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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

CL 80-B

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Director
Chemicals Notification and Assessment

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Clariant (Australia) Pty Ltd (ABN 30 069 435 552)
675 Warrigal Road
Chadstone Vic 3148

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical Name
Other Names
CAS Number
Molecular Formula
Structural Formula
Molecular Weight
Spectral Data
Use (details)
Import quantity
Identity of manufacturer/ recipients
Identity of analogue chemicals for toxicological studies

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Hydrolysis as a Function of pH
Adsorption/ desorption
Dissociation constant
Toxicological data (use of analogue data)
Ecotoxicity data (use of analogue data)

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Not specified

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
CL 80-B
Safebrake 6 M (DOT 4)

METHODS OF DETECTION AND DETERMINATION

Remarks The notified chemical has been characterised by infrared spectroscopy and mass spectrometry. Reference spectra were supplied.

3. COMPOSITION

DEGREE OF PURITY
High

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight)
None

ADDITIVES/ADJUVANTS
None

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported as a major component of brake fluid preparations at a concentration of < 60 %.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 300	< 300	< 300	< 300	< 300

USE
The notified chemical will be imported as a component of brake fluid preparations.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Melbourne, Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
Clariant (Australia) Pty Ltd, 100 Heales Road, Lara, Vic

TRANSPORTATION AND PACKAGING
Transportation of the notified chemical as a component of formulated brake fluids will take place via standard road transport for non-dangerous goods. Road transport will be used from wharf to store to repackaging site to retail customers. The brake fluid preparations will be imported in 200 L steel or plastic drums or in 0.25, 0.5, 1.0, 20 or 40 L plastic packs.

5.2. Operation Description

A large proportion of the brake fluid is to be repackaged for distribution for the after-care market. Repackaging will be undertaken at one site.

Repackage brake fluid from 200 L drums into smaller containers will use 3 or 4 packing lines. The packing lines are automated and operators are involved in attaching and detaching suction nozzles that pump the brake fluid either directly into the filling line or into header tanks.

Spill procedures at the repackaging site include bunding of all tank or drum areas and collection of process spills in onsite collection pits. Spilled material is either collected by licensed disposal firms or consigned to sewer under licence. The 200 L drums when emptied will be sent to a drum recycler. Residues from the cleaning and recycling process are expected to be consigned to sewer under licence.

The brake fluid will also be used in new car manufacture to fill new car hydraulic lines. Where brake

fluid is added to reservoirs during new car manufacture, this is a one person operation where hoses are connected to a drum and fluid pumped via an automated system.

At vehicle service stations, brake fluid reservoirs are refilled by pouring manually from the container and small spills may occur and typically be cleaned up with rags. Where the fluid in an entire vehicle system is replaced, the fluid would be collected in a container and held in a storage vessel for disposal.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Packaging operators	20	2-3 hours /day	< 10 days/year
New vehicle production personnel	20	2-4 hours/day	< 100 days/year
Service station	> 1000	1 hour/day	< 50 days/year

Exposure Details

The process to repackage brake fluid from 200 L drums into smaller containers is to take place using 3 or 4 packing lines. The packing lines are automated and operators are only involved in attaching and detaching suction nozzles that pump the brake fluid either directly into the filling line or into header tanks. Dermal contact with drips and spills of the brake fluid may occur at this point. Packaging line operators wear personal protective equipment (gloves and safety spectacles) during the process. The process takes place in an area with general ventilation.

Where brake fluid is added to reservoirs during new car manufacture, this is a one person operation where hoses are connected to a drum and fluid pumped via an automated system. Exposure is expected to be mainly dermal and restricted to drips and spills while connecting and disconnecting the lines. Gloves and safety spectacles will be worn during this process.

At vehicle service stations, brake fluid reservoirs are refilled by pouring manually from the container and small spills may occur and typically be cleaned up with rags. Greater exposure, largely dermal but also ocular (due to transfer of fluid on the hands), may be expected to occur during brake or clutch repair or as part of a routine service, where the fluid in the entire system may be replaced. The fluid would be collected in a container and held in a storage vessel. Personal protective measures such as gloves and safety spectacles may not always be worn during handling of the brake fluids by personnel involved in vehicle servicing. However, the notifier states that recommendations will be made on brake fluid packaging for users to prevent eye and skin contact. Used fluids are likely to be collected in drums and removed for incineration by licensed contractors, who are likely to have similar exposure to the workers involved in hydraulic system servicing.

5.4. Release

RELEASE OF CHEMICAL AT SITE

No release of the notified chemical during repackaging is anticipated, except in the event of accidental spills. To contain spills at the repackaging site, bunding is in place in all tank/drum areas, where collection of process spills occurs in onsite collection pits. Spilled material is either collected by licensed disposal firms or consigned to sewer under licence.

The notifier expects the amount of new substance left in containers after emptying of drums during the repackaging process or after filling or refilling hydraulic circuits will be low because of the low viscosity (viscosity (kinematic) 15-17.5 mm^2/s at 20ºC) of the brake fluid. It is estimated that up to 0.1 % of the notified chemical may remain in each 200 L drum. This equates to up to 300 kg annually of the new chemical if all imported material was repackaged. When emptied, the 200 L drums will be sent to a drum recycler. Residues from the cleaning/recycling process are expected to be consigned to sewer under licence.

RELEASE OF CHEMICAL FROM USE

At end use, release of the notified chemical contained in the brake fluid could occur mainly through leakages from the hydraulic systems in vehicles, accidental spills during brake fluid changes, and during disposal of used fluids following changes. The notifier anticipates that users of the brake fluid

formulation will include 70 % professional after-care, 20 % private after-care, 10 % new car manufacturers. The notifier has provided the following estimates of releases for each of the these usage patterns:

(a) Professional after-care
Residues in drums, 30 % of (70 % of 300 t) with 0.1 % residues = 63 kg/annum
Residues in small packaging, 40 % of (70 % of 300 t) with 0.1 % residues = 84 kg/annum
Spills and leaks, <0.1 % of (70 % of 300 t) = 210 kg/annum

(b) Private after-care
Residues in small packaging, 20 % of 300 t with <0.1 % residues = 60 kg/annum
Spills and leaks, <0.1 % of (20 % of 300 t) = 60 kg/annum

(c) New car manufacturers
Residues in drums, 10 % of 300 t with 0.1 % residues = 30 kg/annum

The combined annual total of waste is approximately 500 kg notified chemical. Car manufacturers recommend draining and refilling of brake fluid systems every two years. It is expected that most brake fluid removed from the reservoirs in vehicles at motor garages will be collected and mixed with waste oils, which would be sent for oil recycling or incineration.

5.5. Disposal

Material spilled during repackaging is either collected by licensed disposal firms or consigned to sewer under licence, while residues from the cleaning and drum recycling process are consigned to sewer under licence. Empty container residues of the brake fluid are expected to be discarded with domestic garbage and disposed of into landfill. Used brake fluid remaining after oil changes is likely to be recycled or incinerated. The MSDS recommends disposal in accordance with government regulations for the disposal of special waste, which may include incineration in an approved incinerator.

5.6. Public exposure

Public exposure largely will be limited to persons who service their own vehicles and who will therefore have a need on occasion to service the hydraulic brake system on their vehicles. During this activity, substantial dermal exposure may occur if material is spilt, but under normal and foreseeable worst-cases these circumstances are likely to be minimal.

In the event of a transport accident the main potential source of exposure would be from fumes derived from burning brake fluid. In the absence of a fire any spilt material could be recovered through adsorption onto sand, soil or vermiculite with disposal according to local government regulations.

The use of the notified chemical during the manufacture of new cars or the servicing of cars is unlikely to result in exposure of the public. The brake fluids are non-volatile liquids and brake systems on vehicles are essentially sealed. Hence under normal circumstances, the public will not have an opportunity to come into contact with the notified chemical.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa		clear yellow liquid, characteristic odour
Melting Point/Freezing Point		< -60°C
Remarks	No details provided	
Boiling Point		Approximately 290°C (at 102.5 kPa)
Remarks	No details provided	
Density		Approximately 1100 kg/m^3 at 20°C

Remarks No details provided

Vapour Pressure $<6\times10^{-12}$ kPa at 25ºC

METHOD Estimation Method
Remarks Calculated for the most volatile component using EPI Win, Syracuse Research Corp (2000). The notified chemical is very slightly volatile (Lyman *et al*. 1982).

Water Solubility Completely miscible

Remarks No details were provided. The high proportion of polar functionalities in the compound indicate the notified chemical will be completely water soluble.

Hydrolysis as a Function of pH Not determined

Remarks No data on hydrolysis are available. The ether links are very stable and unlikely to hydrolyse in the usual environmental pH region between 4 and 9. Hydrolytic cleavage of the borate ester bonds is possible. Since the components of the brake fluid are hygroscopic, it is likely that water would become absorbed during normal usage of the formulations containing the substance, and consequently it is likely that some hydrolysis to boric acid and the parent compound could occur.

Partition Coefficient (n-octanol/water) log Pow ≤ 0.5

Remarks Calculated using EPI Win, Syracuse Research Corp (2000). The notified chemical is relatively hydrophilic and is not expected to have a high affinity to lipids. The estimated log (BCF) is approximately 0.5, indicating a low bioaccumulation potential (Mensink *et al*. 1995).

Adsorption/Desorption Not determined

Remarks The calculations based on EPI Win (Syracuse Research Corp, 2000) indicate the chemical will have very little affinity for hydrocarbon-like environments and would partition exclusively to water.

Dissociation Constant Not determined

Remarks The notified chemical contains no functional groups which can dissociate in aqueous solution.

Particle Size

Remarks The notified chemical is liquid under ambient conditions.

Flash Point > 140ºC

METHOD DIN 51376
Remarks No details provided

Flammability Limits Not determined

Remarks Not determined as flash point is > 70ºC; also due to low vapour pressure.

Autoignition Temperature Not determined

Remarks Not determined as flash point is > 100ºC

Explosive Properties Not explosive

Remarks The structure does not indicate the likelihood of explosive properties.

Reactivity

Remarks	Not expected to be reactive under normal environmental conditions, apart from the possibility of ester hydrolysis.

7. TOXICOLOGICAL INVESTIGATIONS

Toxicity data for r a number of analogue chemicals, listed as Borate Ester A, Borate Ester B and Borate Ester C were provided. The chemical composition of the analogue chemicals has been claimed as exempt information. All analogues are considered to appropriately represent the toxicity of the notified chemical for the given endpoints. A number of summaries of the toxicity of formulated brake fluids (DOT 4 type), which contain a major proportion of an analogue borate ester, were also provided.

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50 > 5000 mg/kg bw	low toxicity
Rat, acute dermal LD50 > 2000 mg/kg bw	low toxicity (based on analogue data)
Rat, acute inhalation	No information provided
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation - adjuvant test	no evidence of sensitisation.
Rat, oral repeat dose toxicity - 28 days.	NOEL 150 mg/kg bw/day
Genotoxicity - bacterial reverse mutation	non mutagenic (based on analogue data)
Genotoxicity - in vitro Mammalian Chromosomal Aberration Test	non genotoxic (based on analogue data)
Genotoxicity - in vivo	No information provided
Pharmacokinetic/Toxicokinetic studies	No information provided
Developmental and reproductive effects	not teratogenic (based on analogue data)
Carcinogenicity	No information provided

7.1. Acute toxicity – oral

7.1.1. Acute toxicity – oral (Borate Ester C)

TEST SUBSTANCE	Borate Ester C
METHOD	Not specified
Species/Strain	Rat/Wistar Hoe:WSKf(SPF71)
Vehicle	25 % solution in deionised water
Remarks – Method	The test predates GLP guidelines.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	10 / Female	5000	0/10

LD50	> 5000 mg/kg bw
Signs of Toxicity	Approximately 40 minutes after dosing, passivity and stupor were seen in all animals. No clinical signs of toxicity were observed after 24 hours. Body weight development was not affected.
Effects in Organs	Reddened adrenals
Remarks – Results	None
CONCLUSION	The test substance is of low toxicity via the oral route.
TEST FACILITY	Aventis Pharma Deutschland, Hattersheim, Germany (2000a) English translation of a report originally written in 1980 in German.

7.1.2. Acute toxicity – oral (Borate Ester A)

TEST SUBSTANCE	Borate Ester A
METHOD	OECD TG 401 Acute Oral Toxicity. EC Directive 92/69/EEC B.1 Acute Toxicity (Oral).
Species/Strain	Rat/Wistar Hoe:WSKf(SPF71)
Vehicle	undiluted

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5 per sex	2000	0/10

LD50	> 2000 mg/kg bw
Signs of Toxicity	No clinical signs of toxicity were observed. Body weight development was not affected.
Effects in Organs	Gross necropsy revealed no macroscopically visible changes.
Remarks – Results	None
CONCLUSION	The test substance is of low toxicity via the oral route.
TEST FACILITY	Hoechst AG, Toxicology Department, Frankfurt, Germany (1995a)

7.1.3. Acute toxicity – oral (Borate Ester B)

TEST SUBSTANCE	Borate Ester B
METHOD	OECD TG 401 Acute Oral Toxicity. EC Directive 92/69/EEC B.1 Acute Toxicity (Oral).
Species/Strain	Rat/Wistar Hoe:WISKf(SPF71)
Vehicle	25% solution in deionised water

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5 per sex	5000	0/10

LD50	> 5000 mg/kg bw
Signs of Toxicity	No clinical signs of toxicity were observed. Body weight development was not affected.
Effects in Organs	Gross necropsy revealed no macroscopically visible changes.
Remarks – Results	None
CONCLUSION	The test substance is of low toxicity via the oral route.
TEST FACILITY	Hoechst AG, Toxicology Department, Frankfurt, Germany (1984)

7.1.4. Acute toxicity – oral (Borate Ester A)

TEST SUBSTANCE	Borate Ester A
METHOD	OECD TG 401 Acute Oral Toxicity.
Species/Strain	Rat (strain not stated)
Vehicle	No information available
Remarks – Method	The test was not performed under GLP conditions. No method description

was provided.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5 per sex	5000	0/10

LD50	> 5000 mg/kg bw
Signs of Toxicity	Overt signs of toxicity included hunched posture in all of the five females and two of the five males, lacrimation, lethargy and abasia in one or two females and unkempt appearance and encrustation of the periorbital zone in one or two males. Recovery was seen by day 3 after treatment. No effects were reported on body weight gain.
Effects in Organs	No effects were seen at gross necropsy.
Remarks – Results	A IUCLID summary of the test only was provided.

CONCLUSION The test substance is of low toxicity via the oral route.

REFERENCE ECB (2000)

7.1.5. Acute toxicity – oral (Borate Ester A)

TEST SUBSTANCE Borate Ester A

METHOD EC Directive 92/69/EEC B.1 Acute Toxicity (Oral).

Species/Strain	Rat (strain not stated)
Vehicle	No information available
Remarks – Method	No method description was provided.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	Number not stated; both sexes used.	5000	none

LD50	> 5000 mg/kg bw
Signs of Toxicity	Overt signs of toxicity included abasia/ataxia, hunched posture, piloerection, unkempt appearance, lacrimation, prostration and staining of the anogenital fur in both sexes, lethargy amongst males and bradypnoea amongst females. Complete recovery was seen within 8 days of treatment. No effects were reported on body weight gain.
Effects in Organs	No effects at gross necropsy were reported.
Remarks – Results	A IUCLID summary of the test only was provided.

CONCLUSION The test substance is of low toxicity via the oral route.

REFERENCE ECB (2000)

7.2. Acute toxicity - dermal

7.2.1. Acute toxicity – dermal (Brake fluid DOT 4 type)

TEST SUBSTANCE Brake fluid (DOT 4 type)

METHOD OECD TG 402 Acute Dermal Toxicity

Species/Strain	Rat (strain not stated)
Vehicle	No information available
Type of dressing	No information available

Remarks – Method	The test was not performed under GLP conditions. No method description was provided.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	Not stated	2000	None

LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	There were no signs of overt toxicity or effects on body weight gain.
Signs of Toxicity - Systemic	Not stated
Effects in Organs	No macroscopic changes in the principal organs and tissues were observed.
Remarks – Results	A IUCLID summary of the test only was provided.

CONCLUSION The test substance is of low toxicity via the dermal route.

REFERENCE ECB (2000)

7.2.2 Acute toxicity – dermal (Brake fluid DOT 4 type)

TEST SUBSTANCE Brake fluid (DOT 4 type)

METHOD No information available

Species/Strain	Rat (strain not stated)
Vehicle	No information available
Type of dressing	No information available
Remarks – Method	No method description was provided.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5 per sex	2000	0/10

LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	Not stated
Signs of Toxicity - Systemic	There were no overt signs of toxicity. During the first week, some animals showed only a slight body weight gain and one female lost weight. All animals had gained weight by the end of the 14-day observation period.
Effects in Organs	Gross necropsy revealed minor vascular congestion of the dermis at the site of application in two of the five males and three of the five females.
Remarks – Results	A IUCLID summary of the test only was provided.

CONCLUSION The test substance is of low toxicity via the dermal route.

REFERENCE ECB (2000)

7.3. Acute toxicity - inhalation

No study reports were provided by the notifier.

7.4. Irritation – skin

7.4.1 Irritation – skin (Borate Ester C)

TEST SUBSTANCE Borate Ester C

METHOD FDA Guideline (Federal Register 38, No. 187, 27 Sep 1973, p 27019)
Species/Strain Rabbit/Himalayan albino
Number of Animals 6
Vehicle Undiluted
Observation Period 72 hours
Type of Dressing Occlusive.
Remarks – Method The test predates GLP guidelines.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Erythema/Eschar	0.61	2	72h	1
Oedema	0.06	1	24h	0

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

Remarks – Results Half the exposed skin area was abraded prior to application of the notified chemical. The abraded area showed slightly higher scores for erythema (up to grade 3 at 24 hours). The above scores were for unabraded skin only.

CONCLUSION The test substance is slightly irritating to skin.

TEST FACILITY Aventis Pharma Deutschland GmbH, Hattersheim, Germany (2000b) English translation of a report originally written in 1980 in German.

7.4.2 Irritation – skin (Borate Ester A)

TEST SUBSTANCE Borate Ester A

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.
EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).
Species/Strain Rabbit/New Zealand White Chbb: NZW (SPF)
Number of Animals 3
Vehicle Undiluted
Observation Period 72 hours
Type of Dressing Semi-occlusive.

RESULTS
Remarks – Results There was no evidence of an irritant reaction; the individual and mean erythema and oedema scores (on a five point scale) being 0. No other dermal lesions were reported.

CONCLUSION The test substance is non-irritating to skin.

TEST FACILITY Hoechst AG, Pharma Research Toxicology, Frankfurt, Germany (1995b)

7.4.3 Irritation – skin (Brake fluid DOT 4 type)

TEST SUBSTANCE Brake fluid (DOT 4 type)

METHOD EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).
Species/Strain Rabbit (strain not stated)
Number of Animals Not stated
Vehicle Undiluted
Observation Period 7 days

Type of Dressing	Semi-occlusive.
Remarks – Method	The test was not performed under GLP conditions. No method description was provided.

RESULTS

Remarks – Results	There was no evidence of an irritant reaction; the individual and mean erythema and oedema scores (on a five point scale) being 0. No other dermal lesions were reported. A IUCLID summary of the test only was provided.

CONCLUSION The test substance is non-irritating to skin.

REFERENCE ECB (2000)

7.4.4 Irritation – skin (Brake fluid DOT 4 type)

TEST SUBSTANCE Brake fluid (DOT 4 type)

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.

Species/Strain	Rabbit (strain not stated)
Number of Animals	Not stated.
Vehicle	Undiluted
Observation Period	7 days
Type of Dressing	Semi-occlusive.
Remarks – Method	No method description was provided.

RESULTS

Remarks – Results	There was no evidence of an irritant reaction; the individual and mean erythema and oedema scores (on a five point scale) being 0. No other dermal lesions were reported. A IUCLID summary of the test only was provided.

CONCLUSION The test substance is non-irritating to skin.

REFERENCE ECB (2000)

7.5. Irritation - eye

7.5.1 Irritation – eye (Borate Ester C)

TEST SUBSTANCE Borate Ester C

METHOD FDA Guideline (Federal Register 38, No. 187, 27-Sep-1973, p 27019)

Species/Strain	Rabbit/Himalayan albino
Number of Animals	6
Observation Period	72 hours
Remarks – Method	The test predates GLP guidelines. 24 hours after treatment the eyes were rinsed with physiological saline.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	0.78	2	72 h	1
Conjunctiva: chemosis	0.11	1	24 h	0
Conjunctiva:discharge	0.06	1	24 h	0
Corneal opacity	0	0	0	0
Iridial inflammation	0	0	0	0

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

Remarks – Results	Conjunctival redness (grade 1) persisted in 2 animals beyond 72 hours. No findings were made on fluorescein treatment at 48 and 72 hours.

CONCLUSION The test substance is a slight eye irritant.

TEST FACILITY Aventis Pharma Deutschland GmbH, Hattersheim, Germany (2000b) English translation of a report originally written in 1980 in German.

7.5.2 Irritation – eye (Borate Ester A)

TEST SUBSTANCE Borate Ester A

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).

Species/Strain	Rabbit/New Zealand White Chbb: NZW (SPF)
Number of Animals	3
Observation Period	72 h

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	0.33	1	0.66	2	48 h	0
Conjunctiva: chemosis	0	0	0	2	1 h	0
Conjunctiva: discharge	0	0	0	2	1 h	0
Corneal opacity	0	0	0	0	0	0
Iridial inflammation	0	0	0	0	0	0

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

Remarks – Results	One hour up to 2 days after application the conjunctivae of the animals were hyperaemic up to a diffuse, crimson colour. Three days after application all irritation was reversible.

CONCLUSION The test substance is a slight eye irritant.

TEST FACILITY Hoechst AG, Pharma Research Toxicology, Frankfurt, Germany (1995c)

7.5.3 Irritation – eye (Brake fluid DOT 4 type)

TEST SUBSTANCE Brake fluid (DOT 4 type)

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.

Species/Strain	Rabbit (strain not stated)
Number of Animals	3
Observation Period	7 days
Remarks – Method	The test was not performed under GLP conditions. No method description was provided.

RESULTS

Remarks – Results	A moderate initial pain response (grade 4 on a six point scale) immediately following instillation was recorded in all animals. Within 1 hour of treatment, all developed an ocular discharge, slight chemosis (in two females this was sufficient to cause partial eversion of the eye lids 4 hours after treatment) and either injection of the conjuntival blood vasculature or a crimson-red appearence of the conjunctivae. Complete recovery was seen within 48 hours of treatment. The cornea and iris were

not visibly affected. The group mean of the 24, 48 and 72 hours scores for redness, chemosis, corneal opacity and iridial effects were 0.3, 0.3, 0.0 and 0.0 respectively. A IUCLID summary of the test only was provided.

CONCLUSION The test substance is a slight eye irritant.

REFERENCE ECB (2000)

7.5.4 Irritation – eye (Brake fluid DOT 4 type)

TEST SUBSTANCE Brake fluid (DOT 4 type)

METHOD EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).
Species/Strain Rabbit (strain not stated)
Number of Animals 3
Observation Period 7 days
Remarks – Method No method description was provided.

RESULTS
Remarks – Results Instillation resulted in no or practically no initial pain response. All of the animals developed injection of the conjunctival blood vasculature and slight chemosis within 4 h of treatment. Slight ocular discharge was reported in 2 males and one female. Complete recovery was seen within 72 hours of treatment. The cornea and iris were not visibly affected. The group mean of the 24, 48 and 72 hours scores for redness, chemosis, corneal opacity and iridial effects were 0.4, 0.0, 0.0 and 0.0 respectively. A IUCLID summary of the test only was provided.

CONCLUSION The test substance is a slight eye irritant.

REFERENCE ECB (2000)

7.6. Skin sensitisation

TEST SUBSTANCE Brake fluid (DOT 4 type)

METHOD OECD TG 406 Skin Sensitisation - Maximization Test
Species/Strain Guinea pig (strain not stated)
Vehicle Water
MAIN STUDY
Number of Animals Test Group: 10 per sex Control Group: 5 per sex
INDUCTION PHASE Induction Concentration:
intradermal injection 0.6 %
topical application 100 %
Signs of Irritation Not stated
CHALLENGE PHASE
1st challenge topical application: 60 %
Remarks – Method The test was not performed under GLP conditions. No method description was provided.

RESULTS
Remarks – Results None of the 20 test animals showed a positive sensitisation response at 24 hour or 48 hour after removal of the challenge patch.

CONCLUSION There was no evidence of reactions indicative of skin sensitisation to the test substance under the conditions of the test. A IUCLID summary of the test only was provided.

REFERENCE ECB (2000)

7.7. Repeat dose toxicity

TEST SUBSTANCE Brake fluid (DOT 4 type)

METHOD Not specified
Species/Strain Rat/Crl:CD(SD)BR
Route of Administration Oral – gavage
Exposure Information Total exposure days: 28 days;
Dose regimen: 7 days per week
Vehicle Not specified
Remarks – Method All animals were examined daily for overt signs of toxicity and body weight gain and food intake were measured weekly. During Week 4, haematology, blood clinical chemistry and urine analyses were conducted. At study termination, the animals were sacrificed, weighed and examined grossly. The major organs were weighed and tissues from 15 organs and any animals dying during treatment examined microscopically. The liver tissue from all groups and any grossly visible lesions were also examined microscopically.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5 per sex	0	0/10
II (low dose)	5 per sex	25	0/10
III (mid dose)	5 per sex	150	0/10
IV (high dose)	5 per sex	1000	0/10

Mortality and Time to Death
There were no premature decedents during the study.

Clinical Observations
There were no treatment related deaths or overt signs of toxicity and body weight gains were not affected. During the first 2 weeks of the study, mean food intake of the top-dose males was slightly but statistically significantly decreased. There was no such effect on the females or at the lower doses.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
Haematology and blood clinical chemistry analyses showed no treatment-related effects. The mean urinary pH of the males was decreased at the top-dose and increased at the mid-dose and variations in urinary volume, osmolality and glucose in the low- and mid-dose females were reported.

Effects in Organs
No differences in organ weights or macroscopic appearance of the organs, at necropsy, were reported at any dose level. Microscopic examination revealed very slight centrilobular hypertrophy of the liver in 3 of the females and all of the males at the top dose.

Remarks – Results
A IUCLID summary of the test only was provided.

CONCLUSION
Based on the microscopic findings in the liver, the No Observed Effect Level (NOEL) was established as 150 mg/kg bw/day and the Lowest Observed Effect Level (LOAEL) was established at 1000 mg/kg bw/day in this study.

REFERENCE ECB (2000)

7.8. Genotoxicity – bacteria

TEST SUBSTANCE	Brake fluid (DOT 4 type)
METHOD	Method as described by Maron, D.M. and Ames, B.N.: Revised methods for the Salmonella mutagenicity test; Mutation Research 113, 173-215 (1983)
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA1538, TA98, TA100 *E. coli*: WP2 uvrA (pKM101)
Metabolic Activation System	S9 fraction from Aroclor 1254 induced male Fischer 344 rat liver
Concentration Range in Main Test	a) With metabolic activation: 31.25 - 5000 µg/plate. b) Without metabolic activation: 31.25 - 5000 µg/plate.
Vehicle	Not specified
Remarks – Method	No method description was provided.
RESULTS	
Remarks – Results	There was no increase in the reverse gene mutation rate in any strain tested in the absence or presence of metabolic activation. There was no evidence of cytotoxicity. A IUCLID summary of the test only was provided.
CONCLUSION	The test substance was not mutagenic to bacteria under the conditions of the test.
REFERENCE	ECB (2000)

7.9. Genotoxicity – in vitro

TEST SUBSTANCE	Brake fluid (DOT 4 type)
METHOD	OECD TG 473 In vitro Mammalian Chromosomal Aberration Test. EC Directive 84/449/EEC B.10
Species/Strain	Chinese hamster ovary cells
Cell Type/Cell Line	CHO-K1
Metabolic Activation System	S9 fraction from Aroclor 1254 induced rat liver
Vehicle	Methanol
Remarks – Method	The test material was added to the cells either undiluted or diluted in methanol. Cells were exposed to the test material for 24 hours in the absence of metabolic activation and for 3 hours in the presence of Aroclor induced rat liver S9.
RESULTS	
Remarks – Results	There was no evidence of cytotoxicity. In the presence of S9, two experiments were conducted. In the first, there were no significant differences in the numbers of chromosome aberrations in cultures treated at 200, 937.5, or 1875 µg/mL when compared with the solvent control. A significant difference, however, was recorded between the solvent and untreated controls. In the second experiment, cultures were exposed at 1500 (concentration lower than the highest of the first experiment), 3000 or 5000 µg/mL. There was a slight, but significant difference in the number of cells with aberrations including mainly gaps and cells with chromatid gaps and/or isogaps at the lowest concentration, compared with the solvent controls. The number of cells with chromatid gaps and/or isogaps was also slightly significantly different between the highest concentration and the solvent controls, as well as between the untreated and solvent control cultures. Based on the lack of agreement between the controls, the lack of

confirmation in the first experiment, and the absence of linear dose-response, the study authors are stated to have concluded that the observations in the second experiment were not test substance related.

A IUCLID summary of the test only was provided.

CONCLUSION The test substance was not clastogenic to Chinese hamster ovary cells treated in vitro under the conditions of the test.

REFERENCE ECB (2000)

7.10. Genotoxicity – in vivo

No study reports were provided by the notifier.

7.11. Developmental toxicity

TEST SUBSTANCE Brake fluid (DOT 4 type)

METHOD

Species/Strain	Rat (strain not stated)
Route of Administration	Oral – gavage
Exposure Information	Exposure period: days 7-17 of pregnancy
Vehicle	Not stated
Remarks – Method	Chernoff and Kavlock development toxicity screen in the rat.

Control animals were either sham exposed (negative controls) or received ethylene glycol diethyl ether (positive controls). Dams were allowed to litter naturally and animals not giving birth by day 25 being killed to determine pregnancy status.

RESULTS

Group	*Number of Animals*	*Dose mg/kg bw/day*	*Mortality*
I	10	0	0/10
II	10	25	0/10
III	10	150	0/10
IV	10	1000	0/10

Mortality and Time to Death

No deaths occurred among the dams.

Effects on Dams

There were no decreases in maternal care of the pups, overt signs of toxicity or effects on their body weight gain and food intakes.

Effects on Foetus

There were no dose-related differences in gestation length, post implantation loss, pup loss at birth and viability of pups when compared with the sham treated controls and mean litter weights on days 1 and 5 of lactation were comparable with this control group. Necropsy revealed no treatment-related changes.

Remarks – Results

The positive control animals showed total resorption of litters. The study authors concluded that the material is unlikely to be a teratogen.

A IUCLID summary of the test only was provided.

CONCLUSION

NOAEL Maternal toxicity: 1000 mg/kg bw/day

NOAEL Embryotoxicity: 1000 mg/kg bw/day

REFERENCE ECB (2000)

8. ENVIRONMENT

Environmental investigations were carried out on an analogue chemical, closely related to the notified chemical, Borate Ester B, or on a formulated brake fluid (DOT 4 type) containing an analogue similar to the notified chemical. The chemical composition of the analogue chemicals has been claimed as exempt information. All analogues are considered to appropriately represent the toxicity of the notified chemical for the given endpoints.

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE Borate Ester B

METHOD OECD TG 301 E Ready Biodegradability: Modified OECD Screening Test.

Inoculum	Aqueous phase of non-adapted activated sludge
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Dissolved Organic Carbon (DOC)
Remarks - Method	Duplicate samples containing concentrations of 60 mg/L of the test substance, corresponding to a TOC content of 0.475 mg C/mg test item and a carbon content of 28.5 mg C/L, were tested for ready biodegradability. Sodium acetate in a concentration of 130 mg/L was used as the functional control to check the activity of the test system. A test vessel containing both the test substance and the reference substances was used as a toxicity control. The amount of biodegradation of the test item over time was determined by measurement of DOC at regular intervals over the exposure period.

RESULTS

Test substance		*Sodium acetate*	
Day	*% degradation*	*Day*	*% degradation*
7	9	3	>10
17	>70	7	91
28	96	14	92

Remarks - Results After 8 days, 10 % of the test substance was degraded. In the 10-d-window, beginning at day 7, 70 % of the test substance was degraded, while at day 28, 96 % of the test substance was degraded. The test substance attained a pass level (> 70 %) of biodegradation after 17 days. The functional control attained 70 % biodegradation after 3 days. In the toxicity control, biodegradation reached 64 % after 14 days, indicating the test item had no inhibitory effect during the test. The validity criteria of the test were fulfilled according to the guideline.

CONCLUSION The test substance is readily biodegradable.

TEST FACILITY Clariant GmbH Laboratorium für angewandte Biologie, Sarstedt, Germany (2000a)

8.1.2. Bioaccumulation

A bioaccumulation study was not provided. The BCF was estimated based on EPI Win (Syracuse Research Corp., 2000), which gave an estimated log (BCF) of approximately 0.5. Additionally, log Pow was estimated to be ≤ 0.5. These results indicate the chemical has very little affinity for hydrocarbon-like environments and is readily water-soluble. As such the notified chemical is not likely to bioaccumulate.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Borate Ester B
METHOD	OECD TG 203 Fish, Acute Toxicity Test, (Static, Limit test)
Species	*Brachydanio rerio* (Zebra Fish)
Exposure Period	96 h
Auxiliary Solvent	None
Water Hardness	59 mg $CaCO_3$/L
Analytical Monitoring	DOC-analysis; water quality parameters of temperature, pH-value, oxygen saturation measured at 0, 24, 48, 72 and 96 h.
Remarks – Method	Following a preliminary range finding test (static conditions), 7 test organisms each were exposed to nominal test concentrations of 0 (control) and 100 mg/L of test substance for a 96 h period. The test substance was added to filtered water and the test item remained dissolved throughout the test. DOC-analysis of the control and test media was carried out at the start of the test. All effects are based on nominal concentrations.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*			
Nominal mg/L	*Actual DOC mg/L*		*24 h*	*48 h*	*72 h*	*96 h*
Control	1.1	7	0	0	0	0
100	37.8	7	0	0	0	0

LC50	>100 mg/L at 96 hours.
NOEC (or LOEC)	100 mg/L at 96 hours.
Remarks – Results	No fish mortalities or abnormal behaviours were observed during the test. Water quality parameters were determined to be within the acceptable limits.
CONCLUSION	The test substance is very slightly toxic to Zebra fish (Mensink *et al*. 1995).
TEST FACILITY	Clariant GmbH Laboratorium für angewandte Biologie, Sarstedt, Germany (2000b)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Brake Fluid (DOT 4 type)
METHOD	Not specified.
Species	*Daphnia magna (Crustacea)*
Exposure Period	48 hours
Auxiliary Solvent	Not reported
Water Hardness	154 mg $CaCO_3$/L
Analytical Monitoring	Not reported
Remarks – Method	*Daphnia magna*, less than 24 hours old, from a laboratory culture were exposed to the test item. No information was provided on the test

	concentrations. Test conditions included: temperature 18–22ºC; pH 8.1–8.4; total hardness 154 mg $CaCO_3$/L; dissolved oxygen 8.6 – 9.0 mg/L. No further information was provided on the test methods or procedures.
RESULTS	
LC50	> 1000 mg/L at 48 hours
NOEC (or LOEC)	Not reported.
Remarks – Results	No further information on the test results was provided.
CONCLUSION	The test substance is very slightly toxic to *Daphnia magna* (Mensink *et al*. 1995).
REFERENCE	ECB (2000)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	Brake Fluid (DOT 4 type)
METHOD	No method description provided.
Species	*Selenastrum capricornutum* (Algae)
Exposure Period	96 hours
Concentration Range Nominal	Not specified
Concentration Range Actual	Not specified
Auxiliary Solvent	Not specified
Water Hardness	Not specified
Analytical Monitoring	Not specified
Remarks – Method	Test parameters were: temperature 22–26ºC; pH 7.0–7.4; initial concentration of 500 cells/mL; illumination ~3000 lux; cell counts were made using a Coulter Counter. No further information was provided on the test methods or procedures.
RESULTS	
Remarks – Results	EC50 (growth rate), 430 mg/L at 96 h. No further information on the test results was provided.
CONCLUSION	The test substance is very slightly toxic to green algae (Mensink *et al*. 1995).
REFERENCE	ECB (2000)

8.2.4.1 Inhibition of microbial activity

TEST SUBSTANCE	Borate Ester B
METHOD	DIN EN ISO 11348-2 (1999) – Luminescent bacteria test
Inoculum	*Vibrio fischeri* (Bacteria)
Exposure Period	30 minutes
Concentration Range Nominal	Nine test concentrations in the range from 0.3 to 5.1 g/L, using dilution ratios of 1:2, 1:3, 1:4, 1:6, 1:8, 1:12, 1:16, 1:24, 1:32.
Remarks – Method	Test vials containing aqueous suspensions of the bacteria were exposed to the test substance for 30 minutes in a static test. The inhibitory effects of the test substance on the light emissions (luminescence) of bacteria were determined and compared to a blank control.
RESULTS	
EC20	2200 mg/L
EC50	> 5000 mg/L

Remarks – Results	The concentration effect was calculated by linear regression. Deviation of double determinations from the mean were less than or equal to 3%, indicating the validity criteria were fulfilled.
CONCLUSION	The test substance is very slightly toxic to luminescent bacteria (Mensink *et al*. 1995).
TEST FACILITY	Clariant GmbH, Functional Chemicals, Frankfurt, Germany (2002c)

8.2.4.2 Inhibition of microbial activity

TEST SUBSTANCE	Brake Fluid (DOT 4 type)
METHOD	Not specified
Inoculum	*Pseudomonas fluorescens* (Bacteria)
Exposure Period	Not specified
Concentration Range Nominal	Not specified
Remarks – Method	The data was derived from a IUCLID Dataset. No information was provided on the test methods or procedures.
RESULTS	
IC50	>1000 mg/L
NOEC	Not specified
Remarks – Results	The test substance caused a maximum of 19 % inhibition at 1000 mg/L, the highest concentration tested.
CONCLUSION	The test substance is very slightly toxic to bacteria (Mensink *et al*. 1995).
REFERENCE	ECB (2000)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified chemical will be imported into Australia as a major (< 60 %) component of brake and clutch fluids. During use, the notified chemical will be contained within closed hydraulic systems, and hence negligible environmental release is expected during normal operations of motor vehicles. However some release of the chemical could occur during repackaging of the formulated product, and at end use, through operational spills and leaks, and disposal of used brake fluids and container residues.

During repackaging, spills and residues from the cleaning and drum recycling process will either be collected by licensed disposal firms or consigned to sewer under licence. Used brake fluid removed from vehicles is expected to be mixed with waste oil and either incinerated or sent for recycling. Empty brake fluid containers and residues remaining after end use will most likely be discarded with domestic garbage and disposed of into landfill.

The notifier estimates approximately 500 kg per year of notified chemical could be released to the environment as a result of repackaging, spills, leaks, and inappropriate disposal of used oils and container residues. The calculated daily PEC is 0.48 µg/L. In calculating the PEC, it is assumed that release to sewage systems occurs on a nationwide basis and is continuous throughout the year. The value also assumes dilution in the sewer by a population of 19 million people using 150 L of water per day. Further dilution would be expected once reaching the receiving water.

The notified chemical is highly water soluble, hence is expected to remain in the water

compartment in the sewer where it will slowly degrade through microbial processes to water and carbon dioxide. The new chemical contains a small quantity of boron, which would be converted to borates or boric acid. Some hydrolysis of the chemical to boric acid and the parent compound could also occur.

Leaks into soil would initially be assimilated into the soil, however, the high water solubility indicates that the chemical would be mobile and may eventually enter the water compartment through leaching. Incineration of the brake fluid containing the notified chemical would produce water vapour and oxides of carbon, together with solid borates, which will remain in the ash or furnace slag. The high water solubility precludes bioaccumulation.

9.1.2. Environment – effects assessment

Ecotoxicity tests were carried out using an analogue chemical, or a formulated brake fluid containing an analogue chemical, all of which are borate esters closely related to the notified chemical. All analogues are considered to appropriately represent the toxicity of the notified chemical for the given endpoints.

The data indicate the notified chemical is very slightly toxic to fish and bacteria, while the formulated brake fluid is very slightly toxic to daphnia, green alga and bacteria (Mensink *et al*. 1995). The most sensitive species to the formulated brake fluid was the green algae, *Selenastrum capricornutum*, with an EC_{50} of 430 mg/L. The resulting PNEC, assuming a safety factor of 100, is 4.3 mg/L. The most sensitive species to the analogue compound was fish, with an $LC_{50} > 100$ mg/L. The resulting PNEC, assuming a safety factor of 1000, is > 0.1 mg/L.

9.1.3. Environment – risk characterisation

The environmental hazard from the notified chemical is considered to be small provided that the material is used as indicated. As a component of hydraulic brake and clutch fluids, most of the notified chemical will be contained within closed hydraulic systems, but has the potential to be released to the environment as a result of spills, leaks and following lubricant changes. However, release is expected to occur in a diffuse manner and in small amounts.

A worst-case scenario PEC assuming diffuse release of 500 kg per year of the notified chemical into the sewer is 0.48 µg/L. The PNEC for the analogue is 0.1 mg/L, while the PNEC for the formulated product is 4.3 mg/L. The resulting PEC/PNEC ratios are 0.0048 (using the analogue chemical) and 1.1×10^{-4} (using the formulated product), respectively, which are both significantly less than 1, indicating no immediate concern to the aquatic environment.

The majority of spent brake fluids removed from vehicles is likely to be recycled or incinerated, with incineration producing water vapour and oxides of carbon, together with solid borates. The notified chemical is readily biodegradable and is not expected to persist in the environment, but rather will degrade mainly through microbial processes, and with some hydrolytic cleavage of the borate ester bonds being another possible degradation pathway. The high water solubility indicates a low potential to bioaccumulate.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

There may be some exposure to drips and spills of the notified chemical during repackaging and filling of hydraulic systems on new cars, but these processes occur under well-controlled conditions and the exposure would be expected to be limited by the use of protective equipment including gloves.

The most widespread source of occupational exposure is during servicing of automotive brake systems and other hydraulic parts, both during topping up of hydraulic fluids and during servicing of the lines containing the fluid. The conditions of exposure in automotive service centres will vary, and it is not likely that appropriate personal protective equipment will be used in all (or, indeed, most) cases. There may therefore be widespread and regular dermal exposure of a large number (maybe in the hundreds) of workers to the notified chemical. Secondary ocular exposure, from contact with material on the hands, is also possible; direct ocular exposure may also occur.

9.2.2. Public health – exposure assessment

Public exposure is expected to be almost completely restricted to persons who maintain their own vehicles. The more common exposure scenario is expected to be dermal contact with drips and spills while topping up hydraulic fluids, but there may be more extensive dermal and ocular exposure during servicing of hydraulic parts. As for occupational exposure during vehicle servicing, the use of personal protective equipment is expected to be variable; however the frequency of exposure is expected to be much lower for members of the public than for automotive service workers.

9.2.3. Human health - effects assessment

A number of toxicity studies on close analogues of the notified chemical were supplied by the notifier. The chemicals were all found to be of low oral and dermal toxicity, non-irritating and non-sensitising to skin, and slightly irritating to eyes. Eye irritation was limited to low level conjunctival effects (with some higher scores soon after instillation), although the duration was greater than 72 hours in several animals when the notified chemical was tested. No data for inhalation toxicity was provided.

In a repeat dose toxicity test, a NOEL of 150 mg/kg bw/day was established for an analogue chemical, based on slight microscopic changes in the liver in most animals at 1000 mg/kg bw/day. No effects on foetuses or dams were seen at 1000 mg/kg bw/day in a developmental toxicity test.

A bacterial mutagenicity test for an analogue chemical was negative, although small effects were seen in a chromosomal aberration test for the same analogue; these were concluded to not be test substance related due to lack of reproducibility and problems with controls. No data for in vivo toxicity was provided.

Based on the results for the notified chemical and the analogue chemicals, the notified chemical would not be classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999) for the endpoints tested.

9.2.4. Occupational health and safety – risk characterisation

The greatest risk will be for workers using the fluids containing the notified chemical under poorly controlled conditions during vehicle servicing. Particularly during servicing of the hydraulic systems there may be widespread dermal exposure, and possible ocular contact (primarily from hand contamination). The dermal absorption potential of the notified chemical is not known, although the low molecular weight suggests that there may be potential for dermal absorption. Therefore the risk of systemic effects from dermal contact is not able to be assessed. The acute dermal toxicity of a close analogue of the notified chemical is low, but some adverse effects were seen at 1000 mg/kg bw/day in a repeat dose oral toxicity study of a brake fluid containing a close analogue of the notified chemical. Dermal absorption of the notified chemical may lead to some effects at very high exposure levels; however use of the notified chemical is not expected to lead to different risks to those already inherent in use of closely related brake fluids.

The notifier indicated that the containers will be labelled with instructions for users to prevent eye and skin contact. The risk for workers involved in packaging brake fluid and filling brake lines of new vehicles will be much lower than for workers involved in vehicle servicing because of the greater likelihood of proper use of personal protective equipment and the smaller skin areas likely to be exposed.

9.2.5. Public health – risk characterisation

For member of the general public, the risk posed by the new chemical will be negligible except in cases where the person is involved in maintenance of their own vehicle. Some exposure may occur during topping up of hydraulic fluids, but this is likely to be on very isolated occasions and for short times prior to washing hands; longer term and more widespread exposure may

occur on dismantling hydraulic systems. In this case, the same considerations as for professional vehicle mechanics apply, but the risk will be diminished as the procedure is normally likely to be performed on a one off basis. Recommendations for use of skin and eye protection should be followed by members of the public handling brake fluids, particularly during mechanical repairs.

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*.

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio: 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 on a short term basis during normal vehicle maintenance.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the product containing the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994a). It is 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 the product containing the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994b). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

REGULATORY CONTROLS
Hazard Classification and Labelling

- Products containing the notified chemical and available to the public must carry the following safety directions on the label:
  - A recommendation that skin and eye protection be worn while handling the product, including instructions to wash hands well immediately after handling the product.

CONTROL MEASURES
Occupational Health and Safety

- Employers should ensure that the following personal protective equipment is used by

workers to minimise occupational exposure to the notified chemical in brake fluid:
– Safety glasses or goggles, impervious gloves, industrial clothing and footwear.

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

- 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 or sent to a recycling facility.

Emergency procedures

- Spills/release of the notified chemical should be soaked up with a binding material and placed in sealed containers for disposal in accordance with government regulations.

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.

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