File No: STD/1190

June 2006

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

CETEC 2252/CETEC 2253

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

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at:

Library
Australian Safety and Compensation Council
25 Constitution Avenue
CANBERRA ACT 2600
AUSTRALIA

To arrange an appointment contact the Librarian on TEL + 61 2 6279 1162 or email ascc.library@dewr.gov.au

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

Street Address:	334 - 336 Illawarra Road MARRICKVILLE NSW 2204, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

Director
NICNAS

TABLE OF CONTENTS

CETEC 2252/CETEC 2253

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Castrol Performance Lubricants Pty Ltd (ABN 20 003 663 474) of 132 McCredie Rd, Guildford, NSW, 2161.

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:

Chemical Identity
Spectral data & Methods of detection and determination
Degree of purity & identity of impurities

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

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
EU:
Cetec 2252 notified to UK HSE in 1999 & French INRS in 2004. EC Number 443-990-3.
Cetec 2253 notified to UK HSE in 2003 & French INRS in 2004. EC Number 444-210-4.

Korea:
Notification submitted 2005, currently under review.

Canada:
Notification submitted 2005, currently under review.

2. IDENTITY OF CHEMICAL

OTHER NAME(S)
Carboxylic acids, mixed tetraesters with pentaerythritol. (The notified chemical is introduced in two forms, which differ in the ratios and types of tetraester reaction products.)

MARKETING NAME(S)
Cetec 2252, Cetec 2253 (notified chemical)
Castrol Icematic SW 32, SW 46 and SW 68 (formulated products all contain > 99% of the notified chemical)

METHODS OF DETECTION AND DETERMINATION

Remarks The composition of the notified chemical and identity of impurities was determined using high temperature gas chromatography (HTGC) and GC-Mass Spectroscopy. Reference Infrared (IR) and Ultra-violet (UV) Spectra for CETEC 2252 and 2253 were provided.

3. COMPOSITION

DEGREE OF PURITY
> 60%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will not be manufactured in Australia. It will be imported as a component of the Castrol Icematic® range of refrigeration lubricants, at which it is present at concentrations up to 99%.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	15	16	17	18	20

USE
The notified chemical will be used as a lubricant for industrial refrigeration equipment including automotive, chilled-water and air-conditioning equipment.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Sydney, NSW

IDENTITY OF MANUFACTURER/RECIPIENTS
After import by the notifier, the Icematic® products containing the notified chemical are sold via a single distributor, thence to various automotive & refrigeration businesses who are the end-users.

TRANSPORTATION AND PACKAGING
Distribution to direct customers of Castrol Icematic® lubricants containing the notified chemical (at a concentration of 99%) will be by road on trucks. The lubricants are introduced and supplied in 208 litre drums, and 20 litre pails, and 5 and 1 litre containers.

5.2. Operation description

After import, the lubricants containing 99% notified chemical will either be stored & sold their original containers, or re-packaged from 208 litre drums into smaller (20, 5 and 1 litre) containers. The lubricant will then be used at various locations throughout Australia for first filling of equipment (approximately 80% of the imported volume) and subsequent field maintenance operations (approximately 20% of the imported volume). During use the lubricant is in a closed system and runs at temperatures between 80 and -40ºC .

Repackaging is routinely done under nitrogen, by using sampling pumps and quick-fit connections. First-filling is done at room temperature and pressure. The quantity of fluid added to the equipment is 0.25-200 litres.

Due to the hygroscopic nature of the product, end users have to use special methods for transferring the lubricant from the transport container to the end use equipment. The preferred method is to transfer the lubricant via suction. Larger compressors have the facility to suck lubricant into their sump with their own suction. In these cases the end user would remove the lid of the transport container, insert the tube and then suck the lubricant into the compressor. For smaller compressors and automotive applications, a dedicated stirrup pump is used to pump the lubricant from the transport container to the equipment. Both re-packaging and first filling is done in industrial locations (with typical bunding and spill

containment facilities) by professional trained & qualified staff.

The equipment is typically sealed for life, but it requires servicing at 6-24 month intervals. Field maintenance and top-up of the lubricant could lead to small losses of containment.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Transport and storage	10	4 hours/day	10 days/ year
Warehouse	5	4 hours/day	25 days/ year
End-use (first fill of equipment)	10	2 hours / day	25 days/ year
End-use (top-up & maintenance)	200	7 hours / day	300 days/ year

Exposure Details

Transport, storage and warehouse workers are not expected to have any contact with the notified chemical, except in the case of an accident.

Due to the semi-automatic transfer of the lubricants containing the notified chemical to prevent adsorption of water by the notified chemical, limited exposure to workers is expected during re-packaging (from drums to smaller containers), first-fill and subsequent maintenance of the machinery. However, dermal and ocular exposure to drips spills and splashes could occur during connection and disconnection of pumping equipment or insertion of suction tubes or stirrup pumps. Due to the low vapour pressure of the notified chemical, inhalation is not considered to be a major route of exposure.

During use the lubricant is in a closed system and as such negligible exposure is expected. Potential accidental exposure might occur if the sealed unit is punctured or through minor leaks from seals and gaskets in the system. Exposures of service technicians can occur when service equipment or automotive air-conditioning systems leak during servicing. Dermal exposure is expected to be the principal route of exposure although inhalation of lubricant mists could occur. Exposure would be limited by the recommended use of engineering controls and PPE.

5.4. Release

RELEASE OF CHEMICAL AT SITE

The notified chemical will not be manufactured in Australia, hence there will be no related environmental releases. It will be imported into Australia in formulated products in drums, pails and small containers. Some re-packaging from drums to smaller containers will also take place in Australia. Small spills are possible during re-packaging, however, such spillages would be in an industrial location with typical bunding and spill containment facilities.

Residual notified chemical within containers are expected to account for up to 1% of the total volume. These are expected to be removed during drum recycling and be incinerated or otherwise disposed in accordance with applicable local regulations.

RELEASE OF CHEMICAL FROM USE

Small spills are also possible during first-fill, top-up and maintenance operations. In the case of first-fill operations such spillages would be in an industrial location with typical bunding and spill containment facilities. For top-up and maintenance activities carried out by field engineers, such spillages are likely to very small and easily dealt with by containing and absorbing the liquid.

In routine use, no exposure is envisaged unless containment fails due to physical penetration of seals or sealed units. Loss through routine leakage from the system (e.g. through mechanical seals or compressor shaft) is negligible.

Even if the notified chemical is released, it has very low water solubility and vapour pressure, and high octanol/water partition coefficient, and thus is very unlikely to contaminate watercourses or the atmosphere, and be closely associated with soils and sediments.

5.5. Disposal

At the end of equipment's (e.g. compressor) life the lubricant will be incinerated or otherwise disposed in accordance with applicable local regulations.

Used drums will be cleaned and recycled. Empty pails & other small containers will be drained of residual lubricant and will be land-filled or incinerated in accordance with applicable local regulations.

5.6. Public exposure

The notified chemical is intended to be used as a synthetic lubricant in industrial equipment with minimal sales to the general public. Therefore widespread public exposure is not expected.

Car enthusiasts may install their own refrigeration compressor. Typically the compressor will be pre-filled with the lubricant and hence negligible exposure is expected. However, in some case the compressors are supplied dry and therefore exposure to the notified chemical could occur to drips and spills during transfer of the lubricant. A typical automotive compressor takes 800 mL of lubricant. There is also the potential for exposure to lubricant mist inside an automobile in the event of a leak of the vehicle air conditioning system.

6. PHYSICAL AND CHEMICAL PROPERTIES

The notified chemical is introduced in two forms, CETEC 2252 and CETEC 2253 which differ in the ratios and types of tetraester reaction products.

Appearance at 20ºC and 101.3 kPa Straw coloured liquid.

Pour Point <-21ºC (CETEC 2252)
<-20ºC (CETEC 2253)

METHOD EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks Statement of GLP.
TEST FACILITY Safepharm (1999a), Safepharm (1999b)

Boiling Point > 360ºC at 101.5 – 102 kPa (CETEC 2252, CETEC 2253)

METHOD EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks Determined by differential scanning calorimetry (DSC). The notified chemical failed to boil up to 360 ºC. Possible decomposition of impurities was seen at 191.7 ºC.

An attempt to determiner the boiling temperature of CETEC 2253 by distillation at reduced pressure was made. However, the test material bumped vigorously and the determination was considered in valid.

Statement of GLP.
TEST FACILITY Safepharm (1999a), Safepharm (1999b)

Density 993 kg/m^3 at 20.5ºC (CETEC 2252)
962 kg/m^3 at 20.5ºC (CETEC 2253)

METHOD EC Directive 92/69/EEC A.3 Relative Density.
Remarks Determined using a pycnometer. Statement of GLP.
TEST FACILITY Safepharm (1999a), Safepharm (1999b)

Vapour Pressure $2.1x10^{-11}$ kPa at 25°C (CETEC 2252)
$2.1x10^{-11}$ kPa at 25°C (CETEC 2253)

METHOD EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks Determined using a vapour pressure balance. Statement of GLP.
TEST FACILITY Safepharm (1999c), Safepharm (1999d)

Water Solubility $< 3.53x10^{-4}$ g/L at 20°C (CETEC 2252)
$< 9.42x10^{-5}$ g/L at 20°C (CETEC 2253)

METHOD EC Directive 92/69/EEC A.6 Water Solubility.
Remarks Flask Method. Analytical Method: GC. Statement of GLP.

The preliminary method indicated that the column elution method should have been performed as the solubility was less than $1x10^{-2}$ g/L. However, due to the physical nature of the test material, it was not possible to use this method.
TEST FACILITY Safepharm (1999a), Safepharm (1999b)

Hydrolysis as a Function of pH Not determined
Remarks The notified chemical contains hydrolysable functionality, however they are not expected to hydrolyse in the environmental pH range (4-9) due to low water solubility.

Partition Coefficient (n-octanol/water) log Pow = >6.2 at 20°C (CETEC 2252)
log Pow = >6.2 at 20°C (CETEC 2253)

METHOD EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks HPLC Method. The notified chemical in both forms eluted after the highest of 6 reference substances.
TEST FACILITY Safepharm (1999a)

Adsorption/Desorption – screening test log K_{oc} = >5.63 (CETEC 2252)
log K_{oc} = >5.63 (CETEC 2253)

METHOD OECD TG 106 Adsorption - Desorption Using a Batch Equilibrium Method.
Remarks HPLC Method. The notified chemical in both forms eluted after the highest of 11 reference substances.
TEST FACILITY Safepharm (1999a)

Dissociation Constant Not determined

Remarks The notified chemical has very low solubility in water and contains no dissociable groups.

Surface Tension 31.6 mN/m at 25°C (CETEC 2252)

METHOD EC Directive 92/69/EEC A.5 Surface Tension.
Remarks Tensiometer – with surface tension ring – notified chemical is surface active.
TEST FACILITY Chemex (2000)

Particle Size Not applicable

Remarks Notified chemical is a liquid under conditions of handling and use.

Flash Point 231°C at 101.325 kPa (CETEC 2252)

232ºC at 101.325 kPa (CETEC 2253)

METHOD	EC Directive 92/69/EEC A.9 Flash Point.
Remarks	Determined using a closed cup equilibrium method. Statement of GLP. The notified chemical is classified as a C2 combustible liquid according to NOHSC *National Code of Practice for the Storage and Handling of Workplace Dangerous Goods* (NOHSC 2001).
TEST FACILITY	Safepharm (1999e), Safepharm (1999f)

Flammability Limits Not determined

Remarks	Based on the flash point the notified chemical is not classified as flammable according to the Australian Dangerous Goods classification (FORS, 1998)

Autoignition Temperature > 400ºC (CETEC 2252, CETEC 2253)

METHOD	92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases).
Remarks	Statement of GLP.
TEST FACILITY	Safepharm (1999e), Safepharm (1999f)

Explosive Properties Not predicted to be explosive.

Remarks	Test not conducted. From examination of the structure, there are no chemical groups that would infer explosive properties.

Reactivity

Remarks	The notified chemical is expected to be stable under normal conditions of use.

7. TOXICOLOGICAL INVESTIGATIONS

The notified chemical is manufactured in two forms. CETEC 2252 and CETEC 2253 are by definition the same substance manufactured from the same starting materials; however, they differ in the ratios and types of tetraester reaction products. No significant differences are expected between these two forms in terms of their toxicological properties.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral	low toxicity, LD50 > 2000 mg/kg bw
Rat, acute dermal	low toxicity, LD50 > 2000 mg/kg bw
Rat, acute inhalation	not determined
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – adjuvant test	no evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days.	NOAEL 1000 mg/kg bw/day
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosome aberration test	non genotoxic
Genotoxicity – in vivo	not determined

7.1. Acute toxicity – oral

The acute toxicity of CETEC 2252 and CETEC 2253 was characterized in two separate studies conducted according to the acute toxic class method (OECD TG 423). In both instances, Sprague-Dawley rats (3/sex) were administered a single 2000 mg/kg bw dose of the test substance by gavage. No mortalities or clinical signs of systemic toxicity were observed during the 14-day observation period, and no treatment-related gross pathological abnormalities were observed upon necropsy. As a result, the LD50 for the notified chemical exceeded 2000 mg/kg bw in both studies, which is indicative of low acute toxicity by the oral route (Safepharm, 1999g; Safepharm,1999h). The LD50 cut-off estimated using the flow chart in annex 2d of the OECD TG423 would be $\geq$ 5000 mg/kg bw.

7.2. Acute toxicity – dermal

A dose of 2000 mg/kg bw of the test substance (CETEC 2252) was applied to the shaved skin of Sprague-Dawley rats (5/sex) for a 24 hour period, over an area approximately equivalent to 10% of the body surface area. No mortality or clinical signs of systemic toxicity were observed during the 14-day observation period, and no treatment-related gross pathological abnormalities were observed upon necropsy. No evidence of skin irritation was observed. As a result, the LD50 for the notified chemical exceeded 2000 mg/kg bw, which is indicative of low acute toxicity by the percutaneous route (Safepharm, 1999i).

7.3. Acute toxicity – inhalation

Not determined. The notified chemical is of low vapour pressure liquid which is not intended to be aerosolised during use. Therefore, inhalation exposure to the notified chemical is not expected to be a major route of exposure.

7.4. Irritation – skin

The test substance (CETEC 2252) was applied to the shaved dorsal flank of two male and one female NZW rabbits. All animals exhibited very slight erythema – two from 24-72 hours after exposure and the third from 24-48 hours; two animals also exhibited very slight oedema – one at 24 hours after exposure and the other from 24-72 hours. All signs of erythema and oedema had reversed by day 7, although desquamation was noted at two sites at this time. The irritation scores for the individual animals are provided below. The notified chemical is slightly irritating to the skin (Safepharm, 1999j).

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0.7	1	1	1	3-7 days	0
Oedema	0.3	1	0	1	3-7 days	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

7.5. Irritation – eye

The notified chemical was applied to the conjunctiva of three NZW rabbits (2 males and 1 female). Moderate conjunctival irritation was noted in all treated eyes 1 hour after treatment, reducing to minimal conjuctival irritation after 24 hours. All evidence of ocular irritation had fully reversed by 48 hours (2 animals) or 72 hours (1 animal) after treatment. No corneal or iridial effects were noted. The irritation scores for the individual animals are provided below. The notified chemical is slightly irritating to the eye (Safepharm,1999k).

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	0.7	0.3	0.3	2	< 72 hours	0
Conjunctiva: chemosis	0.7	0.3	0	2	< 72 hours	0
Conjunctiva: discharge	0.3	0.3	0	2	< 48 hours	0
Corneal opacity	0	0	0	0	n/a	0
Iridial inflammation	0	0	0	0	n/a	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

7.6. Skin sensitisation

The potential for the notified chemical (CETEC 2252) to induce skin sensitisation was determined using a guinea pig maximisation test. In accordance with protocol guidelines, concentrations were selected on the basis of a preliminary study. For induction treatments, the highest concentration producing only mild to moderate dermal irritation was selected; for challenge, the highest non-irritant concentration was used. Treatment group animals (10 males) received 0.1 mL intradermal induction injections of Freund's complete adjuvant (FCA) in distilled water, 25% test substance in arachis oil, and 25% test substance in a 1:1 mixture of FCA/distilled water. One week after intradermal induction, treatment group animals received a topical induction application of undiluted test substance under an occlusive dressing for 48 hours. Negative control group animals received the vehicle (intradermal) or a null treatment (topical) according to the same regimen. All test animals exhibited well defined erythema after intradermal induction; very slight or well-defined erythema and an isolated incident of very slight oedema was noted at the induction sites of four test group animals after topical induction. After a 24-hour challenge application to each animal three weeks following topical induction, consisting of the undiluted substance (right flank) and 75% dilution of the test substance in arachis oil (left flank), no treatment or control group animals showed evidence of dermal reactions indicative of skin sensitisation at either site, 24 or 48 hours after exposure. Based on these observations, the notified chemical is not likely to induce skin sensitisation (Safepharm, 1999l).

7.7. Repeat dose toxicity

A 28-day repeated-dose oral toxicity study was conducted with Sprague-Dawley rats. Five animals per sex per group were administered the notified chemical (CETEC 2252) once daily by gavage at doses of 0, 15, 150 or 1000 mg/kg bw/day in arachis oil. Sporadic instances of diuresis, wet fur and red/brown staining of the ano-genital region were observed during the last half of the study. No toxicologically relevant effects on functional and behavioural parameters, bodyweight and bodyweight gain, food consumption and haematological parameters were observed. A statistically significant decrease in plasma albumin concentration and an increase in plasma creatinine concentration observed in high dose group males is unlikely indicative of renal or hepatic dysfunction in the absence of correlated biomarkers of hepatic injury, alterations in

plasma electrolyte levels and histopathological findings. High dose group males had a significant increase in relative (to bodyweight) kidney weights, which is likely related to the accumulation of α2-microglobulin in the proximal tubules observed during histopathological examination. The significant increase in relative liver weight in high dose group females and hepatocytic hypertrophy observed histologically in high dose group animals of both sexes is an indication of adaptation to increased metabolic requirements and is not toxicologically significant. Gross pathological examination identified speckled kidneys in high dose males. The histopathological evidence of accumulated eosinophilic material within the renal proximal tubules of high and middose males is consistent with α2-microglobulin nephropathy. On the basis of these observations, repeated administration of the notified chemical to Sprague-Dawley rats did not produce evidence of treatment-related adverse effects in female animals. Male animals exhibited characteristics of α2-microglobulin nephropathy, a phenomenon known to occur only in adult male rats; as such, this finding is without any interspecies toxicological significance. Consequently, the NOAEL for the notified chemical is 1000 mg/kg bw/day, indicative of low repeated-dose toxicity by the oral route (Safepharm, 1999m).

7.8. Genotoxicity – bacteria

Bacterial reverse mutation assays of CETEC 2252 and CETEC 2253 were conducted according to the plate incorporation method in separate experiments. In either case, the test substance did not induce a toxicologically significant increase in the number of revertant colonies of *Salmonella typhimurium* (TA1535, TA1537, TA98, TA100) or *Escherichia coli* WP2*uvr*A-, in the presence or absence of metabolic activation (10% Aroclor 1254 induced rat liver S9 fraction in standard cofactors), at concentrations ranging from 0 to 5000 μg/plate in acetone. The standard positive control substances induced clear increases in the number of revertant colonies, confirming the sensitivity of the test system to known mutagens and the activity of the S9 fraction. The test substance was not mutagenic under the conditions of this *in vitro* assay (Safepharm, 1999n; Safepharm, 1999o).

7.9. Genotoxicity – in vitro

An *in vitro* chromosomal aberration assay was conducted with human peripheral blood lymphocytes using concentrations of 1250, 2500 and 5000 μg/mL in acetone. The notified chemical (CETEC 2252) did not induce a statistically significant, doseresponsive increase in the frequency of cells with structural aberrations or the frequency of polyploid cells following a 4-hour exposure in the presence or absence of metabolic activation (Aroclor 1254 induced rat liver S9 fraction in standard cofactors) or a 20-hour exposure in the absence of metabolic activation. Precipitation of the test substance occurred at all three concentrations, but no evidence of cytotoxicity was observed and no marked reductions in the mitotic index occurred. The positive control substances (-S9: 500/750 μg/mL EMS; +S9: 25 μg/mL CP) induced clear increases in the frequency of structural aberrations, confirming the sensitivity of the test system to known clastogens and the activity of the S9 fraction. The test substance was not clastogenic under the conditions of this *in vitro* assay (Safepharm, 2000).

7.10. Genotoxicity – in vivo

Not determined. Both *in vitro* studies showed no evidence of mutagenicity or clastogenicity and the structure or substructure of the substance is not related to a known mutagen or carcinogen.

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE: CETEC 2252

METHOD: OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test.
- Inoculum: Activated Sewage Sludge (domestic)
- Exposure Period: 28 d
- Auxiliary Solvent:
- Analytical Monitoring: CO_2 analysis, DOC analysis
- Remarks - Method: In order to aid dispersion of the test material in the test system and to increase the surface area of test material available to the activated sewage sludge micro-organisms, the test material was adsorbed onto silica gel prior to addition to the test vessels.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
0	0	0	0
3	1	3	54
6	14	6	67
10	32	10	79
16	33	16	82
24	34	24	91
28	39	28	100

Remarks - Results: The TC/IC ratio of the test material dispersions was in excess of the recommended level of 5% given in the Test Guidelines. This is considered to be due to the low TC concentration in the test medium and hence the IC contribution is relatively large. This was not considered to affect the integrity of the study or the results obtained, given that the CO_2 evolution in the control vessels did not exceed the upper limit of 70 mg/L given in the OECD Guidelines.

The toxicity control attained 38% degradation after 28 days thereby confirming that the test material was not toxic to the sewage treatment micro-organisms used in the study. Sodium benzoate attained 100% degradation after 28 days thereby confirming the suitability of the inoculum and test conditions.

CONCLUSION: The test material cannot be considered to be ready biodegradable under the strict terms and conditions of OECD TG 301B.

TEST FACILITY: Safepharm (1999p)

8.1.2. Bioaccumulation

Remarks - Results: Given the low molecular weight and water solubility of the notified chemical, bioaccumulation may potentially occur. However, release to the aquatic environment is not expected, and the notified chemical is inherently biodegradable.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

A 96 h acute toxicity study (method/guideline: EEC 92/69 C.1/OECD 203) performed on rainbow trout (*Oncorhynchus mykiss*) was provided by the notifier. Fish were exposed to CETEC 2252 (70-100% a.i. of lower molecular weight formulation) at nominal concentrations of 0 and 100 mg/L under semi-static conditions. Ten fish were exposed to each dose (2 replicates). Endpoints are reported in loading rates (e.g. LLR50, NOELR) instead of concentrations as measured concentrations were below the analytical detection limit (using gas chromatography (GC) analysis). The reported 96 h NOELR value, based on 0% mortality and no sub lethal effects, was 100 mg/L. The 96 h LLR50 was calculated to be > 100 mg/L. The test was conducted under Good Laboratory Practices and the report included a signed Compliance with Good Laboratory Practice Standards. The test was conducted on water soluble fractions (WSF). WSF were prepared by mixing for 23 hours and left to settle for 1 hour. Undissolved matter remained and an oily film was observed on the surface and throughout the water column after 1 hour of settling period. The solution was filtered (using a 0.45 µm filter) to ensure exposure to the bioavailable fraction only. The 100 mg/L nominal test concentration was measured and found to be below detection limit (< 0.02 mg/L) (Safepharm, 1999)). Based on the results of this study, CETEC 2252 would be classified as a low hazard to rainbow trout in accordance with the ecotoxicity classification system of the US EPA.

8.2.2. Acute/chronic toxicity to aquatic invertebrates

A 48 h acute toxicity study (Method/Guideline: EEC 92/69 C.2/OECD 202) performed on daphnia (*Daphnia magna*) was provided by the notifier. Daphnia were exposed to CETEC 2252 (70-100% a.i. of lower molecular weight formulation) at nominal concentrations of 0 and 100 mg/L under static conditions. Ten daphnia were exposed to each dose (4 replicates). Endpoints are reported in loading rates (e.g. ELR50, NOELR) instead of concentrations as measured concentrations were below the analytical detection limit (using gas chromatography (GC) analysis). The reported 48 h NOELR value, based on immobilization and no sub lethal effects, was 100 mg/L. The 48 h ELR50 was calculated to be > 100 mg/L. The test was conducted under Good Laboratory Practices and the report included a signed Compliance with Good Laboratory Practice Standards. The test was conducted on water soluble fractions (WSF). WSF were prepared by mixing for 23 hours and left to settle for 1 hour. Undissolved matter remained and an oily film was observed on the surface and throughout the water column after 1 hour of settling period. The solution was filtered (using a 0.45 µm filter) to ensure exposure to the bioavailable fraction only. The 100 mg/L nominal test concentration was measured and found to be below detection limit (< 0.02 mg/L) (Safepharm, 1999r). Based on the results of this study, CETEC 2252 would be classified as a low hazard to daphnia in accordance with the ecotoxicity classification system of the US EPA.

A second 48 h acute toxicity study (Method/Guideline: EEC 92/69 C.2/OECD 202) performed on daphnia (*Daphnia magna*) was provided by the notifier. Daphnia were exposed to CETEC 2253 (70-100% a.i. of higher molecular weight formulation) at nominal concentrations of 0 and 1000 mg/L under static conditions. Ten daphnia were exposed to each dose (4 replicates). Endpoints are reported in loading rates (e.g. EL50, NOEL) instead of concentrations as measured concentrations were below the analytical detection limit (using gas chromatography (GC) analysis). The reported 48 h NOEL value, based on immobilization and no sub lethal effects, was 1000 mg/L. The 48 h EL50 was calculated to be > 1000 mg/L. The test was conducted under Good Laboratory Practices and the report included a signed Compliance with Good Laboratory Practice Standards. The test was conducted on water accommodated fractions (WAF). WAF were prepared by mixing for 23 hours and left to settle for 1 hour. Undissolved matter remained and an oily film was observed on the surface and throughout the water column after 1 hour of settling period. The solution was filtered (using a 0.45 µm filter) to ensure exposure to the bioavailable fraction only. The 1000 mg/L nominal test concentration was measured and found to be below detection limit (< 0.032 mg/L) (Safepharm, 2003). Based on the results of this study, CETEC 2253 would be classified as a low hazard to daphnia in accordance with the ecotoxicity classification system of the US EPA.

8.2.3. Algal growth inhibition test

A 72 h acute toxicity study (Method/Guideline: EEC 92/69 C.3/OECD 201) performed on green algae (*Scenedesmus subspicatus*) was provided by the notifier. Green algae were exposed to CETEC 2252 (70-100% a.i.) at nominal concentrations of 0 and 100 mg/L under static conditions. Six replicates were used for the 100 mg/L dose and 3 replicates were used for the 0 mg/L control. Endpoints are reported in loading rates (e.g. ELR50(r), ELR50(b), NOELR) instead of concentrations as measured concentrations were below the analytical detection limit (using gas chromatography (GC) analysis). The reported 72 h NOELR value, based on cell growth and decrease in total biomass, was 100 mg/L. The 72 h ELR50(r) and 72 h ELR50(b) were calculated to be > 100 mg/L. The test was conducted under Good Laboratory Practices and the report included a signed Compliance with Good Laboratory Practice Standards. The test was conducted on water soluble fractions (WSF). Water soluble fractions were prepared by mixing for 23 hours and left to settle for 1 hour. Undissolved globules and a white cloudy dispersion were observed throughout the water column during and at the end of the mixing. This observation was evident throughout the settling period with the appearance of an oily film on the surface. The solution was filtered (using a 0.45 µm filter) to ensure exposure to the bioavailable fraction only. The 100 mg/L nominal test concentration was measured and found to be below detection limit (< 0.033 mg/L) (Safepharm, 1999s). Based on the results of this study, CETEC 2252 would be classified as a low hazard to green algae in accordance with the ecotoxicity classification system of the US EPA.

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE	CETEC 2252
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test. EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test
Exposure Period	3 hours
Concentration Range	Nominal: 1000 mg/L
Remarks – Method	Following a preliminary range-finding study, activated sewage sludge was exposed to an aqueous dispersion (ultrasonification for 30 minutes) of the test material with the addition of a synthetic sewage as a respiratory substrate. The rate of respiration was determined after 30 minutes and 3 hours contact time and compared to data for the control and a reference material, 3,5-dichlorophenol.
RESULTS	
IC50	>1000 mg/L
NOEC	1000 mg/L
Remarks – Results	The validation criteria for the control respiration rates and reference material EC50 values were satisfied, thereby validating the test.
CONCLUSION	The test substance did not inhibit microbial activity at a concentration of 1000 mg/L.
TEST FACILITY	Safepharm (1999t)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified chemical will be neither manufactured nor reformulated in Australia. Repackaging may occur, with the resultant potential for accidental spills to occur. It is expected that any spilt notified chemical will be contained and disposed of mostly likely by incineration or potentially to landfill. At the end of the useful life of the equipment in which the notified chemical is used, the notified chemical is expected to be drained and disposed of by incineration. Release to the aquatic environment is not anticipated, and correspondingly, a PEC is not able to be calculated.

9.1.2. Environment – effects assessment

The notified chemical was found to be not toxic to the aquatic environment up to its level of water solubility to fish, daphnids and algae.

9.1.3. Environment – risk characterisation

The notified chemical is not expected to be released to the aquatic environment and therefore pose a low risk. Notified chemical that is disposed of by incineration is expected to thermally decompose to form oxides of carbon and water. Notified chemical that is disposed of to landfill is expected to associate with soil and eventually biodegrade to simple organic compounds via biotic and abiotic processes.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Transport, storage and warehouse workers are not expected to have any contact with the notified chemical, except in the case of an accident.

Due to the semi-automatic transfer of lubricants containing the notified chemical (to prevent adsorption of water by the notified chemical), limited exposure to workers is expected during re-packaging (from drums to smaller containers), first-fill and subsequent maintenance of the refrigeration equipment. The estimated dermal exposure is 42 mg/day, based on EASE model (EASE) using reasonable worst case defaults for the exposure scenario 'coupling and decoupling of a transfer line (European Commission, 2003) and assuming the notified polymer is present at concentration of 100%. Therefore, for a 70 kg worker and a 10% dermal absorption factor (based on the high molecular weight and high log P_{ow}), systemic exposure is estimated to be 0.06 mg/kg bw/day.

During use the lubricant is in a closed system and as such negligible exposure is expected. Potential accidental exposure might occur if the sealed unit is punctured or through minor leaks from seals and gaskets in the system. Exposures of service technicians can occur when service equipment or automotive air-conditioning systems leak during servicing. Dermal exposure is expected to be the principal route of exposure although inhalation of lubricant mists could occur. Exposure is only expected to occur less than once per year and only be for a short period of time (< 5 minutes). Exposure would be limited by the recommended use of engineering controls and PPE.

9.2.2. Public health – exposure assessment

The notified chemical is intended to be used as a synthetic lubricant in industrial equipment with minimal sales to the general public. Therefore widespread public exposure is not expected.

Individuals who fill their own automobile refrigeration compressor may de exposed to drips and spills during the transfer of the lubricant containing the notified chemical. The frequency of exposure is expected to be low.

There is also the potential for exposure to lubricant mist inside an automobile in the event of a leak of the vehicle air conditioning system, however, the frequency of exposure is expected to

be very low (<< 1 year).

9.2.3. Human health – effects assessment

The notified chemical is manufactured in two forms which differ in the ratios and types of tetraester reaction products. No significant differences are expected between these two forms in terms of their toxicological properties.

Acute toxicity
The notified chemical is of low acute toxicity by the oral and dermal routes.

Irritation and Sensitisation
Based on the studies provided the notified chemical is considered to be slightly irritating to the skin and eyes but is not likely to induce skin sensitisation.

Repeated Dose Toxicity
In a 28-day oral repeat dose study in rats, a No Observed Adverse Effect Level (NOAEL) was established as 1000 mg/kg bw/day, based on the absence of adverse toxicologically significant treatment related effects observed at any of the doses tested.

Mutagenicity
The notified chemical showed no evidence of mutagenicity or clastogenicity *in vitro.* The structure or substructures of the substance is not related to a known mutagen or carcinogen.

Hazard classification for health effects
Based on the available data, the notified chemical is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004).

9.2.4. Occupational health and safety – risk characterisation

Worker exposure is expected to be greatest for workers involved in the transfer of the lubricant containing the notified chemical (99%) during repackaging or first fill and top up of refrigeration equipment. Exposure to the notified chemical during transfer was estimated to be 0.06 mg/kg bw/day. Based on a NOAEL of 1000 mg/kg bw/day, derived from a 28-day rat oral study the margin of exposure (MOE) is calculated as 16600. MOE greater than or equal to 100 are considered acceptable to account for intra- and inter-species differences. Therefore, the risk of systemic effects using modelled worker data is acceptable for workers. The notified chemical is a slight skin and eye irritant and therefore to reduce the risk of adverse irritant effects workers should wear appropriate PPE (coveralls, impervious gloves and eye protection) to limit exposure.

Acute exposure to the notified chemical could occur during servicing if there is a leak in the equipment, however the notified chemical is of low acute toxicity and as such the risk to top-up/maintenance workers is expected to be low. As a precaution the refrigeration equipment should be located in well-ventilated areas and top up/maintenance workers should wear appropriate PPE as detailed above.

9.2.5. Public health – risk characterisation

Widespread public exposure to the notified chemical is not expected. Where routes of exposure have been identified (DIY automotive compressor filling and automotive air conditioning leaks), the risk to the public is considered to be low due to the low toxicity profile of the notified chemical and the expected low frequency of exposure.

10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

10.1. Hazard classification

Based on the available data the notified chemical is not classified as hazardous under the

NOHSC *Approved Criteria for Classifying Hazardous Substances*.

and

The classification of notified chemical using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003) is presented below. The notified chemical is not classified as hazardous for health endpoints. This system is not mandated in Australia and carries no legal status but is presented in our reports for information purposes.

	Hazard category	***Hazard statement***
Chronic hazards to the aquatic environment	4	May cause long lasting harmful effects to the aquatic environment

10.2. Environmental risk assessment

The chemical is not considered to pose a risk to the environment based on its reported use pattern.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

10.3.2. Public health

There is No Significant Concern to public health when used in the proposed manner.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the products containing the notified chemical provided by the notifier were in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 2003). They are published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

The label for products containing the notified chemical provided by the notifier were in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC 1994). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during servicing of equipment containing the notified chemical:
  - Refrigeration equipment should be located in well-ventilated areas.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introducedand during servicing of equipment containing the notified chemical:
  - Coveralls
  - Eye protection
  - Impervious gloves

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

- The notified chemical as introduced should be handled consistent with provisions of State and Territory legislation regarding the Handling of Combustible and Flammable Liquids.

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

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

Disposal

- The notified chemical should be disposed of by incineration.

Storage

- The notified chemical as introduced should be stored consistent with provisions of State and Territory legislation regarding the Storage of Combustible and Flammable Liquids.

Emergency procedures

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

12.1. Secondary notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(2) of the Act:
  - if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

13. BIBLIOGRAPHY

Chemex (2000) Determination of the surface tension of 2 products. (Chemex reference: ENV5134 2 August 2000) Chemex International plc, Bar Hill Business Park, 37 Saxon Way, Bay Hill, Cambridge CB3 8EL, England (Unpublished report provided by notifier).

Estimation and Assessment of Substance Exposure (EASE). The EASE system was developed by the UK Health and Safety Executive in conjunction with the Artificial Intelligence Applications Institute. For a further description see: Marquart et al., Evaluation of Methods of Exposure Assessment for Premarket Notifications, TNO Report V 94.229 TNO Nutrition and Food Research (Zeist), 1994.

European Commission (2003) Technical Guidance Document on Risk Assessment in Support of Commission Directive 93/67/EEC on Risk Assessment for New Notified Substances and Commission Regulation (EC) No 1488/94 on Risk Assessment for Existing Substances and Directive 98/8/EC of the European Parliament and of the Council Concerning the Placing of Biocidal Products on the Market – Part I. Institute for Health and Consumer protection, European Chemicals Bureau, European Communities.

FORS **(**Federal Office of Road Safety) (1998) Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG code), 6th Edition, Canberra, Australian Government Publishing Service.

NOHSC (1994) National Code of Practice for the Labelling of Workplace Substances [NOHSC:2012(1994)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (2001) *NOHSC National Code of Practice for the Storage and Handling of Workplace Dangerous Goods* [NOHSC:2017(2004)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (2003) National Code of Practice for the Preparation of Material Safety Data Sheets, 2nd edn [NOHSC:2011(2003)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (2004) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

Safepharm (1999a) CETEC 2252: Determination of General Physico-chemical Properties (SPL Project No. 334/130, 30 November 1999). Derby, UK, Safepharm Laboratories Ltd. Sponsor: Castrol International, UK (Unpublished report provided by notifier).

Safepharm (1999b) CETEC 2253: Determination of General Physico-chemical Properties (SPL Project No. 334/166, 10 December 1999). Derby, UK, Safepharm Laboratories Ltd. Sponsor: Castrol International, UK (Unpublished report provided by notifier).

Safepharm (1999c) CETEC 2252: Determination of vapour pressure (SPL Project No. 334/132, 1 December 1999). Derby, UK, Safepharm Laboratories Ltd. Sponsor: Castrol International, UK (Unpublished report provided by notifier).

Safepharm (1999d) CETEC 2253: Determination of vapour pressure (SPL Project No. 334/168, 14 December 1999). Derby, UK, Safepharm Laboratories Ltd. Sponsor: Castrol International, UK (Unpublished report provided by notifier).

Safepharm (1999e) CETEC 2252: Determination of Hazardous Physico-chemical Properties (SPL Project No. 334/131, 1 December 1999). Derby, UK, Safepharm Laboratories Ltd. Sponsor: Castrol International, UK (Unpublished report provided by notifier).

Safepharm (1999f) CETEC 2253: Determination of Hazardous Physico-chemical Properties (SPL Project No. 334/166, 10 December 1999). Derby, UK, Safepharm Laboratories Ltd. Sponsor: Castrol International, UK (Unpublished report provided by notifier).

Safepharm (1999g) CETEC 2252: Acute Oral Toxicity Study in the Rat –Acute Toxic Class Method (SPL Project No. 334/133, 17 May 1999). Derby, UK, Safepharm Laboratories Ltd. Sponsor: Castrol International, UK (Unpublished report provided by notifier).

Safepharm (1999h) CETEC 2253: Acute Oral Toxicity Study in the Rat –Acute Toxic Class Method (SPL Project No. 334/169, 27 May 1999). Derby, UK, Safepharm Laboratories Ltd. Sponsor: Castrol International, UK (Unpublished report provided by notifier).

Safepharm (1999i) CETEC 2252: Acute Dermal Toxicity (Limit Test) in the Rat (SPL Project No. 334/134, 14 May 1999). Derby, UK, Safepharm Laboratories Ltd. Sponsor: Castrol International, UK (Unpublished report provided by notifier).

Safepharm (1999j) CETEC 2252: Acute Dermal Irritation Test in the Rabbit (SPL Project No. 334/135, 14 May 1999). Derby, UK, Safepharm Laboratories Ltd. Sponsor: Castrol International, UK (Unpublished report provided by notifier).

Safepharm (1999k) CETEC 2252: Acute Eye Irritation Test in the Rabbit (SPL Project No. 334/136, 14 May 1999). Derby, UK, Safepharm Laboratories Ltd. Sponsor: Castrol International, UK (Unpublished report provided by notifier).

Safepharm (1999l) CETEC 2252: Magnusson & Kligman Maximisation Study in the Guinea Pig (SPL Project No. 334/137, 14 May 1999). Derby, UK, Safepharm Laboratories Ltd. Sponsor: Castrol International, UK (Unpublished report provided by notifier).

Safepharm (1999m) CETEC 2252: Twenty-eight Day Repeated Dose Oral (Gavage) Toxicity Study in the Rat (SPL Project No. 334/138, 3 December 1999). Derby, UK, Safepharm Laboratories Ltd. Sponsor: Castrol International, UK (Unpublished report provided by notifier).

Safepharm (1999n) CETEC 2252: Reverse mutation assay "Ames test" using Salmonella Typhimurium and Escherichia Coli (SPL Project No. 334/139, 22 April 1999). Derby, UK, Safepharm Laboratories Ltd. Sponsor: Castrol International, UK (Unpublished report provided by notifier).

Safepharm (1999o) CETEC 2253: Reverse mutation assay "Ames test" using Salmonella Typhimurium and Escherichia Coli (SPL Project No. 334/170, 21 April 1999). Derby, UK, Safepharm Laboratories Ltd. Sponsor: Castrol International, UK (Unpublished report provided by notifier).

Safepharm (1999p) CETEC 2252: Assessment of ready biodegradability; CO_2 Evolution Test. (SPL Project No. 334/144, 6 May 1999). Derby, UK, Safepharm Laboratories Ltd. Sponsor: Castrol International, UK (Unpublished report provided by notifier).

Safepharm (1999q) CETEC 2252: Acute toxicity to rainbow trout (*Oncorhynchus mykiss)*. (SPL Project No. 334/141, 13 December 1999). Derby, UK, Safepharm Laboratories Ltd. Sponsor: Castrol International, UK (Unpublished report provided by notifier).

Safepharm (1999r) CETEC 2252: Acute toxicity to *Daphnia magna*. (SPL Project No. 334/142, 3 December 1999). Derby, UK, Safepharm Laboratories Ltd. Sponsor: Castrol International, UK (Unpublished report provided by notifier).

Safepharm (1999s) CETEC 2252: Algal inhibition test. (SPL Project No. 334/143, 15 December 1999). Derby, UK, Safepharm Laboratories Ltd. Sponsor: Castrol International, UK (Unpublished report provided by notifier).

Safepharm (1999t) CETEC 2252: Assessment of the inhibitory effect on the respiration of activated sewage sludge. (SPL Project No. 334/145, 6 May 1999). Derby, UK, Safepharm Laboratories Ltd. Sponsor: Castrol International, UK (Unpublished report provided by notifier).

Safepharm (2000) CETEC 2252: Chromosome Aberration Test in Human Lymphocytes In Vitro (SPL Project No. 334/140, 7 January 2001). Derby, UK, Safepharm Laboratories Ltd. Sponsor: Castrol International, UK (Unpublished report provided by notifier).

Safepharm (2003) CETEC 2253: Acute toxicity to *Daphnia magna*. (SPL Project No. 1271/006, 20 February 2003). Derby, UK, Safepharm Laboratories Ltd. Sponsor: Castrol International, UK (Unpublished report provided by notifier).

United Nations (2003) Globally Harmonised System of Classification and Labelling of Chemicals (GHS). United Nations Economic Commission for Europe (UN/ECE), New York and Geneva.