File No: NA/574

November 1997

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME**

# FULL PUBLIC REPORT

**TKA 40138**

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Director
Chemicals Notification and Assessment

# FULL PUBLIC REPORT

## TKA 40138

## 1. APPLICANT

Ciba Specialty Chemicals of 235 Settlement Road THOMASTOWN VIC 3074 has submitted a standard notification statement in support of their application for an assessment certificate for TKA 40138.

## 2. IDENTITY OF THE CHEMICAL

TKA 40138 is not considered to be hazardous based on the nature of the chemical and the data provided. Therefore the chemical name, CAS number, molecular and structural formulae, molecular weight, spectral data, details of the composition and details of exact import volume and customers have been exempted from publication in the Full Public Report and the Summary Report.

**Other Names:** TKA 40138, CG 31-1017

**Trade Name:** Irganox L 160

## 3. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance at 20°C and 101.3 kPa:** colourless liquid with no odour

**Melting Point/Range:** -20 to 8°C

**Boiling Point:** decomposition ≥ 320°C

**Specific Gravity:** 1.0098 at 60°C

**Vapour Pressure:** 0.179 kPa at 25°C
0.137 kPa at 20°C

**Water Solubility:** 0.53 $mg.L^{-1}$ (Metilox, see comments below)

**Partition Co-efficient (n-octanol/water):** log $P_{ow}$ > 3.634 at 20°C (see comments below)

| | |
|---|---|
| **Hydrolysis as a Function of pH:** | $T_{1/2}$ (pH 4.0, 50°C), stable<br>$T_{1/2}$ (pH 7.0, 25°C) = 4 559 h<br>$T_{1/2}$ (pH 7.0, 50°C) = 223 h<br>$T_{1/2}$ (pH 7.0, 70°C) = 28 h<br>$T_{1/2}$ (pH 7.0, 80°C) = 10 h<br>$T_{1/2}$ (pH 9.0, 25°C) = 80 h<br>$T_{1/2}$ (pH 9.0, 35°C) = 24 h<br>$T_{1/2}$ (pH 9.0, 50°C) = 5 h |
| **Adsorption/Desorption:** | Log $K_{oc}$ = 4.95 (see comments below) |
| **Dissociation Constant:** | not available (see comments below) |
| **Flash Point:** | > 75°C |
| **Flammability Limits:** | not available |
| **Autoignition Temperature:** | 395°C |
| **Explosive Properties:** | not considered explosive |
| **Reactivity/Stability:** | not an oxidising agent |
| **Surface Activity:** | 38.8 $m.mN^{-1}$ at 21.4°C |

**Comments on Physico-Chemical Properties**

Tests were performed according to EEC/OECD test guidelines (1) at facilities complying with OECD Principles of Good Laboratory Practice.

The notifier claims that the notified chemical is composed of more than twenty components with very different properties. Therefore, there is no distinct vapour pressure, melting and boiling point, dissociation constant, partition coefficient or water solubility results for this notified chemical.

The notified chemical does not have a defined melting point. Crystallisation during cooling was observed at -20°C, while melting during heating occurred at 8°C. Vapour pressure results were calculated by extrapolation as no boiling point was observed under 400°C. Decomposition occurred at 320°C. Density was determined for 60°C. Due to the viscosity of the notified chemical, its density using an oscillating densitometer could not be determined at 20°C.

The individual components of the notified chemical have specific and mostly different water solubilities. Visual preliminary tests revealed insoluble components at nominal concentrations of 10 $mg.L^{-1}$ and higher. The main test (flask method) performed on an over-saturated solution of the notified chemical showed that only two components were soluble in water at 20°C. Component A, although not quantified, arrives at saturation at approximately 50 $g.L^{-1}$. Component B (Metilox) is soluble at 0.53 $mg.L^{-1}$.

Hydrolysis testing was performed on the UV-detectable water soluble component (component A) of the notified chemical only. The concentration of component B (Metilox) in aqueous buffer solutions was too low to be determined with the equipment used in this test (HPLC with UV detector). Component A was determined to be stable at pH 4 (less than 10% decomposition after 5 days at 50°C), and has half-lives at 25°C of 4 559 and 80 hours at pH 7 and 9, respectively. Environment Australia notes the presence of ester linkages on some of the other components, but hydrolysis in the environmental pH range would be precluded by low solubility.

The notifier supplied partition coefficient values for several typical components of the mixture, calculated using MedChem ClogP Version 2.12. Components 1 to 7 have calculated log $K_{OW}$ between 3.634 and 18.603. However, the notifier claims that log $K_{OW}$ greater than 9.413 are considered as gross estimates and unrealistic as the particular fragments could not be measured. These components are still expected to have log $K_{OW}$ greater than 6.

The adsorption/desorption was calculated using a set of suitable reference substances, for which adsorption coefficients were known, and regression lines. The adsorption coefficient of the notified chemical ($K_{OC}$ = 91 201) classifies it as “immobile” according to McCall, Laskowski and Dishburger (2).

The notifier claims that due to the composition and determined water solubilities for the various components of the notified chemical, determination of a dissociation constant is technically not possible according to OECD Test Guideline 112 (1). Further, the result would not elicit a meaningful value for scientific or environmental evaluation. It is noted that the components contain potentially dissociable, weakly acidic phenolic groups, but that these are sterically hindered by flanking t-butyl groups. Significant dissociation under environmental conditions is therefore not expected.

The notified chemical in water (90% of saturation concentration) is expected to display surface active properties. By definition, a chemical has surface activity when the surface tension is less than 60 $mN.m^{-1}$ (3).

## 5. USE, VOLUME AND FORMULATION

The notified chemical is an anti-oxidant/friction modifier additive. It is used at levels of 0.4% to 1.2% in lubricating oils to impart improved resistance to oxidation and lower friction characteristics.

The notified chemical will not be manufactured in Australia. It will be imported into Australia as Irganox L 160. Irganox L 160 containing the notified chemical (80%) and a diluent (20%), is in ready-to-sell 200 L sturdy closed head steel drums, suitable for international transport.

## 6. OCCUPATIONAL EXPOSURE

Since the notified chemical has very low vapour pressure, dermal contact would be the main route of exposure.

Irganox L 160 will be imported into Australia in 200 L fixed head steel drums. Transport and storage workers are unlikely to be exposed to the notified chemical except spillage occurs in the event of an accident. The Material Safety Data Sheet (MSDS) specifies that spilled material should be contained and taken up in a dry absorbant prior to disposal, preferably by incineration or landfill.

Formulation of the lubricants will be undertaken in Australia, initially by one customer. Potentially three or more are envisaged. Formulators will transfer the notified chemical into a blending vessel. The blended oil is discharged via a closed transfer system to package-filling machines. This will be undertaken in the plant equipped with automatic dosing facilities and local exhaust ventilation. The formulated product will contain 0.4 to 1.2% of the notified chemical. Exposure during formulation is expected to be low during the transferring process.

Engine service workers will be the main end users of the product. Possible exposure will take place during addition to the machinery, replacement of engine parts, and recycling or disposal of the product. The exposure to end users is expected to be infrequent and limited.

## 7. PUBLIC EXPOSURE

Members of the public may be exposed to the notified chemical in finished lubricating oil when inspecting or servicing engines, primarily via the dermal route. Although moderate numbers of persons could potentially be exposed, the frequency of contact would be low and the duration of contact would not be prolonged. The potential for exposure would be further reduced by the low concentration of the notified chemical in finished oils.

At the end of their working life, used oils containing the notified chemical would be recycled, burned in fuel oil or disposed of by incineration. Public exposure from these activities is not anticipated.

## 8. ENVIRONMENTAL EXPOSURE

### Release

It is claimed that residues in blending and packaging equipment will be low. Fugitive emissions during transport and blending should be negligible due to the very low vapour pressure of the chemical. Product containing the notified chemical is compatible with a wide range of lubricants, thus purging of equipment will not be necessary between product runs. Disposal of wastes from the formulation plant will be limited to residues from the cleaning cycle prior to maintenance work. This will be carried out using base oil with the majority recycled into the next product batch. No wastes will be directed to sewer from the blending and packaging operations.

The notifier claims that the notified chemical will generally displace chemicals already used in similar applications. During use, the finished lubricant oils containing the notified chemical are generally considered to be contained in the sumps of diesel and gasoline engines until the lubricant is changed. Some of the notified chemical will be combusted during use. Collected used lubricants will be either re-used, recycled, cleaned or burnt (for their fuel value). Release of the lubricants to the environment may occur due to engine leaks and during engine oil changes.

Each empty Irganox L 160 drum will be flushed with hot oil base with the rinses passed to the blending process. Drums will then be disposed of by an accredited drum reconditioner. Consumer containers with lubricant residues may be recycled. However, most of these containers will be disposed of to landfill.

### Fate

The notified chemical will be used in lubricants and will share their fate. Therefore, most spent oil will be combusted (if used for fuel value) or recycled. A minor component will be released to the environment from spills and leaks, but this would be widely dispersed. If the notified chemical was washed off road surfaces, it is expected to be adsorbed to the soil and sediments adjacent.

Collection of waste lubricants is more easily accomplished from industrial and commercial users than from the section of the community that changes its own, the do-it-yourself (D-I-Y) market (4). However, it is claimed that the D-I-Y market accounts for only 4.9% of total oil sales in Australia (14% of auto-engine oils sales), though the availability of this oil for collection is not well understood (5). This could potentially lead to a release of used oil to the environment. The 1995 survey undertaken by the Australian Institute of Petroleum determined that 56% of used oil[1] generated will be collected (6). The balance (44%) will remain uncollected, either stored, or disposed of inappropriately, eg. through burial, landfill and stormwater drains, used as fence paint or dust suppressant or to kill grass.

[1] Used oil is defined as oil contaminated through use that has the potential for collection. It is approximately 41% of total Australian lubricant sales, with the balance consumed (combusted) during use.

The notified chemical was found to be slightly biodegradable, calculated as the ratio of the amount of $CO_2$ produced to the theoretical carbon dioxide ($ThCO_2$), and then expressed as a percentage (7). However, its biodegradation was not sufficient for it to be classified as readily. biodegradable

| **Biodegradation Rate Results** | **Rate (%)** | |
|---|---|---|
| | Flask One | Flask Two |
| Notified Chemical | | |
| Degradation rate after 7 days | 5.5 | 5.9 |
| Degradation rate after 14 days | 11.9 | 10.9 |
| Degradation rate after 28 days | 12.0 | 14.2 |
| Abiotic Control[1] | | |
| Degradation rate after 7 days | 3.2 | |
| Degradation rate after 14 days | 3.2 | |
| Degradation rate after 28 days | 9.4 | |

[1] Containing the notified chemical and sterile test medium.

Biodegradation amounted to 13.1% at the end of the 28-day exposure to activated sludge from a domestic sewage treatment facility in the OECD 301B $CO_2$ Evolution (Modified Sturm Test) for ready biodegradability. Abiotic degradation of 9.4% after 28-days was noted in the abiotic control. It is claimed that no inhibitory effect on the micro-organisms was observed, which is consistent with the ecotoxicity test results (see *Environmental Effects* below). The notified chemical's inherent biodegradability was not measured.

The potential for bioaccumulation was not determined. Due to the chemical's low water solubility, partition coefficient (log $K_{OW}$ greater than 3.6) and potential high fat solubility, bioaccumulation may be perceived as an issue of concern (8). However, biological membranes are not permeable to chemicals of very large molecular size. Also, the notified chemical is expected to undergo some degradation in the environment and metabolism in organisms. In any event, significant exposure to aquatic organisms should not occur as any environmental release should be low and diffuse throughout Australia. Therefore, significant bioaccumulation is unlikely.

## 9. EVALUATION OF TOXICOLOGICAL DATA

### 9.1 Acute Toxicity

**Summary of the acute toxicity of TKA 40138**

| *Test* | *Species* | *Outcome* | *Reference* |
|---|---|---|---|
| acute oral toxicity | rat | $LD_{50}$ > 2 000 mg.kg$^{-1}$ | (9) |
| acute dermal toxicity | rat | $LD_{50}$ > 2 000 mg.kg$^{-1}$ | (10) |
| skin irritation | rabbit | not a skin irritant | (11) |
| eye irritation | rabbit | a slight to moderate eye irritant | (12) |
| skin sensitisation | guinea pig | not a skin sensitiser | (13) |

#### 9.1.1 Oral Toxicity (9)

| | |
|---|---|
| *Species/strain:* | rat/HanIbm:WIST (SPF) |
| *Number/sex of animals:* | 5/sex |
| *Observation period:* | 14 days |
| *Method of administration:* | the notified chemical in PEG 400 (0.2 g.mL$^{-1}$) was administered by oral gavage |
| *Clinical observations:* | no clinical signs of toxicity related to the treatment were observed |
| *Mortality:* | nil |
| *Morphological findings:* | no macroscopic findings related to treatment were observed at necropsy |
| *Test method:* | based on OECD Guidelines (1) |
| *$LD_{50}$:* | > 2 000 mg.kg$^{-1}$ |
| *Result:* | the notified chemical had low acute oral toxicity in rats |

### 9.1.2 Dermal Toxicity (10)

| | |
|---|---|
| *Species/strain:* | rat/HanIbm:WIST (SPF) |
| *Number/sex of animals:* | 5/sex |
| *Observation period:* | 14 days |
| *Method of administration:* | the notified chemical in PEG 400 (1 $g.mL^{-1}$) was applied evenly on the intact skin and covered with a semi-occlusive dressing for 24 hours |
| *Clinical observations:* | no clinical signs of toxicity related to the treatment were observed |
| *Mortality:* | nil |
| *Morphological findings:* | no deviation from normal morphology was observed |
| *Test method:* | based on OECD Guidelines (1) |
| *$LD_{50}$:* | > 2 000 $mg.kg^{-1}$ |
| *Result:* | the notified chemical had low acute dermal toxicity in rats |

### 9.1.3 Inhalation Toxicity

Inhalation toxicity was not determined. This was considered to be acceptable. As the notified chemical has low vapour pressure, this is unlikely to be a route of exposure.

### 9.1.4 Skin Irritation (11)

| | |
|---|---|
| *Species/strain:* | rabbit/New Zealand White |
| *Number/sex of animals:* | 1 male, 2 females |
| *Observation period:* | 72 hours |
| *Method of administration:* | the notified chemical (0.5 mL) was applied undiluted to the intact skin and covered with surgical gauze and semi-occlusive dressing for 4 hours |
| *Test method:* | based on OECD Guidelines (1) |

*Result:* Draize (14) scores for erythema and oedema were all zero during the study; the notified chemical was not a skin irritant in rabbits

### 9.1.5 Eye Irritation (12)

*Species/strain:* rabbit/New Zealand White

*Number/sex of animals:* 1 male, 2 females

*Observation period:* 7 days

*Method of administration:* the notified chemical (0.1 mL) was administered undiluted to the conjunctival sac of the left eye of each animal; the right eye remained untreated and served as the control

***Time after instillation***

| ***Animal*** | ***1 day*** | | | | ***2 days*** | | | ***3 days*** | | | ***7 days*** | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| ***Conjuncti*** | ***'a*** | ***r[a]*** | ***c[b]*** | ***d[c]*** | ***r[a]*** | ***c[b]*** | ***d[c]*** | ***r[a]*** | ***c[b]*** | ***d[c]*** | ***r[a]*** | ***c[b]*** | ***d[c]*** |
| | 1 | 1[1] | 0 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 2 | 1 | 0 | 2 | 1 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 |
| | 3 | 1 | 0 | 2 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

[1] see Attachment 1 for Draize scales
[a] redness [b] chemosis [c] discharge

*Observation:* Draize scores for cornea (opacity and area) and iris were all zero during the test; moderate reddening and slight to moderate swelling of the conjunctivae, accompanying by moderate watery discharge and hyperaemia of the scleral blood vessels were observed in all animals; slight conjunctival reddening persisted in two animals for at least 48 hours and in one animal for at least 72 hours, whereas hyperaemia of the scleral blood vessels persisted for at least 48 hours; all findings were reversible after seven days

*Test method:* based on OECD Guidelines (1)

*Result:* TKA 40138 was considered to be a slight to moderate eye irritant with short to medium term persistence in rabbits

### 9.1.6 Skin Sensitisation (13)

*Species/strain:* guinea pig/Ibm: GOHI; SPF-quality

*Number of animals:* 30 females (20 test, 10 control)

*Induction procedure:* 3 pairs of intradermal injections (0.1 mL per site) were carried out on day 1: Freund's complete adjuvant (FCA) with physiological saline (1:1); 5% notified chemical in PEG 400; and 5% notified chemical emulsion in FCA and physiological saline (1:1)

on day 8, a filter paper patch saturated with undiluted notified chemical (approximately 0.3 g) was applied dermally on the injection sites for 48 hours

*Challenge procedure:* on day 22, a filter paper saturated with undiluted notified chemical was applied dermally under occlusive dressing for 24 hours

*Challenge outcome:*

| | ***Test animals*** | | ***Control animals*** | |
|---|---|---|---|---|
| ***Challenge concentration*** | ***24 hours**** | ***48 hours**** | ***24 hours*** | ***48 hours*** |
| 100% | **0/20 | 0/20 | 0/10 | 0/10 |

* time after patch removal
** number of animals exhibiting positive response

*Test method:* based on OECD Guidelines (1)

*Result:* TKA 40138 was not a skin sensitiser in guinea pigs under the experimental conditions employed

### 9.2 Repeated Dose Toxicity (15)

*Species/strain:* rat/HanIbm:WIST (SPF)

*Number/sex of animals:* 5 dose groups (5/sex each); 2 recovery groups (0 and 200 $mg.kg^{-1}.day^{-1}$, 5/sex each)

*Method of administration:* oral gavage

| | |
|---|---|
| *Dose/Study duration:* | 5 doses (0, 50, 100 and 200 $mg.kg^{-1}.day^{-1}$ in PEG 400 ) were administered for 28 days; the recovery groups had an additional 14 day treatment-free recovery period |
| *Clinical observations:* | all animals survived except for a female (50 $mg.kg^{-1}.day^{-1}$) which died on day 25; the cause of death could not be established and a possible misgavage could not be excluded; the males in the high-dose group (200 $mg.kg^{-1}.day^{-1}$) had a slightly lower food consumption and slightly lower body weight |
| *Clinical chemistry/Haematology* | there were no treatment-related effects on haematology, clinical chemistry or urinalysis data |
| *Histopathology:* | dose-related higher liver/body weight ratio was observed in animals at 100 and 200 $mg.kg^{-1}.day^{-1}$, this effect was reversed after the treatment-free recovery period; higher thyroid weights at 200 $mg.kg^{-1}.day^{-1}$ were recorded during treatment and after the recovery period in males; no statistical significance was attained |
| *Test method:* | based on OECD Guidelines (1) |
| *Result:* | the findings indicated that treatment with the notified chemical at greater than 100 $mg.kg^{-1}$ $day^{-1}$ induced reversible dose-related higher liver weights in rats |

## 9.3 Genotoxicity

### 9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (16)

| | |
|---|---|
| *Strains:* | TA 1535, TA 1537, TA 98, TA 100 and *Escherichia coli* strain WP2 *uvrA* |
| *Concentration range:* | 33.3, 100, 333.3, 1 000, 2 500 and 5 000 μg per plate with or without metabolic activation provided by rat liver S9 fraction |
| *Test method:* | based on OECD Guidelines (1) |
| *Result:* | under the experimental conditions, the notified chemical did not induce gene mutations by base pair changes or frameshifts in the genome of the strains used with or without metabolic activation |

### 9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse (17)

| | |
|---|---|
| *Species/strain:* | mouse/NMRI |
| *Number and sex of animals:* | 6 groups (6/sex each) |
| *Doses:* | 200, 670 and 2 000 $mg.kg^{-1}$ |
| *Method of administration:* | the notified chemical in PEG 400 was administered orally; sampling of the bone marrow was performed 24 and 48 hours after treatment |
| *Test method:* | based on OECD Guidelines (1) |
| *Result:* | under the experimental conditions, the notified chemical did not induce micronuclei in mouse bone marrow cells, and was considered to be non-clastogenic in the micronucleus assay |

### 9.3.3 Chromosome Aberration Assay in Chinese Hamster V79 Cells (18)

| | |
|---|---|
| *Species/strain:* | Chinese Hamster V79 cells |
| *Doses:* | experiment I:<br>10-5 000 μg.mL$^{-1}$ (with metabolic activation)<br>50-2 000 μg.mL$^{-1}$ (without metabolic activation)<br><br>experiment II:<br>30-5 000 μg.mL$^{-1}$ (with metabolic activation)<br>30-500 μg.mL$^{-1}$ (without metabolic activation) |
| *Method of administration:* | the notified chemical in DMSO was introduced into the culture medium; exposure periods were 4 hours with metabolic activation, 18 or 28 hours for those without metabolic activation |
| *Test method:* | based on OECD Guidelines (3) |
| *Result:* | some aberrations were noted; no statistically relevant increase in the frequency of aberrations per cell or in the proportion of aberrant metaphases at any dose level at any time interval evaluated with or without S9 mix |

## 9.4 Overall Assessment of Toxicological Data

The notified chemical was of low acute oral ($LD_{50}$ > 2 000 mg.kg$^{-1}$) and dermal ($LD_{50}$ > 2 000 mg.kg$^{-1}$) toxicity in rats. It was not a skin irritant in rabbits or a skin sensitiser in guinea pigs. However, the notified chemical was a slight to moderate eye irritant in rabbits. An acute inhalation toxicity study has not been performed with the notified chemical which was considered to be acceptable.

In a 28-day oral repeat dose study, no organ toxicity related to the notified chemical was identified in clinical observations, or chemical and haematological investigations. Histopathological examination revealed a dose-related higher liver weights in the animals at 100 and 200 mg.kg$^{-1}$.day$^{-1}$. This effect was reversed after 14-day recovery period.

In two *in vitro* genotoxicity assays, the notified chemical did not induce gene mutations in the *Salmonella typhimurium* reverse mutation assay either with or without metabolic activation, but seemed to induce chromosomal

aberrations in Chinese Hamster V79 cells. The latter finding was suggested to be caused by the formation of micelles that interfered with the membrane of the cells and thus induced unspecific toxic effects. The results should therefore be regarded as inconclusive. In an *in vivo* genotoxicity test, the notified chemical was demonstrated to be non-mutagenic in the micronucleus assay in mice.

On the basis of submitted data, the notified chemical would not be classified as hazardous in accordance with the National Commission's *Approved Criteria for Classifying Hazardous Substances* (19) in relation to acute lethal effects (oral, dermal), irritation effects (skin, dermal), sensitising effect (skin), sub-acute effects (oral) and mutagenic effects.

## 10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following ecotoxicity studies have been supplied by the notifier. The tests were carried out to OECD Test Methods (1) at facilities complying with the Principles of Good Laboratory Practice.

| *Test* | *Species* | *Results ($mg.L^{-1}$)* | *Reference* |
|---|---|---|---|
| Acute Toxicity<br>96 h Static WAF[1] | Zebra fish<br>*Brachydanio rerio* | $LC_{50}$ > 100<br>NOEC[2] = 33<br>LOEC = 100 | (20) |
| Acute Immobilisation<br>48 h Static WAF[1] | Water Flea<br>*Daphnia magna* | $EC_{50}$ > 100<br>NOEC = 33<br>LOEC = 100 | (21) |
| Growth Inhibition<br>72 h Static WAF[1]<br>Growth rate[3] ($\mu$) &<br>Biomass[4] (b) | Algae<br>*Scenedesmus subspicatus* | $E_bC_{50}$ = 69[5]<br>$E_\mu C_{50}$ > 100<br>$NOEC_{b\&\mu}$ = 33<br>$LOEC_{b\&\mu}$ = 100 | (22) |
| Respiration Inhibition<br>30 min Static[6] | Aerobic Waste Water Bacteria | $EC_{50}$ > 100 | (23) |

1. Water Accommodated Fractions - see comments below.
2. NOEC - no observable effect concentration
3. The rate of change of the number of cells with time.
4. The actual number of cells per volume of medium (cell/mL) calculated as the area under the growth curve.
5. Estimated by linear regression.
6. Nominal test concentrations of 10, 20, 32, 50 & 100 $mg.L^{-1}$.

The acute toxicity of the notified chemical on fish, invertebrates and algae examined three WAFs (Water Accommodated Fractions) with loadings of 10, 33 and 100 $mg.L^{-1}$. Test media were stirred for 48 hours at room temperature and then filtered through

membrane filters. The resulting filtrate, determined to contain Components A and B and a new unknown component, was used in the exposures. Complete quantitative analysis was not performed due to the large number of components present in the notified chemical.

No clinical (sublethal) effects were noted in the fish toxicity test at loadings of 10 and 33 $mg.L^{-1}$. At the 100 $mg.L^{-1}$, all ten fish showed light clinical signs, such as hypoactivity, between 24 and 72 hours. Fish were observed remaining at the bottom of the tank between 24 and 96 hours. There were no recorded fish mortalities at any loading.

No immobility of the daphnids occurred at loadings of 10 and 33 $mg.L^{-1}$. At the 100 $mg.L^{-1}$ loading, 30% immobilisation (of 10 daphnids) was noted after 48 hours of exposure (0% after 24 hours).

There was no observed inhibition of algal growth (with respect to growth rate and biomass) at loadings of 10 and 33 $mg.L^{-1}$. At the 100 $mg.L^{-1}$ loading, 75.6% growth inhibition with respect to biomass and 27.3% growth inhibition with respect to growth rate were noted, both of statistical significance. The biomass $EC_{50}$ was estimated by linear regression.

The respiration rate (oxygen consumption) of the aerobic waste water bacteria was not inhibited when exposed to nominal test concentrations equal or less than 50 $mg.L^{-1}$. At the highest test concentration of 100 $mg.L^{-1}$, a slight inhibition (1.8%) was noted.

In conclusion, the ecotoxicity data for the notified chemical indicate that its water soluble fraction is non-toxic to fish and aquatic invertebrates, and slightly toxic to algae (with respect to biomass), up to the limit of the mixture's solubility in water. The chemical can be classed as practically non-toxic to aerobic waste water bacteria.

## 11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The end use of the notified chemical is as a small (0.4 to 1.2%) component of lubricants. The main environmental exposure will be from inappropriate disposal of waste lubricant. A worst case scenario would be if all the uncollected oil was dumped into a sewer in some country centre. This would give a concentration in the sewage treatment plant of about 1.48 $mg.L^{-1}$ per day[2]. For a major city, the amount would only be about 10 $\mu g.L^{-1}$ per day, due to the much higher dilution factors expected during sewage treatment.

However, it is expected that the chemical will be moderately adsorbed to the sludge during the waste water treatment process due to the notified chemical's relatively low water solubility. Therefore, the actual concentration in the effluent will be significantly less. With its use Australia wide, *ie* not concentrated in one town or city, and with good industrial and public practice, concentrations of the notified chemical exposed to the environment are expected to be further reduced. It has also been shown that the D-I-Y

[2] Used oil should account for 41% of the notified chemical imported. Given 44% of used oil is not collected, then of the 15 tonnes of notified chemical imported at maximum import rates, 2.7 tonnes would not be collected (ie. 18% x 15 tonnes). This would give 7.40 $kg.d^{-1}$ (ie. 2.7 tonnes/365 d) entering the sewage treatment plant. The dilution at a rural town could reasonably be expected to be about 5 ML, while for a major city, say Melbourne, it would be 500 ML.

market only accounts for approximately 4.9% of total lubricant sales in Australia. It is believed that a large proportion of such sales are used for top-up purposes, and do not generate used oil directly (6). Ecotoxicity tests showed that the water accommodated fraction of the notified chemical is expected to be non-toxic to aquatic organisms, except to algae for which it was shown to be slightly toxic.

Disposal of containers with waste oil (oil residues and used oil containing the notified chemical) should not result in any significant environmental exposure. Waste oil may be recycled or incinerated. Incineration of the oil for fuel value or due to container reconditioning will destroy the substance. Used/waste oil collected by industrial and commercial users, that is not re-used, is expected to be disposed of to approved industrial facilities. D-I-Y consumer oil, if disposed of to domestic landfills, should remain in the containers. If leaks occur, the notified chemical should be contained within the landfill site, due to its immobility. Also, the substance is expected to be present at low concentrations in and widely dispersed throughout landfills in Australia.

Overall, the environmental hazard from the proposed use of the notified chemical is expected to be low.

## 12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Based on the animal data provided by the notifier, the notified chemical would not be classified as hazardous according to the Approved Criteria for Classifying Hazardous Substances in relation to acute (oral, dermal routes) or subchronic (oral route) toxicity, skin and eye irritancy, skin sensitisation or genotoxicity. However, an animal study revealed that the notified chemical is a slight to moderate eye irritant.

The occupational health risk for transport and storage workers is expected to be negligible except in the event of incident.

Dermal or ocular exposure to the notified chemical may occur during formulation, when workers transfer the notified chemical from the drum to the mixing vessel. The risk of skin irritant effects or acute toxicity is expected to be minimal. However, as the notified chemical is a slight to moderate eye irritant, eye protection should be worn during the transfer.

The blending process will take place in a closed system. The blended oil is then transferred via a closed system to automatic package-filling machines. The exposure for workers at the packaging site is expected to be negligible.

Workers at the servicing workshops could be exposed to the notified chemical during engine services. The health risk due to exposure to the notified chemical is expected to be minimal because the concentration of the notified chemical in the product is very low and the exposure will be infrequent and limited.

There is negligible potential for public exposure to the notified chemical arising from transportation, industrial formulation or disposal activities. A moderate level of public contact with the notified chemical is anticipated, arising from its use in engine lubricant oils.

However, public exposure to the notified chemical would be low, given its low concentration in finished oils, and that use of oils would generally involve only intermittent and brief dermal contact.

## 13. RECOMMENDATIONS

To minimise occupational exposure to TKA 40138 the following guidelines and precautions should be observed:

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (24) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (25);
- Spillage of the notified chemical should be avoided, spillages should be cleaned up promptly with absorbents which should then be put into containers for disposal;
- Good personal hygiene should be practised to minimise the potential for ingestion;
- A copy of the MSDS should be easily accessible to employees.

## 14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (26).

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

## 15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, 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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## Attachment 1

The Draize Scale for evaluation of skin reactions is as follows:

| *Erythema Formation* | *Rating* | *Oedema Formation* | *Rating* |
|---|---|---|---|
| No erythema | 0 | No oedema | 0 |
| Very slight erythema (barely perceptible) | 1 | Very slight oedema (barely perceptible) | 1 |
| Well-defined erythema | 2 | Slight oedema (edges of area well-defined by definite raising | 2 |
| Moderate to severe erythema | 3 | Moderate oedema (raised approx. 1 mm) | 3 |
| Severe erythema (beet redness) | 4 | Severe oedema (raised more than 1 mm and extending beyond area of exposure) | 4 |

The Draize scale for evaluation of eye reactions is as follows:

***CORNEA***

| *Opacity* | *Rating* | *Area of Cornea involved* | *Rating* |
|---|---|---|---|
| No opacity | 0 none | 25% or less (not zero) | 1 |
| Diffuse area, details of iris clearly visible | 1 slight | 25% to 50% | 2 |
| Easily visible translucent areas, details of iris slightly obscure | 2 mild | 50% to 75% | 3 |
| Opalescent areas, no details of iris visible, size of pupil barely discernible | 3 moderate | Greater than 75% | 4 |
| Opaque, iris invisible | 4 severe | | |

***CONJUNCTIVAE***

| *Redness* | *Rating* | *Chemosis* | *Rating* | *Discharge* | *Rating* |
|---|---|---|---|---|---|
| Vessels normal | 0 none | No swelling | 0 none | No discharge | 0 none |
| Vessels definitely injected above normal | 1 slight | Any swelling above normal | 1 slight | Any amount different from normal | 1 slight |
| More diffuse, deeper crimson red with individual vessels not easily discernible | 2 mod. | Obvious swelling with partial eversion of lids | 2 mild | Discharge with moistening of lids and adjacent hairs | 2 mod. |
| Diffuse beefy red | 3 severe | Swelling with lids half-closed | 3 mod. | Discharge with moistening of lids and hairs and considerable area around eye | 3 severe |
| | | Swelling with lids half-closed to completely closed | 4 severe | | |

***IRIS***

| *Values* | *Rating* |
|---|---|
| Normal | 0 none |
| Folds above normal, congestion, swelling, circumcorneal injection, iris reacts to light | 1 slight |
| No reaction to light, haemorrhage, gross destruction | 2 severe |