rat liver. Cells were treated with 100, 1000, 1500, 2000, 4000 or 50000 µg/ml for 2 days, and then plated for determination of viability and mutant frequency. Triplicate plates were prepared for each treatment. The positive controls were 7, 12-dimethylbenzanthracene (DMBA) with S9 and ethyl methanesulfonate (EMS) without S9.

OLOA 247E produced no changes in mutation frequency in mouse lymphoma L5178Y cells under the conditions of the assay. DMBA induced clear increases in mutation frequency. The effects of EMS were not recorded. Under the experimental conditions of this test OLOA 247E showed no mutagenic activity.

9.4 Overall Assessment of Toxicological Data

Studies with formulations containing similar chemicals suggest that the notified chemical has low oral and dermal toxicity, may be a slight to moderate skin irritant and may be a slight to moderate eye irritant. Skin irritation, however, is unlikely as the notified chemical was found to be non-irritating to human skin in a repeated insult patch test.

OLOA 247Z was non-sensitising in humans but sensitising in guinea pigs. The related test substance OLOA 246S was also sensitising in guinea pigs. Based on the negative results in humans the notified chemical is not likely to be a skin sensitiser in humans.

A 28-day repeated dose study with AS 702 calcium sulfonate administered orally showed the only treatment-related effect to be decreased serum cholesterol in both male and female rats given 1000 mg/kg (500 mg/kg showed no treatment-related effects). OLOA 247E administered dermally for 28 days produced no treatment-related effects (all doses including 100%).

Based on the negative in vitro mutagenicity results in bacteria (Salmonella typhimurium and Escherichia coli: AS 702 calcium sulfonate and OLOA 247E) and in mouse lymphoma L5178Y cells (AS 702 calcium sulfonate), the notified chemical is not expected to have mutagenic activity. Based on the negative results of a mouse micronucleus assay with AS 702 calcium sulfonate, the notified chemical is unlikely to be clastogenic.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

All toxicity tests and the ready biodegradation tests were claimed to be conducted using AS 702 Calcium Sulphonate (the low overbased calcium salt of the alkylbenzene sulphonic acid that is a combination of mono- and di-C_{20-40} alkyl derivatives of benzenesulfonic acid and C_{4-9} branched and straight-chain alkyl derivatives of benzenesulfonic acid) or OLOA 247E (a mixture of high-overbased calcium sulphonates derived from sulphonation of lubricating oil containing 1% calcium and 25% calcium carbonate). The company claims that as the substance used to prepare OLOA 247Z, AS 304, is a C_{20-24} alkylbenzenesulfonic acid closely related to AS 702, similar toxicological properties can be expected in the two compounds.

The table below shows the ecotoxicological test results. Tests were carried out in accordance with US EPA GLP procedures, and according to the Guidelines shown below. Tests marked with a # were conducted using the substance AS 702 Calcium Sulphonate.

Tests not so marked were made with the substance CMA Test Material Code 504. This substance is regarded by the company to be equivalent structurally, toxicologically and in performance to OLOA 247E.

Ecotoxicity Results :

Species	Test	Guideline	Result	Ref.
Rainbow Trout, *Oncorhynchus mykiss*	Acute Toxicity, Static Renewal#	Chevron Environmental Health Centre Protocol No. 89-315, Protocol Amendments No. , and 3, 1 May, 2 August and 6 October 1989 resp.*	LC_{50} 96 hr > 1000 mg/L NOEC=1000 mg/L	36
Sheepshead Minnow[1], *Cyprinodon variegatus*	Acute Toxicity, Static Renewal	Based on OECD Guideline 203, Feb. 1986, Protocol Amendments 18 Feb. 1986. N.B. Non-standard species used	LC_{50} 96 hr - 0% at 100% WSF (ie. 10 g/ml)	37
Daphnia magna[2]	Acute Toxicity, Static Renewal, Immobilisation#	CEHC Protocol No. 89-316, Protocol Amendments No. 1-3, 1 May, 27 July and 22 August 1989	EC_{50} 48 hr = >830 mg/L ** NOEC<63 mg/L***	38
Mysid shrimp, *Mysidopsis bahia*[1]	Acute Toxicity, 96 hour Static Renewal	claimed to be OECD Guideline, but appears to be based on US EPA 540/9-85-010 SEP	96 hr mortality 0% at 100% WSF (ie 10 mg/L nominal concentration)	39
Brown Shrimp, *Crangon crangon*[3]	Acute Toxicity Tier 1 Testing, 96 hour Semi-static	Based on UK MAFF guidelines	LC_{50} 96 hr >10000 mg/L****	40

1) Test conducted using 100% water soluble fraction (WSF) at 10 $g.L^{-1}$. As 0% mortality occurred, Tier 2 testing was not conducted.

2) Many of the test organisms were caught in the test solution and/or particulate matter. Some of the test vessels were clouded.

3) A fine dispersion was observed throughout the water column of the test vessels, with most of the test material remaining on the bottom of the tanks, despite good water circulation. A foaming scum was also noticed on the surface of the water at concentrations of 500, 1000 and 10 000 $mg.L^{-1}$.

* Test Guideline is in accordance to 1985 EPA/TSCA Part 797 - Environmental Effects Testing Guidelines, subpart E - Aquatic Guidelines, Section 797.1440 Fish Acute Toxicity Test.

** estimated by non-linear interpolation (95% confidence interval calculated by binomial probability of 130-1000 $mg.L^{-1}$).

*** reported as less than the lowest level tested, ie 63 $mg.L^{-1}$. Examination of the test results presented showed no effects on test organisms at this level. Immobilisation of Daphnia was noted at concentrations of 250 $mg.L^{-1}$ and greater.

**** Although the company claims that an LC_{50} could not be calculated because there was no mortality in tests, mortalities from 5-20% did occur, in controls and all concentrations tested. Mortality increased with increasing concentrations.

These results indicate that the test materials, AL 702 and CMA Test Material Code 504 (assumed to be equivalent to OLOA 247E) are practically non-toxic to the aquatic organisms tested. As these

substance appear structurally to be very similar to the main constituents of the notified substance, the test results will be accepted in the absence of data on the notified substance.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Based on ANZEC figures (2), approximately 40% of oil products are consumed during combustion in vehicle motors (ie. 8 tonnes of the notified substance). Thus 12 tonnes will be available to enter the waste streams. Of this amount, based on the ANZEC report 96% (ie. approximately 11.5 tonnes) is likely to be correctly disposed of, going to either waste oil recylers, used as fuel, or landfilled in secure sites. The remaining approximately 0.5 tonnes may be disposed of by dumping with household garbage, buried, stored or used as weed or dust suppressants. Total daily disposal of the waste oil resulting from DIY oil changes would therefore result in an approximate maximum of 1.5 kg per day being disposed of in a highly dispersed manner.

The notifier has provided estimates of 3 kg per day as losses resulting from analysis and cleaning activities during blending processes. As it is expected that such activities will occur on a maximum of 220 days each year, a total of 660 kg per year may be released to sewers following treatment as waste water, or 1.8 kg per day.

This equates to approximately 3.5 kg per day released for a whole year for both blending processes and used oil disposal.

Given the number of people who may possibly change their engine oil in one day, and taking a worst-case of all waste oil and spills going to sewers, only a minute amount could be expected in any one area at any one time (for example if all the 3.5 kg were discharged to sewers in Sydney on one day, expected amounts released to waterways would be lower than 7 ppb). If this amount was disposed of to drains in country areas (with sewage effluent dilution of only 5 ML per day), levels would still remain below ecotoxic levels (at approximately < 1 ppm).

As levels expected to occur in waterways are far lower than toxic levels noted in the ecotoxicity data presented above, the notified substance is not expected to present a significant hazard to the environment.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

According to animal studies on related chemicals the notified chemical is expected to have low acute oral and dermal toxicity, but may be irritating to the skin and eyes. Based on a human study with the notified chemical, no skin sensitisation is expected. Genotoxicity studies showed related chemicals to be neither mutagenic nor clastogenic.

The notified chemical will be imported as an additive package and blended further into automotive engine oils. Occupational exposure will, therefore, be limited to the chemical in liquid form only. Skin and eye contact with formulations containing the notified chemical will be possible during transfer, sampling and drumming operations. Workers carrying out these activities will usually be exposed for short periods of time (~10 minutes) and will wear gloves, coveralls and eye protection. Exposure to the notified chemical via inhalation is not a concern as the chemical has a low vapour pressure. Therefore, under normal use situations the notified chemical should not pose a significant risk to workers.

The public may be exposed to the notified chemical when changing engine oils. The low concentration of the chemical and its low toxicity indicate that it will not pose a significant hazard to public health when used in the proposed manner.

13. RECOMMENDATIONS

To minimise occupational exposure to the notified chemical the following guidelines and precautions should be observed.

- If engineering controls and work practices are insufficient to reduce exposure to a safe level, the following personal protective equipment should be used:
  - chemical-type goggles conforming to Australian Standards 1336 (41) and 1337 (42);
  - impervious gloves conforming to Australian Standard 2161 (43); and
  - protective clothing conforming to Australian Standards 2919 (44).
- Good work practices should be implemented to avoid splashing and spillages.
- Spills should be cleaned up promptly.
- Good personal hygiene practices, such as washing of hands prior to eating food, should be observed.
- A copy of the Material Safety Data Sheet for products containing the notified chemical should be easily accessible to all employees.

14. MATERIAL SAFETY DATA SHEET

The attached Material Safety Data Sheet (MSDS) for OLOA 247Z was provided in Worksafe Australia format (45).

This MSDS was provided by Chevron Chemical Company as part of their notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of Chevron Chemical Company.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989*, secondary notification of the notified chemical shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

16. REFERENCES

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