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December 1998

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Irgalube 232

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Irgalube 232

1. APPLICANT

Ciba Specialty Chemicals Ltd of 235 Settlement Road THOMASTOWN VIC 3074 has submitted a standard notification statement in support of their application for an assessment certificate for Irgalube 232.

2. IDENTITY OF THE CHEMICAL

Claims were made and accepted for the identity of the notified chemical to be exempt from publication in the Full Public Report. The data were:

Chemical name
CAS No.
Molecular and structural formulae
Molecular weight
Spectral data
Estimated import, and
Number and identify of sites at which the product will be formulated.

Other Names: CGA 28-0132, TKA 40116

Trade Name: Irgalube 232

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa: yellow liquid, no odour

Boiling Point: 432°C

Density: 1 154 kg/m^3

Vapour Pressure: 10^{-7} kPa at 25°C (extrapolated)

Water Solubility: approximately 0.1 mg/L (arylthiophosphate)

Partition Co-efficient (n-octanol/water):	log $P_{ow} \geq 4.8$
Hydrolysis as a Function of pH:	stable at pH 4 – 9 and 50°C
Adsorption/Desorption:	log $K_{oc} \geq 5.31$
Dissociation Constant:	$pK_a > 9.9$ for all phenolic moieties
Flash Point:	approximately 162°C
Flammability Limits:	not flammable
Autoignition Temperature:	no self-ignition below 150°C
Explosive Properties:	not considered explosive
Surface Tension:	67 mN/m at 20.8°C
Reactivity/Stability:	not an oxidising agent

Comments on Physico-Chemical Properties

The notified liquid is of low volatility and practically insoluble at room temperature.
The hydrolysis testing at pH 4, 7 and 9 gave less than 1% decomposition after 5 days at 50ºC.
Partition coefficient (range 4.8-8.8) suggests a strong affinity to the organic fraction and a likelihood to adhere to the soil organic fraction. Adsorption/desorption results suggest strong adsorption and are discussed in the Environmental Fate section below. The notified chemical is not a surface active agent (less than 60 mN/m).

4. PURITY OF THE CHEMICAL

Degree of Purity: 96.5% (94.2 – 99%)

Impurities:

Chemical Name	*Weight %*
free phenols (phenol, 2-tert-butyl phenol, 4-tert-butyl phenol, 2,4-di-tert-butyl phenol)	1.6
N-containing byproduct	< 0.1%
unknown byproducts	0.5

Additives/Adjuvants: none

5. USE, VOLUME AND FORMULATION

The notified chemical is to be used as an anti-wear additive at levels of 0.3 – 0.6% in hydraulic fluids and compressor lubricating oils.

The notified chemical will be imported in 200 L steel drums either undiluted as Irgalube 232 or as a formulation, Irgalube ML 3010A, and blended with other ingredients into hydraulic fluid or oils and repackaged for customer use in volumes of 4 L to 200 L. End users will add the fluid or oil to hydraulic machinery or compressors either as an addition or replacement.

6. OCCUPATIONAL EXPOSURE

Exposure of workers during transport or storage of the notified chemical is not expected to occur except in the case of accidental spillage.

The notified chemical will be blended into hydraulic fluids or oils. Two workers at each site, a plant operator and quality control technician, would carry out the formulation for a maximum of 18 days per year. The chemical is either decanted into the blending vessel under local exhaust ventilation or transferred through a closed system such as a pump immersed in the liquid. Decanting is performed by a foot-operated mechanical lifting and tilting device and the drum bung is replaced with a valve designed for smooth addition of the drum contents. The blend is discharged from the blender, usually via a closed transfer system, to package-filling machines. The notifier states that the only opportunity for exposure is in cleaning up spills or leaks and during machine maintenance. Local exhaust ventilation is employed during addition of the notified chemical to the blending vessel. Typically a batch size is between 2 and 20 tonnes or continuous in-line blending and pack sizes for hydraulic fluids or oils can vary between 1 L cans or plastic bottles to 200 L steel drums or 1 tonne IBCs.

The blended fluids or oils containing the notified chemical at a level of less than 0.6% will be manually added to machinery by maintenance workers. If an addition, the fluid or oil would be added manually to a reservoir; if a replacement of oil in a large machine, used for pressing car bodies for example, pumping of up to one tonne of oil into the machine would be required. Dermal exposure is possible during these tasks and is controlled by the use of personal protective equipment.

7. PUBLIC EXPOSURE

The notified chemical is for industrial use only and will not be sold to the general public. It is expected that during transport and storage, exposure of the general public to the notified chemical will not occur except in the event of accidental spillage.

No significant public exposure is expected during reformulation of the notified chemical into hydraulic fluids or oils, during use of these products or during disposal.

8. ENVIRONMENTAL EXPOSURE

Release

The notified chemical is imported in concentrated form. It is transferred direct from the 200 L drums (used for importation) to blenders where it is mixed in the correct proportion for the intended use then packaged into 1, 5, 20 or 200 litre containers. Equipment used for packaging is not cleaned between product runs resulting in no waste.

No environmental release is envisaged in reconditioning of the 200 L import drums as drums are cleaned with the base fluid which is reused.

Estimated losses from the above two processes are expected to be no more than 10 kg per year.

While hydraulic and compressor systems are noted to lose very little volume over the service life of the oil, and a very high proportion is available as waste oil (AIP, 1995), the notifier has indicated the notified chemical is not normally used within a fully closed system. Thus releases to the environment may occur if the machinery is not functioning properly. However, it is difficult to determine the amount that may be released in this way as the size of the hydraulic equipment is a factor.

Loss of notified chemical will also occur via regular maintenance and replacement. Again, it is difficult to estimate the volume released in this way due to several factors, such as the expertise of the worker and the conditions of the equipment. Losses would not be expected to be of high volume (less than 1 L per change).

Losses attributed to accidental spills of larger amounts are likely to be extensively adsorbed to soils or absorbent materials. They can be shovelled up or recovered by vacuum equipment and disposed of at an appropriate waste disposal facility. The notified chemical is unlikely to enter the aquatic environment due to its low water solubility, except when sorbed to eroded soil particles.

Waste oil is likely to account for the greatest level of environmental exposure of the notified chemical, and may be disposed of in two ways. Some customers may elect to drain the used oil and store it in a used oil container for later collection by a contractor. The MSDS recommends disposal through burning in enclosed systems for fuel value, or under supervised incineration. However, it is realistic to assume that smaller and more remote facilities may dispose of the oil by fuel extension (adding used oils to distillate for engine or small boiler use), or unapproved disposal to soil or water (AIP, 1995).

Fate

The majority of the notified chemical released to the environment would be via spillage of the hydraulic oil during either servicing or use. This material will be collected and then recycled or disposed of at an approved incineration facility. When used oil is not contaminated with water the notified chemical may be recycled by reprocessing. The notifier reports that up to 60% of the oils containing the notified substance may be treated in this manner. The remainder may be directly burned for fuel. Incineration of the notified chemical will result in oxides of carbon and, to a lesser extent phosphorus and sulphur dispersal to the atmosphere.

Adsorption/desorption results were obtained from standard flask equilibrium tests along the lines of OECD TG106 using a HPLC screening method. They were conducted on the main component of the notified substance and five reference components containing butylated derivatives of the main component sorbed to a standard column and compared to reference substances of known log K_{oc} value. Seven substances with known log K_{oc} were used. They ranged from 1,2,3-trichlorobenzene (log K_{oc} 3.16) to 4,4'-DDT (log K_{oc} 5.63). A calibration plot is then used to determine the log K_{oc} of the components of the notified substance.

Component	*adsorption coefficient (log K_{oc})*
arylthiophosphate (main component)	5.31
alkylated derivatives of main component	>>5.63[1]

[1] log K_{oc} is much higher than 5.6 (which is the log K_{oc} of 4,4'-DDT)

The observed high percentage of adsorption compared to the reference substances suggests the notified chemical would strongly adsorb to soils, especially if they have a high clay and/or silt content. The observed low percent desorption of the notified chemical, combined with its low solubility, would act to mitigate movement through soils.

Biodegradation

The biodegradation of the notified chemical has been determined by the modified OECD screening test TG 301 B. This protocol determines the aerobic biodegradation potential of organic material by measuring the loss of dissolved organic carbon in these test systems over a period of 28 days. The notified adduct showed 0% biodegradation over the 28 day period which indicates the chemical is not readily biodegradable.

Bioaccumulation

The waste generated by use of the notified substance will, in the general case, be collected during servicing and sent to appropriate recycling or waste disposal facilities. The quantities of the hydraulic oil that might exposed to the aquatic environment via accidental spills should be negligible. In spite of its low water solubility (less than 1.10^{-5} g/L) and high fat solubility (log P_{ow} > 4.8) and expected strong adsorption of the notified chemical coupled with the low exposure to the aquatic environment, the potential for bioaccumulation seems low.

Distribution in the Environment

According to fugacity modeling supplied (Mackay et al., 1996)[1], the division between compartments would be as follows:

Compartment	*% of substance*
Soil	96.1
Sediment	2.1
Water	1.7
Suspended Sediment	0.007
Biota	0.005

This is consistent with the partition coefficient and adsorption/desorption results.

[1] EQC Model version 1.01 (Environmental partitioning Mackay level 1; thermodynamic equilibrium partitioning without degradation) 1997 University of Toronto, Canada

9. EVALUATION OF TOXICOLOGICAL DATA

All toxicology studies were performed using TKA 40116.

9.1 Acute Toxicity

Summary of the acute toxicity of TKA 40116

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 2 000 mg/kg	(McRae & Mason, 1995)
acute dermal toxicity	rat	LD_{50} > 2 000 mg/kg	(Arcelin, 1997)
skin irritation	rabbit	slight to moderate irritant	(Parcell, 1995b)
eye irritation	rabbit	slight irritant	(Parcell, 1995a)
skin sensitisation	guinea pig	non-sensitiser	(Allan, 1995)

9.1.1 Oral Toxicity (McRae & Mason, 1995)

Species/strain:	rat/Sprague-Dawley
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	gavage
Clinical observations:	piloerection in all rats within seven minutes of dosing and over five days
Mortality:	none
Morphological findings:	none
Test method:	EEC Method B.1 (European Economic Community, 1992)
LD_{50}:	> 2 000 mg/kg
Result:	the notified chemical was of very low acute oral toxicity in rats

9.1.2 Dermal Toxicity (Arcelin, 1997)

Species/strain:	rat/HanIbm:WIST(SPF)
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	under semi-occlusive dressing for 24 hours
Clinical observations:	no clinical signs or local effects on the skin
Mortality:	none
Morphological findings:	none
Test method:	OECD guideline TG 402 (Organisation for Economic Co-operation and Development, 1995-1996)
LD_{50}:	> 2 000 mg/kg
Result:	the notified chemical was of low acute dermal toxicity in rats

9.1.3 Inhalation Toxicity

not available

9.1.4 Skin Irritation (Parcell, 1995b)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	3/unspecified
Observation period:	4 days
Method of administration:	0.5 mL of the notified chemical under semi-occlusive dressing for 4 hours

Draize scores (Draize, 1959):

Time after treatment (days)	***Animal #***		
	1	***2***	***3***
Erythema			
1 hour	1[a]	2	1
2	0	2	1
3	0	1	0
4	0	0	0
Oedema			
1 hour	1	1	1
2	0	1	1
3	0	0	0
4	0	0	0

[a] see Attachment 1 for Draize scales

Test method: EEC method B.4 (European Economic Community, 1992)

Result: the notified chemical was a slight to moderate skin irritant in rabbits

9.1.5 Eye Irritation (Parcell, 1995a)

Species/strain: rabbit/New Zealand White

Number/sex of animals: 3/unspecified

Observation period: 7 days

Method of administration: 0.1 mL into the lower everted lid of one eye of each animal

Test method: EEC method B.5 (European Economic Community, 1992)

Result:	the notified chemical was a slight eye irritant in rabbits; no effects were observed on the cornea or iris; moderate conjunctival redness was seen in all animals at 1 hour post-instillation persisting as slight redness in one animal at 24 hours; mild conjunctival swelling was observed in two animals and slight swelling in one animal at the 1 hour time point

9.1.6 Skin Sensitisation (Allan, 1995)

Species/strain:	guinea pig/Dunkin-Hartley
Number of animals:	10 test, 5 control; all males
Induction procedure:	3 pairs of intradermal injections in the scapular region as follows: - Freund's Complete Adjuvant (FCA) diluted 1:1 with water; - Irgalube 232, 1% v/v in Alembicol D - Irgalube 232, 1% v/v in FCA and Alembicol D 1:1 <u>topical induction:</u> six days after the above treatment, the same scapular region was pre-treated with 0.5 mL of 10% w/w sodium lauryl sulphate in petrolatum; twenty-four hours later a 8 cm^2 filter paper patch soaked with 0.4 mL Irgalube 232 was applied to this area under occlusive dressing for 48 hours; control animals were similarly treated but without the notified chemical
Challenge procedure:	14 days after topical induction, sites on the left flank of each test animal were treated with neat Irgalube 232 or a 50% v/v solution in Alembicol D under occlusive dressing for 24 hours; control animals were similarly treated but without the notified chemical
Challenge outcome:	no erythema or oedema was observed in any test animal on the challenge sites at 24 or 48 hours after patch removal

Test method:	EEC method B.6 (European Economic Community, 1992)
Result:	the notified chemical was not a skin sensitiser in guinea pigs

9.2 Repeated Dose Toxicity (Allard et al., 1997)

Species/strain:	rat/Wistar
Number/sex of animals:	5/sex/group with an extra 5/sex in recovery groups
Method of administration:	gavage; vehicle: polyethylene glycol
Dose/Study duration::	doses were: 0 (control), 50 (low), 100 (mid) or 200 (high) mg/kg/day for 28 days; 14 day recovery groups received 0 or 200 mg/kg/day
Body weight gain/Food consumption:	no effect of treatment
Clinical observations:	none related to the test article
Clinical chemistry/ Haematology/Urinalysis	*clinical chemistry:* slight decrease in glucose and increases in triglyceride and phosphorus levels in HD females; slight increases in γ -glutamyl transferase in MD and HD females *haematology:* no significant findings *urinalysis:* no significant findings
Mortality:	none related to treatment
Organ weights:	relative liver weights (relative to brain weight) were increased by 23%, 35% and 51% in LD, MD and HD males, respectively and by 27% in HD females; liver weight relative to body weight was increased by 16% and 31% in MD and HD females, respectively; liver weights in HD females were significantly higher than controls at the end of the recovery period; all weight increases were statistically significant
Macroscopic findings:	no treatment-related findings

Histopathology:	treatment-related effects were centrilobular hepatocellular hypertrophy in all HD males and females, in all MD males and 4 MD females; the severity was minimal to moderate in MD animals and, in all but one female with a minimal level, slight to moderate in HD animals; no treatment-related changes in liver histopathology were observed in the HD group at the end of the recovery period
Test method:	OECD guideline TG 407 (Organisation for Economic Co-operation and Development, 1995-1996)
Result:	the target organ was identified as the liver; clinical chemistry changes indicated effects of the notified chemical on the liver and these were correlated with increased liver weights and centrilobular hepatocellular hypertrophy; these effects were ascribed to metabolic adaptation in the liver and were not considered to be toxicologically significant as there was no association with changes in serum enzyme levels or other measures of hepatocyte integrity; hepatocellular hypertrophy was absent in rats after the 2-week recovery period; the authors defined the NOAEL as 200 mg/kg/day; a NOEL could not be established because of liver weight changes at all doses

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (Kitching, 1995)

Strains:	TA 1535, TA 1537, TA 98, TA 100
Concentration range:	0 – 5 000 µg/plate
Test method:	OECD guideline TG 471 (Organisation for Economic Co-operation and Development, 1995-1996)

Result: no mutagenic activity of the notified chemical was observed in bacteria at doses up to 5 000 µg/plate in the presence or absence of metabolic activation provided by rat liver S9 fraction; positive controls demonstrated the sensitivity of the assay and negative controls were within normal limits; no cytotoxicity was evident at the top dose

9.3.2 Chromosomal Aberration Assay in Chinese Hamster V79 Cells (Czich, 1997)

Cell line: Chinese Hamster V79

Doses:

preparation interval	***concentrations (µg/mL)***
without S9 mix:	
18 hours	10 – 300 (plus 1 000 in one replicate)
28 hours	50 – 300 (plus 1 000 in one replicate)
with S9 mix:	
18 hours	10 – 1 000
28 hours	50 – 1 000

Treatment details: S9 mix was prepared from Wistar rats treated with phenobarbital and β-naphthoflavone; treatment with S9 was for 4 hours, followed by 18 or 28 hours in the test article, with colcemid added 2.5 hours prior to harvest

Test method: OECD guideline TG 473 (Organisation for Economic Co-operation and Development, 1995-1996)

Result: no increase in chromosomal aberrations was induced by the notified chemical; negative controls were within historical limits and positive controls demonstrated the sensitivity of the assay

9.4 Overall Assessment of Toxicological Data

The notified chemical exhibited very low acute oral toxicity (LD_{50} > 2 000 mg/kg) and low acute dermal toxicity (LD_{50} > 2 000 mg/kg) in rats. The liver was the target organ in a 28-day oral repeated dose study at doses up to 200 mg/kg/day. However, the effects were judged to be adaptive and not toxicologically significant. The NOEL could not be established because significant increases liver weight were found at all doses. The notified chemical was a slight eye irritant and a slight to moderate skin irritant in rabbits, was not a skin sensitiser in guinea pigs and was not mutagenic in bacteria or clastogenic in Chinese Hamster V79 cells.

The notified chemical would not be determined to be a hazardous substance according to NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1994a).

Additional summary toxicokinetic assessment provided by the notifier indicates that the notified chemical is expected to be stable under the acid conditions in the stomach and under the alkaline conditions in the duodenum. The very low water solubility and high lipophilicity are indicative of a moderate resorption potential in the gastrointestinal tract. This is supported by the effects observed in the 28-day oral repeat dose study. Due to the high fat solubility, low water solubility and relatively low molecular weight range, a moderate resorption potential through the skin is assumed.

The liver effects observed in the 28-day oral repeat dose study indicate that the notified chemical is resorbed and metabolised in the liver. On structure-activity grounds, it can be assumed that metabolism can occur via different pathways. One involves oxidation of the sulphur group from aryl phosphate/alkylated phosphate. Another possible pathway is dearylation of the aryl/alkylated groups. A further possible pathway involves oxidation of the terminal carbon atoms of the alkyl groups or of the aryl groups and conjugation with glucuronic acid or sulphate. The metabolites are expected to be excreted mainly via urine or to a lesser extent via the bile.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following ecotoxicity studies have been provided by the notifier. The toxicity tests were carried out according to the notifier's protocols.

Test	*Species*	*Results (Nominal WAF*)*
Acute Renewal Toxicity (semi static)	Zebra fish (*Brachydanio rerio*)	96 h NOEC > 100 ppm
Acute Immobilisation	Daphnid (*Daphnia magna*)	48 h NOEC = 100 ppm
Acute Growth Inhibition	Algae (*Selenastrum capricornutum*)	72 h NOEC > 100 ppm
Respiration Inhibition	Activated sludge	3 h EC_{20} = 403 mg/L 3 h EC_{50} >1000 mg/L

*WAF = water accommodated fractions

For the toxicity tests on the fish, daphnid and algae species, organisms were exposed to the highest concentration that could be dissolved in the test water.

The WAF were prepared by adding the appropriate quantities to containers that were then stirred for 24 h and allowed to settle for 72 h. Supernatants were removed and the remainder tested and defined as the WAFs of nominal concentration, 100 mg/L.

The levels measured by the above tests, suggest this chemical would be considered non-toxic to the fish, daphnid and algae tested, up to the level of its solubility. No deaths or sub lethal effects were noted in any test.

Activated sludge testing showed that the substance is non toxic to the microorganisms tested at concentrations well above known water solubility limits.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The notified chemical is unlikely to present a hazard to the environment at any stage of its use. Considering the original quantity of the notified chemical imported (between 5-15 tonnes per annum in the first 5 years), it is expected that negligible amounts will be released from the blending and repackaging sites.

Maintained machinery should have minimal leakage of hydraulic and compressor oils. The ultimate fate of the waste hydraulic and compressor oil is to recycling or incineration at an approved industrial facility; burning for fuel value; or by unapproved on-site burning of waste oil or disposal to land or water.

Any accidental spillage would be expected to sorb strongly to soils, and only reach the aquatic compartment if sorbed to eroded soil particles. Combustion of the notified product will produce oxides of carbon, phosphorus, sulphur and hydrogen.

A low environmental hazard is expected through the use of this chemical.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

On the basis of the submitted toxicological data the notified chemical is unlikely to exhibit acute or subchronic toxicity, is not likely to be a skin sensitiser and is not likely to be genotoxic. However, it may be a slight eye irritant and a slight to moderate skin irritant. The notified chemical would not be determined to be a hazardous substance according to NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1994a). The notifier provided a toxicokinetic analysis for the notified chemical which concluded there is a moderate resorption potential through the gut and skin. It was also concluded that the chemical should be stable in the gastro-intestinal tract. The observation of increased liver weight in rats during the 28-day study (judged to be an adaptive response) at a dose of 50 mg/kg/day supports these conclusions.

The risk of eye or skin irritancy in transport or storage workers is considered to be low given that exposure may only occur in the event of accidental spillage.

The risk of eye or skin irritancy in workers involved in blending of fluids or oils is limited to exposure to residues in lines and on drum bungs and couplings where the notified chemical is pumped from the drum in which it is imported to a blending vessel. There may also be a risk of eye or skin irritancy should exposure occur during clean up of spills. The notifier states that gloves are worn during these operations. If the chemical is transferred by decanting, there may be a risk of eye or skin irritancy from drips and spills. Following blending, package filling is accomplished in a closed system. The risk of eye or skin irritancy to workers involved in these operations or to maintenance workers should be negligible given that the concentration of the notified chemical in the blends is 0.6%. The risk of systemic toxicity is also judged to be low. The chemical may be absorbed. However, given the frequency of handling by blending workers, the engineering controls and use of gloves and the low concentration of chemical in the final blend (maximum of 0.6%), dermal exposure and absorption would be low. This is also the case for maintenance workers adding the blended fluid or oil to machinery.

A Material Safety Data Sheet was provided for Irgalube ML 3010A, which contains the notified chemical at a concentration of up to 10%, and will be imported in addition to the undiluted notified chemical. This formulation contains hazardous components and may cause allergic skin disease as well as causing a sufficient degree of skin and eye irritation to warrant a hazardous substances health effects classification as an irritant. There is a risk of this occurring following exposure to residues in lines, on drum bungs and couplings or from clean up of spills. It is not likely that these sensitising effects can be attributable to the notified chemical, since it has not been shown to be a hazardous substance. Other ingredients in the Irgalube ML 3010A formulation may be responsible for the sensitising and irritant effects.

The risk of eye or skin irritancy from exposure of the general public to the notified chemical is considered to be negligible as is the risk of skin sensitisation, skin irritation and eye irritation from exposure to Irgalube ML 3010A.

13. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical and a formulation to be imported containing the notified chemical were provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (National Occupational Health and Safety Commission, 1994b).

These MSDS were provided by the applicant as part of the notification statement. They are reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

14. RECOMMENDATIONS

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

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (Standards Australia, 1994) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand, 1992);
- Industrial clothing should conform to the specifications detailed in AS 2919 (Standards Australia, 1987);
- Impermeable gloves should conform to AS/NZS 2161.2 (Standards Australia/Standards New Zealand, 1998);
- All occupational footwear should conform to AS/NZS 2210 (Standards Australia/Standards New Zealand, 1994);

- Spillage of the notified chemical should be avoided. Spillage 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.

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

Allan SA (1995) TKA 40116 (CD 28-0132) Skin Sensitisation in the Guinea Pig, Project No. CBG 739/952772/SS, Huntingdon Life Sciences Ltd, Cambridgeshire, England.

Allard G, Becker H, Luetkemeier H, et al. (1997) Subacute 28-Day Oral Toxicity (Gavage) Study with TKA 40116 (CD 28-132) in the Rat, Project No. 646604, Research and Consulting Company Ltd, Itingen, Switzerland.

Arcelin G (1997) Acute Dermal Toxicity Study with TKA 40116 (CD 28-132), Project No. 666393, Research and Consulting Company Ltd, Itingen, Switzerland.

AIP (1995) AIP Survey of Used Oil 1995, Australian Institute of Petroleum.

Czich A (1997) *In vitro* Chromosome Aberration Assay in Chinese Hamster V79 Cells with TKA 40116 (CD 28-132), Project No. 5936000, Research and Consulting Company Ltd, Itingen, Switzerland.

Draize JH (1959) Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics. Association of Food and Drug Officials of the US, 49 : 2-56.

European Economic Community (1992) EEC Directive 92/69/EEC on the Approximation of the Laws, Regulations and Administrative Provisions Relating to the Classification, Packaging and Labelling of Dangerous Preparations

Kitching J (1995) TKA 40116 (CD 28-0132) Bacterial Mutation Assay, Project No. CBG 731/952570, Huntingdon Life Sciences Ltd, Cambridgeshire, England.

Mackay D, DiGuardo A, Paterson S, et al. (1996) Evaluating the environmental fate of a variety of types of chemicals using the EQC model. Environ. Toxicol. Chem., 15 : 1627-1637.

McRae LA & Mason SJ (1995) TKA 40116 - Acute Oral Toxicity to the Rat, Project No. CBG 736/952346/AC, Huntingdon Life Sciences Ltd, Cambridgeshire, England.

National Occupational Health and Safety Commission (1994a) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1994)]. Australian Government Publishing Service, Canberra.

National Occupational Health and Safety Commission (1994b) National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)]. Australian Government Publishing Service, Canberra.

Organisation for Economic Co-operation and Development (1995-1996) OECD Guidelines for the Testing of Chemicals on CD-Rom. OECD, Paris.

Parcell BI (1995a) TKA 40116 (CD 28-0132) Eye Irritation to the Rabbit, Project No. CBG 738/952663/SE, Huntingdon Life Sciences Ltd, Cambridgeshire, England.

Parcell BI (1995b) TKA 40116 (CD 28-0132) Skin Irritation to the Rabbit, Project No. CBG 737/952766/SE, Huntingdon Life Sciences Ltd, Cambridgeshire, England.

Standards Australia (1987) Australian Standard 2919-1987, Industrial Clothing. Standards Association of Australia, Sydney.

Standards Australia (1994) Australian Standard 1336-1994, Eye protection in the Industrial Environment. Standards Association of Australia, Sydney.

Standards Australia/Standards New Zealand (1992) Australian/New Zealand Standard 1337-1992, Eye Protectors for Industrial Applications. Standards Association of Australia/Standards Association of New Zealand, Sydney/Wellington.

Standards Australia/Standards New Zealand (1994) Australian/New Zealand Standard 2210-1994, Occupational Protective Footwear. Standards Association of Australia/Standards Association of New Zealand, Sydney/Wellington.

Standards Australia/Standards New Zealand (1998) Australian/New Zealand Standard 2161.2-1998, Occupational protective gloves, Part 2: General requirements. Standards Association of Australia, Sydney.

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