File No: STD/1313

February 2009

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Chemical A in CP4579

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, Water, Heritage and the Arts.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at 334-336 Illawarra Road, Marrickville NSW 2204.

This Full Public Report is also 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

FULL PUBLIC REPORT

Chemical A in CP4579

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Oronite Australia Pty. Ltd.
Level 10, 45 William St
Melbourne VIC 3000

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, CAS Number, Molecular Formula, Structural Formula, Molecular Weight, Spectral Data, Purity, Identity of Toxic Impurities, Import Volumes, Identity of Recipients, and Details of Use.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: Acute Inhalation Toxicity, Hydrolysis as a function of pH, and Dissociation Constant.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None.

NOTIFICATION IN OTHER COUNTRIES
This substance was being notified in the following countries:
US
Korea
New Zealand

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
CP4579 (product containing the notified chemical)
OLOA 24671 (product containing the notified chemical)

OTHER NAME(S)
OLOA 17508
Alkanoic polyamide

ANALYTICAL DATA
Reference IR spectra were provided for the product CP4579 containing the notified chemical.

3. COMPOSITION

DEGREE OF PURITY 50 - 70% of CP4579

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

ADDITIVES/ADJUVANTS
None

4. PHYSICAL AND CHEMICAL PROPERTIES

All physico-chemical properties were tested on CP4579 product containing 50-70% of the notified chemical.

APPEARANCE AT 20°C AND 101.3 kPa: Brown liquid

Property	Value	Data Source/Justification
Melting Point	-17°C (Pour point)	Measured
Boiling Point	300-735°C	Measured
Density	0.91 g/mL at 20°C	Measured
Vapour Pressure	2.649 x 10^{-9} kPa at 20°C	Measured
Water Solubility	< 2.4 x 10^{-5} g/L at 20°C	Measured
Hydrolysis as a Function of pH	Not measured	Expected to be stable, based on the structure.
Partition Coefficient (n-octanol/water)	log P_{ow} > 7.4 at 20°C	Measured
Adsorption/Desorption	log K_{oc} > 5.6 at 30°C	Measured
Dissociation Constant	pKa = 7.1, 3.5	Estimated
Particle Size	Not applicable	The notified chemical is a liquid.
Flash Point	228°C	Measured (study not provided)
Autoignition Temperature	390°C	Measured
Explosive Properties	Not expected to be explosive	Based on experience with handling of similar materials.

DISCUSSION OF PROPERTIES
For full details of tests on physical and chemical properties, please refer to Appendix A.

Reactivity
The notified chemical is considered stable under normal conditions. It is not reactive with water or air. It may react with strong oxidizing agents, such as chlorates, nitrates, and peroxides. Hazardous polymerization is unlikely to occur.

Dangerous Goods classification
Based on the available data, the notified chemical is not classified as a Dangerous Goods according to the Australian Dangerous Goods Code (NTC, 2007).

5. 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 an ingredient of lubricating oil additive packages at approximately <15%.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	3-10	3-10	3-10	3-10	3-10

PORT OF ENTRY
Sydney, Melbourne, Perth, and Brisbane.

IDENTITY OF MANUFACTURER/RECIPIENTS
The notified chemical will be supplied to major lubricant oil manufacturers in Australia.

TRANSPORTATION AND PACKAGING
The notified chemical will be shipped either in 1000-liter isotanks, which will be offloaded to tank trucks or rail cars for distribution to a blending facility, or in 250-liter steel drums, which will be shipped directly to the customer.

USE
Lubricating oil additive for use in automatic transmission systems.

OPERATION DESCRIPTION
The notified chemical will not be manufactured in Australia and only blending will be performed in Australia.

At blending sites, additive packages containing the notified chemical will be transferred from drums, rail cars, and tank trucks into storage tanks. The transfer process from the tank truck occurs by use of a 10 cm hosing. Connection of the hose takes 10 minutes. A special air back flush system is used to prevent spillage during transfer. The transfer is performed adhering to ISO 9001 procedures.

Transfer from storage tanks to blending tank will be automated, using computer controlled valves. The additive package containing approximately 10% of the notified chemical is blended into the finished lubricant. Depending on the end uses, the finished lubricant contains 0.5-1% of the notified chemical. The blending process occurs in a closed system at 60ºC and is computer controlled. The blended lubricant (containing a maximum of 1% notified chemical) is transferred automatically to a storage tank. The finished lubricants are packaged for shipment in tank trucks, drums and small containers.

The drumming facility uses automated weight scales to fill the drums. The operator watches from about 3-6 feet away to ensure the drum filling mechanism properly enters the drum before the drum is filled. The operator also puts the bungs and labels. A pneumatic pump will be inserted into the drum, which will pump the finished lubricant. A transfer hose is used to fill bulk tank truck or rail car. The small containers packaging machine is a fully-automated machine and fills 1 L and 4 L containers. The operator watches from about 3-6 feet away to ensure the filling mechanism properly enters the container before it is filled.

The finished oil will be distributed about 10% in tank trucks, 50% in drums, and 40% in small containers (1L & 4 L). The finished lubricants will be sold mostly to high volume industrial and commercial lubricant customers for use in automatic transmission fluids in gasoline and diesel engines. In many cases, any stationary engines involved will be routinely lubricated using dedicated lubricating oil reservoirs and piping to add fluids directly without human intervention. For non-stationary automotive applications, workers will check lubricant levels in the engine manually and top-off as needed, using fluids added via pneumatic delivery equipment. In the industrial or commercial environment, engines are maintained by highly trained professional mechanics.

The small packages will be sold to service stations and consumer users. Consumer users will be automotive do-it-yourself consumers, farmers, or anyone who changes their own transmission fluid.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

Category of Worker	*Number*	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Analysing additive package on arrival	1	10 min	30
Unloading tank trucks and drums	1-2	½ hr	30
Sampling and analysing finished lubricant	1-2	10 min	220
Loading finished lubricant into tank trucks, drums, small containers	1-2	½ hr	220

EXPOSURE DETAILS
The main routes of occupational exposure are *via* dermal, ocular and inhalation. Occupational exposure to mixture containing the notified chemical is possible during import, transport, unloading, blending and handling of the finished lubricant containing the notified chemical.

During importation, transportation and unloading, worker exposure is expected to be low, as transfer process involves the use of a hosing. A special air back flush system is also used to prevent spillage during transfer. However, during connection and disconnection of pipes, incidental skin contact to mixtures containing 1% of the notified chemical from splashes, drips, and spills is possible. By adopting ISO 9001 procedures, spills and leaks will be minimized.

Worker exposure is also expected to be low during transferring from storage tank to the blending tank, as the transfer will be automatic through computers controlled valves. The blending process occurs in a closed system and is computer controlled, thereby minimising the potential for occupational exposure. As the blended lubricant is transferred automatically to a storage tank from blending tank, exposure is also expected to be low.

Workers may be exposed to the finished lubricant (containing a maximum of 1% of notified chemical) during the filling operations. However, as the filling operation is fully-automated, exposure will be limited to splashes from watching at a distance of 3-6 feet. Dermal exposure to drips and spills of blended lubricant is also possible during the connection and disconnection of transfer hoses during the filling of bulk containers.

Laboratory staff may also be exposed to the notified chemical during sampling and analysis of the additive packages and of the finished lubricant.

During end use, occupational exposure is expected during manually checking lubricant levels in the engine and also during manually top-off as needed, via pneumatic delivery equipment. In the industrial or commercial environment, exposure is expected to be low as engines are maintained by professional mechanics, who are expected to have access to engineering controls and personal protective equipment.

6.1.2. Public exposure

About 30% of the small packages (1L & 4L) containing the notified chemical at a maximum concentration of 1% will be sold to service stations and consumer users. Consumer users will be automotive do-it-yourself consumers, farmers, or anyone who changes lubricants in vehicles. Therefore, public may be exposed to the notified chemical through dermal and ocular routes while topping-off or changing the transmission fluid in their cars.

6.2. Human health effects assessment

The notified chemical is never isolated alone and only exists as a mixture either in the presence of another unreacted chemical or in the product CP4579. The product CP4579 is a mixture cotaining 50-70% of the notified chemical and 30-50% of another chemical, which is being notified separately under STD/1314 assessment.

The results from toxicological investigations conducted on the product CP4579 containing the notified chemical are used in the present assessment to evaluate the toxicity of the notified chemical and are summarised in the table below. Details of the studies conducted can be found in Appendix B.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 >2000 mg/kg bw, low toxicity
Rat, acute dermal toxicity	LD50 >2000 mg/kg bw, low toxicity
Rat, acute inhalation toxicity	No data available
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation–non-adjuvant test	inadequate evidence of sensitisation
Guinea pig, skin sensitisation–non-adjuvant test*	no evidence of sensitisation
Rat, repeat dose oral toxicity – 28days.	NOEL-1000 mg/kg bw/day in males NOEL-250 mg/kg bw/day in females
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro human lymphocytes	non genotoxic
Genotoxicity–in vivo mouse bone marrow micronucleus test	non genotoxic

*Conducted on test substance SP 4293

Toxicokinetics, metabolism and distribution.
No data was available to assess toxicokinetics, metabolism and distribution of the notified chemical.

Acute toxicity.
CP4579 was of low acute oral and dermal toxicity in rats. An acute inhalation toxicity study was not conducted on the notified chemical.

Irritation and Sensitisation.
CP4579 was found to be slightly irritating to the skin and eyes of rabbits in acute studies.

Although overall weight of evidence indicates that the mixture containing the notified chemical is not a skin sensitiser, significant positive responses were observed at 24 and 48 hrs intervals during the 1st challenge in one of the skin sensitisation test. Based on these results, the notified chemical would have been classified as a skin sensitiser. However, significant positive responses were not observed in the subsequent three challenges in this test. Also no increase in scores between 24 and 48 hrs, which would be indicative of sensitisation, occurred in the study. NICNAS notes that the concentration used for challenge purposes was low in this test (1% & 2.5% of a formulation containing 50-70% notified chemical). No evidence of skin sensitisation was observed in the second skin sensitisation test conducted with another formulation where higher concentration (10% of a formulation containing 50-70% notified chemical) was used for challenge purposes.

Repeated Dose Toxicity (sub acute, sub chronic, chronic).
In an oral toxicity study in rats, CP4579 was administered orally by gavage once daily for 28 consecutive days rats at 0, 60, 250 or 1000 mg/kg bw/day. There were no test substance-related effects on clinical observations, body weights, food consumption, clinical pathology, and organ weights. There were no test substance related effects noted from home cage, handling, open field, sensory, neuromuscular or physiological observations. Macroscopic and microscopic examination revealed no test substance-related findings. The only possible effect of the notified chemical was a reduction in locomotor activity in the 1000 mg/kg bw/day group females during study week 3.

The No-Observed-Effect-Level (NOEL) was established as 1000 mg/kg bw/day in this study for males and 250 mg/kg bw/day for females, based on no effect at the highest tested dose of 1000 mg/kg bw/day in males and possible effect on locomotor activity at 1000 mg/kg bw/day in females. The No-Observed-Adverse-Effect-Level (NOAEL) was 1000 mg/kg bw/day in females.

Mutagenicity
CP4579 was found to be non-mutagenic in a bacterial reverse mutation test and also showed no evidence of clastogenicity to human lymphocytes *in vitro*, either with or without metabolic activation and in mouse bone marrow micronucleus test. Based on these results, the notified chemical is not expected to be genotoxic.

Carcinogenicity
No data was available to assess the potentials for carcinogenicity.

Toxicity for reproduction
No data was available to assess the potentials for toxicity for reproduction.

Health hazard classification
Based on the available data the notified chemical is not classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety
The notified chemical was of low acute oral and dermal toxicity in rats. An acute inhalation toxicity study was not conducted on the notified chemical. The notified chemical was found to be slightly irritating to the skin and eyes of rabbits in acute studies. Although overall weight of evidence indicates that the mixture containing the notified chemical is not a skin sensitiser, significant positive responses were observed at 24 and 48 hrs intervals during the 1st challenge in one of the skin sensitisation test. The notified chemical was not mutagenic in *in vivo* or *in vitro* assays.

In an oral toxicity study in rats, the NOEL was established as 1000 mg/kg bw/day in this study for males and 250 mg/kg bw/day for females, based on no effect at the highest tested dose of 1000 mg/kg bw/day in males and possible effect on locomotor activity at 1000 mg/kg bw/day in females. The NOAEL was 1000 mg/kg bw/day in females.

There is potential for occupational exposure during importation, loading/unloading, transfer, blending, sampling and analysis of the additive packages, and during transportation and handling of the finished oil lubricant containing the notified chemical. The main routes of occupational exposure are *via* dermal, ocular and inhalation.

During transport and storage, worker exposure is minimal as workers will wear overalls, safety glasses, hard hat, and gloves when handling containers. Engineering controls are also used during transferring, blending and filling operations to minimise exposure to workers. The blending facilities are well ventilated with control systems for accidental spills and wastewater treatment. Workers involved in the blending activities receive training in the handling of additive packages, and wear personal protective equipment (PPE) such as gloves, eye protection, protective clothing and hard hats. Considering the use of engineering controls and PPE during these procedures, the risk to workers is expected to be low and is considered acceptable.

Exposure to end-use products containing the notified chemical is expected during manually checking lubricant levels in the engine and also during manually top-off as needed, via pneumatic delivery equipment. In the industrial or commercial environment, engines are maintained by professional mechanics, who are expected to have access to engineering controls and personal protective equipment. Furthermore, the notified chemical is present at a maximum concentration of 1% in the finished oil product. Therefore, considering the above, the risk to workers during end use is expected to be low and is considered acceptable.

Even though the overall weight of evidence indicates that the mixture containing the notified chemical is not a skin sensitiser, significant positive responses were observed at 24 and 48 hrs intervals during the 1st challenge in one of the skin sensitisation test. These responses were observed when challenged with a low concentration of the test substance, suggesting the possibility that some level of skin responses may be observed in some cases. Therefore, it is recommended to avoid contact with skin when using the notified chemical.

6.3.2. Public health

The public may be exposed to notified chemical in the lubricating oil during do-it-yourself changing or topping-off of the transmission fluid of their cars. Considering that the finished lubricant will be supplied in small containers (i.e., quarts), the maximum concentration of the notified chemical in finished lubricant is 1%, and the infrequent use of the notified chemical, the exposure is expected to be low and the risk to public health is considered acceptable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The additive package containing the notified chemical will not be manufactured in Australia, but will be blended into lubricant products by lubricant manufacturers. Blending occurs in fully enclosed automated systems. Solvents used for cleaning are typically recycled or incinerated. Spills are typically washed to on-site treatment facilities, which separate the oily components for incineration, and discharge aqueous fractions to sewer. The notifier estimates that annual releases of the notified chemical to sewer from blending and handling of finished lubricants will only amount to a few grams.

RELEASE OF CHEMICAL FROM USE

There may be some spillage while adding the finished lubricant to the transmission. The notifier expects that these losses will be small.

RELEASE OF CHEMICAL FROM DISPOSAL

Automatic transmission fluids are usually changed by specialists and collected and disposed of appropriately. Used oil is most likely to be burnt for fuel or recycled. If burnt, the notified chemical will be destroyed. Recycling into fresh oil leaves an asphalt residue, in which residues of the notified chemical are expected to be retained.

Drums used to transport the additive package and the finished lubricants will be steam cleaned, with the resultant aqueous waste discharged to on-site treatment facilities, which separate the oily components for incineration, and discharge aqueous fractions to sewer. The notifier estimates that annual releases of the notified chemical to sewer from drum washing will only amount to a few grams.

Smaller containers are expected to be sent to landfill.

7.1.2 Environmental fate

The lubricant additive containing the notified chemical was tested for ready biodegradability in an aerobic aqueous medium and found not to be readily biodegradable. The test material attained 18% degradation. While this suggests that the notified chemical will slowly degrade if released to the environment, biodegradation is likely to be very slow as the notified chemical is the less likely of the two components in the test substance to be biodegradable, based on its structure. Modelling using the EPIWIN (v3.11) Software Suite indicated that the notified chemical is likely to be recalcitrant, and not readily biodegradable. The notified chemical is expected to partition to soils and sediments, where it will remain immobile and very slowly degrade. Bioaccumulation was not tested but is not expected as the high molecular weight will preclude absorption. For the details of the environmental fate studies please refer to Appendix C.

7.1.3 Predicted Environmental Concentration (PEC)

The calculation of a PEC has not been undertaken as the low water solubility and proposed use pattern in automatic transmission system of the notified chemical will lead to little aquatic exposure.

7.2. Environmental effects assessment

The results from ecotoxicological investigations conducted on the notified chemical are summarised in the table below. Details of these studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	LL50 > 1000 mg/L	Not toxic up to the limit of water solubility.
Daphnia Toxicity	EL50 > 1000 mg/L	Not toxic up to the limit of water solubility.
Algal Toxicity	EL50 > 1000 mg/L	Not toxic up to the limit of water solubility.

It is not possible to reach firm conclusions regarding the aquatic toxicity of the notified chemical, as the test substance contained other components and could not be measured in the water accommodated fractions used as test media. The limit of quantification (0.17 mg/L) exceeds the measured solubility limit (0.024 mg/L).

7.2.1 Predicted No-Effect Concentration

A PNEC cannot be calculated as no harmful effects were seen in aquatic toxicity testing. The test substance containing the notified chemical is not toxic up to the limit of water solubility.

7.3. Environmental risk assessment

As PNEC could not be determined, the risk quotient cannot be calculated. As the worst case PEC is well below the measured solubility limit, and no toxicity was observed at the limit of water solubility, the notified chemical is not considered to pose a risk to the environment.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available data the notified chemical is not classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

and

As a comparison only, the classification of the notified chemical using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

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

Human health risk assessment
Under the conditions of the occupational settings described, the notified chemical is not considered to pose an unacceptable risk to the health of workers.

When used in the proposed manner, the notified chemical is not considered to pose an unacceptable risk to public health.

Environmental risk assessment
On the basis of the very low solubility in water and absence of aquatic toxicity at the limit of water solubility, and the reported use pattern, the notified chemical is not considered to pose a risk to the environment.

Recommendations

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced and in the product CP4579:
  - Avoid skin and eye contact
  - Electrostatic charge may accumulate and create a hazardous condition when handling this product. Therefore, review all operations, which have the potential of generating and accumulating an electrostatic charge and/or a flammable atmosphere.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced and when:
  - Safety glasses if splashing is expected
  - Gloves
  - Coveralls

  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 *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] 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 burning as fuel, or to landfill.

Storage

- There are no special requirements regarding the storage of this product. However, precautions should be taken against the accumulation of electrostatic charge, which may create a hazardous condition when handling this product.

Emergency procedures

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

Regulatory Obligations

Secondary Notification
This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(1) of the Act; if
  - toxicology data has become available on Chemical A in CP4579.

(2) Under Section 64(2) of the Act; if
  - the function or use of the chemical has changed from lubricating oil additive for use in automatic transmission system, or is likely to change significantly;
  - the amount of chemical being introduced has increased from 10 tonnes, or is likely to increase, significantly;
  - the chemical has begun to be manufactured in Australia;
  - additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

No additional secondary notification conditions are stipulated.

Material Safety Data Sheet
The MSDS of the notified chemical provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

All physico-chemical properties were conducted using a batch of CP4579 product cotaining 50-70% of the notified chemical.

Melting Point -17°C (Pour point)

METHOD ASTM D5950
Remarks Although ASTM D97 is referenced in the Appendix to Guideline 102, ASTM D5950 using an automatic apparatus, offers better repeatability and reproducibility and was used.
TESTFACILITY Integrated Laboratory Technology (2008)

Boiling Point 300-735°C

METHOD OECD TG 103 Boiling Point (ASTM D 6352)
Remarks
TEST FACILITY Integrated Laboratory Technology (2008)

Density 0.91 g/mL at 20°C

METHOD OECD TG 109 Density of Liquids and Solids (ASTM D 4052)
Remarks
TEST FACILITY Integrated Laboratory Technology (2008)

Vapour Pressure 2.648×10^{-3} Pa at 20°C

METHOD Maxwell-Bonnell/ProVision Method
Remarks This method, which is detailed in Guideline 104'Appendix, was deemed more appropriate for this sample type.
TEST FACILITY Integrated Laboratory Technology (2008)

Water Solubility $< 2.4 \times 10^{-5}$ g/L at 20°C

Method OECD TG 105 Water Solubility.
Remarks Flask Method. Although the test guideline suggests using the column elution method where water solubility is very low, experience had shown that columns tend to become clogged when this method is used to determine the solubility of petroleum additives. The value cited is the detection limit of the analytical method (HPLC). The test was conducted at 30°C.
Test Facility Integrated Laboratory Technology (2008)

Hydrolysis as a Function of pH

Method The test was not conducted because of the very low water solubility and lack of suitable analytical methodology for the test substance, which is expected to be stable to abiotic hydrolysis under environmental conditions.

Partition Coefficient (n-octanol/water) log Pow > 7.4 at 20°C

Method OECD TG 117 Partition Coefficient (n-octanol/water).
EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks HPLC Method. Five peaks were observed. The two major components had values of 7.7 and 9.5.
Test Facility Integrated Laboratory Technology (2008)

Adsorption/Desorption – screening test $\log K_{oc} > 5.6$ at 30°C

Method	OECD TG 121 Adsorption - Desorption – HPLC Screening Method.
Remarks	The test substance eluted from the column after the reference substance DDT, as four peaks. The nominal pH was 7.5. At lower pH, sorption is expected to be stronger as cationic species typically have strongly sorptive properties.
Test Facility	SafePharm Laboratories Ltd. (2008)

Flash Point 228ºC

METHOD	Cleveland Open Cup
Remarks	The test material was CP4579. Refer to the attached specification sheet.
TEST FACILITY	Chevron Oronite Laboratory (reference not stated)

Autoignition Temperature 390 ± 5ºC

Method	EC Directive 92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases).
Remarks	Aliquots of test material were introduced to the flask and were then observed for signs of ignitions over a 300 second period. The procedure was repeated, varying the sample size, as necessary, until the lowest temperature, at which the ignition, if any, occurred within 300 seconds of insertion, was determined. The atmospheric pressure was in the range of 100.09 to 102.19 kPa.
Test Facility	SafePharm Laboratories Ltd. (2008)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

All toxicological studies were conducted using a batch of CP4579 product cotaining 50-70% of the notified chemical.

B.1. Acute toxicity – oral

TEST SUBSTANCE CP4579

METHOD OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain Rat/ Sprague-Dawley
Vehicle None (undiluted)
Remarks - Method No significant protocol deviations

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	6 F	300	0
2	6 F	2000	0

LD50 >2000 mg/kg bw
Signs of Toxicity There were no signs of toxicity and there were no deaths. All animals gained bodyweight during the test period.
Effects in Organs No abnormalities were noted at necropsy on study day 14.
Remarks - Results

CONCLUSION The notified chemical is of low toxicity via the oral route.

TEST FACILITY Charles River Laboratories (2007a)

B.2. Acute toxicity – dermal

TEST SUBSTANCE CP4579

METHOD OECD TG 402 Acute Dermal Toxicity – Limit Test.
Species/Strain Rat/ Sprague-Dawley
Vehicle None (undiluted)
Type of dressing Occlusive
Remarks - Method No significant protocol deviations. The test substance was removed from the skin after the 24 hrs application period by wiping first with mineral oil, then with deionised water.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 per sex	300	0
2	5 per sex	2000	0

LD50 >2000 mg/kg bw
Signs of Toxicity - Local Dermal irritation at the test site consisting of very slight to moderate erythema was noted in three animals. Desquamation was also noted in all animals.
Signs of Toxicity - Systemic Clinical abnormalities observed during the study included transient incidences of dark material around the facial area, swelling, incisor(s) broken, and rough coat. All animals gained weight during the test period
Effects in Organs No gross internal findings were observed during necropsy on day 14.

CONCLUSION The notified chemical is of low toxicity via the dermal route.

TEST FACILITY Charles River Laboratories (2008)

B.3. Irritation – skin

TEST SUBSTANCE CP4579

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain Rabbit/New Zealand White
Number of Animals 3
Vehicle None (undiluted)
Observation Period 10 days
Type of Dressing Semi-occlusive.
Remarks - Method No significant protocol deviations. After the 4 hr application period, the test substance was removed and the remaining test article was wiped from the skin using gauze moistened with mineral oil, USP, followed by dry gauze, followed by gauze moistened with deionized water and followed by dry gauze.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	1	1.67	1	2	7 days	0
Oedema	0.00	0.33	0.00	1	24 hrs	0

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

Remarks - Results Exposure to the test article produced very slight to well-defined erythema and very slight oedema at 3/3 test sites by the 1-hour scoring interval. The dermal irritation resolved completely at 2/3 test sites by the study day 7 scoring interval and at the remaining 1/3 test site by the study day 10 scoring interval. Additional dermal findings of superficial lightening (3/3 test sites) and desquamation (1/3 test sites) were noted during the study. Based on the results of this study, the Primary Irritation Index for the notified chemical was determined to be 1.67

CONCLUSION The notified chemical is slightly irritating to the skin.

TEST FACILITY Charles River Laboratories (2007b)

B.4. Irritation – eye

TEST SUBSTANCE CP4579

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain Rabbit/New Zealand White
Number of Animals 3
Observation Period 96 hrs following dosing
Remarks - Method No significant protocol deviations. Fluorescein examination of eyes was carried out at 24 hr and any residual test material was rinsed from the eyes at this time.

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	0.33	0.33	1	24 hrs	0
Conjunctiva: chemosis	0	0	0	0	0	0
Conjunctiva: discharge	0	0	0	0	0	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: Exposure to the test substance produced conjunctivitis (redness, swelling, and discharge) in 3/3 test eyes at the 1-hr scoring interval. The conjunctival irritation resolved completely in 3/3 test eyes by the 48-hrs scoring interval.

CONCLUSION: The notified chemical is slightly irritating to the eye.

TEST FACILITY: Charles River Laboratories (2007c)

B.5. Skin sensitisation

TEST SUBSTANCE: CP4579

METHOD: OECD TG 406 Skin Sensitisation - Modified Buehler Design.
Species/Strain: Guinea pig/Albino-Hartley strain
PRELIMINARY STUDY: Maximum Non-irritating Concentration:
topical: 2.5% in mineral oil, USP
MAIN STUDY
Number of Animals: Test Group: 20 Control Group: 20
INDUCTION PHASE: Induction Concentration:
topical 50% in mineral oil, USP
Signs of Irritation
CHALLENGE PHASE
1st challenge: topical: 2.5% in mineral oil, USP
2nd challenge: topical: 2.5% in mineral oil, USP
3rd challenge: topical: 2.5% in mineral oil, USP
4th challenge: topical: 1% in mineral oil, USP
Remarks - Method: No significant protocol deviations.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after: 1st challenge*		*2nd challenge*	
		24 h	*48 h*	*24 h*	*48 h*
Test Group	2.5% in mineral oil, USP	7/20	5/20	2/20	1/20
Challenge Control Group	2.5% in mineral oil, USP	0/10	0/10	0/10	0/10

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after: 3rd challenge*		*4th challenge*	
		24 h	*48 h*	*24 h*	*48 h*
Test Group	2.5% in mineral oil, USP	0/20	0/20	0/20	0/20
Challenge Control Group	1% in mineral oil, USP	0/7	0/7	0/7	0/7

Remarks - Results	Although overall there was no evidence of skin sensitisation, significant positive responses were observed at 24 and 48 hrs interval during the 1st challenge. Based on these results, the notified chemical would have been classified as a skin sensitiser. However, significant positive responses were not observed in the future challenges. NICNAS also notes that the concentration used for challenge purposes was quite low (1% & 2.5% of formulation containing 50-70% notified chemical).
CONCLUSION	There was inadequate evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	Charles River Laboratories (2007d)

B.6. Skin sensitisation

TEST SUBSTANCE	SP4293 containing the notified chemical at 50-70% concentration and 25-45% of unreactive constituents
METHOD	OECD TG 406 Skin Sensitisation - Modified Buehler Design.
Species/Strain	Guinea pig/Albino-Hartley strain
PRELIMINARY STUDY	Maximum Non-irritating Concentration: topical: 10% in mineral oil, USP
MAIN STUDY	
Number of Animals	Test Group: 20 Control Group: 20
INDUCTION PHASE	Induction Concentration: topical 50% in mineral oil, USP
Signs of Irritation	
CHALLENGE PHASE	
Challenge (only one challenge)	topical: 10% in mineral oil, USP
Remarks - Method	No significant protocol deviations.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after: Challenge (only one challege)*	
		24 h	*48 h*
Test Group	10% in mineral oil, USP	1/20	0/20
Challenge Control Group	10% in mineral oil, USP	0/10	0/10

CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	Charles River Laboratories (2006)

B.7. Repeat dose toxicity

TEST SUBSTANCE	CP4579
METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.
Species/Strain	Rats/Crl:CD(SD)
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28days Dose regimen: 7 days per week Post-exposure observation period: 14 days for the control and high dose rats.
Vehicle	Corn oil
Physical Form	liquid aerosol
Remarks - Method	The dosage volume was 5 mL/kg bw for all groups. Functional observational battery and locomotor activity data were recorded for 5 animals/sex/group during study week 3 and for the remaining 5 animals/sec

in groups 1 and 4 during study week 5 (recovery period).

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
control	5 per sex	0	0
low dose	5 per sex	60	0
mid dose	5 per sex	250	0
high dose	5 per sex	1000	0
control recovery	5 per sex	0	0
high dose recovery	5 per sex	1000	0

Mortality and Time to Death
All animals survived to the scheduled necropsies.

Clinical Observations including functional observational battery and locomotor activity data
There were no test substance-related effects on clinical observations, body weights, and food consumption. There were no test substance related home cage, handling, open field, sensory, neuromuscular or physiological observations.

Reduced locomotor activity (total and ambulatory activity counts) was observed in the 1000 mg/kg bw group females during the dosing period; the overall total motor activity mean was reduced by 43.5% when compared to the control group at study week 3. At study week 5 recovery evaluation, at least partial recovery was apparent for mean total and ambulatory activity in the high dose group females; the overall total motor activity was reduced by 26.6% when compared to the control group at study week 5. The first 2 epochs (0-15 minutes and 16-30 minutes) were affected at both test periods.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
There were no test substance-related effects on clinical pathology.

Effects in Organs
There were no test substance-related effects on organ weights. Macroscopic and microscopic examination revealed no test substance-related findings.

Remarks – Results
The only possible effect of the notified chemical administered orally to rats for 28 days was a reduction in locomotor activity in the 1000 mg/kg bw/day group females during study week 3. This observation did not appear to be adverse to the general health of the animals and was less pronounced following a recovery period. There were no test substance-related effects on body weights, food consumption and organ weights or clinical pathology and FOB parameters. Macroscopic and microscopic examination revealed no test substance related finding.

CONCLUSION
The NOEL was established as 1000 mg/kg bw/day in this study for males and 250 mg/kg bw/day for females, based on no effect at the highest tested dose of 1000 mg/kg bw/day in males and possible effect on locomotor activity at 1000 mg/kg bw/day in females. The NOAEL was 1000 mg/kg bw/day in females.

TEST FACILITY WIL Research Laboratories, LLC (2008)

B.8. Genotoxicity – bacteria

TEST SUBSTANCE CP4579

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria.

Species/Strain *S. typhimurium*: TA1535, TA1537, TA98, TA100
E. coli: WP2uvrA$^-$

Metabolic Activation System Liver fraction (S9 mix) from rats pretreated with phenobarbitone/β-

	naphthoflavone
Concentration Range in Main Test	a) With metabolic activation: 0, 15, 50, 150, 500, 1500, 5000 µg/plate b) Without metabolic activation: 0, 15, 50, 150, 500, 1500, 5000 µg/plate
Vehicle	Acetone
Remarks - Method	No significant protocol deviations. Plate incorporation method. The test material caused no visible reduction in the growth of the bacterial background lawn at any dose level. The test material was, therefore, tested up to the maximum recommended dose level of 5000 µg/plate. An opaque film was observed at and above 1500 µg/plate with an associated oily precipitate at 5000 µg/plate. Neither of these observations prevented the scoring of revertant colonies.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent	> 5000			
Test 1		> 5000	≥ 1500	Negative
Test 2		> 5000	≥ 1500	Negative
Present	> 5000			
Test 1		> 5000	≥ 1500	Negative
Test 2		> 5000	≥ 1500	Negative

Remarks - Results	No significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains, with any dose of the test material, either with or without metabolic activation.

CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	SafePharm Laboratories Ltd. (2007e)

B.9. Genotoxicity – in vitro

TEST SUBSTANCE	CP4579
METHOD	OECD TG 473 In vitro Mammalian Chromosome Aberration Test.
Species/Strain	Human
Cell Type/Cell Line	Peripheral blood lymphocyte cells
Metabolic Activation System	Liver fraction (S9 mix) from rats pretreated with Aroclor 1254
Vehicle	Ethanol
Remarks - Method	No significant protocol deviations.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0*, 51.9*, 69.2*, 92.3*, 127*, 169, 225, 300, 400, MMC 1*	3 hr	22 hr
Test 2	0*, 3.13, 6.25, 12.5, 25*, 50*, 75*, 100*, 150, 225, 300, MMC 0.3*	22 hr	22 hr
Present			
Test 1	0*, 51.9*, 69.2*, 92.3*, 127*, 169, 225, 300, 400, CP 40*	3 hr	22 hr
Test 2	0*, 25, 50*, 75*, 100*, 150*, 225, 300, CP 40*	3 hr	22 hr

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	Not indicated	≥ 127 µg/mL	≥ 92.9 µg/mL	Negative
Test 2	Not indicated	≥ 100 µg/mL	≥ 100 µg/mL	Negative
Present				
Test 1	Not indicated	≥ 127 µg/mL	≥ 92.9 µg/mL	Negative
Test 2	Not indicated	> 100 µg/mL	≥ 100 µg/mL	Negative

Remarks - Results: No significant increase in chromosomal aberrations, polyploidy, or endoreduplication was observed in the cultures analyzed.

CONCLUSION: The notified chemical was not clastogenic to cultured human peripheral blood lymphocytes treated in vitro under the conditions of the test.

TEST FACILITY: Clovance Laboratories Inc. (2007a)

B.10. Genotoxicity – in vivo

TEST SUBSTANCE: CP4579

METHOD: OECD TG 474 Mammalian Erythrocyte Micronucleus Test.
Species/Strain: Mouse/CD-1 (ICR)
Route of Administration: Intraperitoneal
Vehicle: Corn oil
Remarks - Method: In a dose-finding study, three females and three males were dosed at 500, 1000, or 2000 mg/kg bw and observed for up to 2 days after dosing for signs of toxicity. Based on these results, the maximum tolerated dose was estimated to be 2000 mg/kg bw. Only males were used in the assay since no gender difference was found. The route of administration was oral gavage for the positive control group.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Animals/Harvest Time point*	
			24 hour	48 hour
I (vehicle control)	10, male	0	5	5
II (low dose)	5, male	125	5	-
III (mid dose)	5, male	500	5	-
IV (high dose)	10, male	2000	5	5
V (positive control, CP)	5, male	80	5	-

CP=cyclophosphamid.

RESULTS
Doses Producing Toxicity: 500, 1000, and 2000 mg/kg bw
Genotoxic Effects: Negative
Remarks - Results: The notified chemical did not induce statistically significant increases in micronucleated polychromatic erythrocytes (PCEs) at any test article dose examined. The notified chemical was demonstrated to be cytotoxic to the bone marrow (i.e., statistically significant decreases in the PCE:NCE ratios were found) at all doses of the test article.

CONCLUSION: The notified chemical was not clastogenic under the conditions of this in vivo mouse bone marrow micronucleus test.

TEST FACILITY: Clovance Laboratories Inc. (2007b)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE CP4579

METHOD OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test.
Inoculum: Aerobic sludge from UK plant handling predominantly domestic sewage.
Exposure Period: 28 days
Auxiliary Solvent: None.
Analytical Monitoring: Carbon dioxide analysis.
Remarks – Method: The test substance was adsorbed to filter paper before addition to the culture medium.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
1	0	1	23
28	18	28	75

Remarks - Results: A toxicity control found no microbial inhibition.

CONCLUSION Not readily biodegradable

TEST FACILITY SafePharm Laboratories Ltd. (2007a)

C.1.2. Bioaccumulation

The test was not conducted because of the very low water solubility and lack of suitable analytical methodology for the test substance containing the notified chemical. Bioaccumulation is not expected because of the high molecular weight, which is expected to preclude absorption through biological membranes.

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE CP4579

METHOD OECD TG 203 Fish, Acute Toxicity Test – semi-static.
EC Directive 92/69/EEC C.1 Acute Toxicity for Fish - semi-static.
Species: Rainbow trout
Exposure Period: 96 hours
Auxiliary Solvent: None
Water Hardness: 140 mg $CaCO_3$/L
Analytical Monitoring: HPLC
Remarks – Method: The test was conducted using the WAF obtained by mid-depth siphon from a mixture that had been stirred for 24 hours and allowed to settle for 4 hours. Microscopic examination of the WAF revealed no micro-dispersions or undissolved test material.

RESULTS All fish survived. Initial measured concentrations were below the limit of quantification (0.17 mg/L). Final measured concentrations of 0.19-0.30 mg/L were recorded, but these should be treated with caution given their proximity to the LOQ and uncertainty as to whether the peaks observed represented the test substance.
LL50: > 1000 mg/L at 96 hours.

NOEL	1000 mg/L at 96 hours.
Remarks – Results	Results are expressed as nominal loadings.
CONCLUSION	Not toxic up to the limit of water solubility.
TEST FACILITY	SafePharm Laboratories Ltd. (2007b)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	CP4579
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test - static. EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia - static.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	260 mg $CaCO_3$/L
Analytical Monitoring	HPLC
Remarks – Method	The test was conducted using the WAF obtained as in the fish test.
RESULTS	No daphnids were immobilised.
EL50	> 1000 mg/L at 48 hours
NOEL	1000 mg/L at 48 hours
Remarks – Results	Results are expressed as nominal loadings. The test substance was not detectable in any samples of the test medium.
CONCLUSION	Not toxic up to the limit of water solubility.
TEST FACILITY	SafePharm Laboratories Ltd. (2007c)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE	CP4579
METHOD	OECD TG 201 Alga, Growth Inhibition Test. EC Directive 92/69/EEC C.3 Algal Inhibition Test.
Species	*Pseudokirchneriella subcapitata*
Exposure Period	96 hours
Concentration Range	The definitive test was conducted using the WAF obtained as in the fish test.
Auxiliary Solvent	None
Analytical Monitoring	HPLC
RESULTS	There were no significant differences between growth rates, yields and biomass in the test and control cultures. These parameters showed a small increase in some samples, and a small decline in others.
Remarks – Results	Results are expressed as nominal loadings. The test substance was not detectable in any samples of the test medium.
CONCLUSION	Not toxic up to the limit of water solubility.
TEST FACILITY	SafePharm Laboratories Ltd. (2007c)

BIBLIOGRAPHY

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

NOHSC (2004) Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

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.

Charles River Laboratories (2006) SP 4293: A dermal sensitisation study in guinea pigs. Final Report No: LMT00003, October 2006 for Chevron Energy Technology Company, Richmond, USA. Charles River Laboratories, Spencerville, Ohio, USA (Unpublished report provided by the notifier).

Charles River Laboratories (2007a) CP4579: An acute oral toxicity study in rats (Acute Toxic Class Method)-OECD 423. Final Report No: LMT00062, September 2007 for Chevron Energy Technology Company, Richmond, USA. Charles River Laboratories, Spencerville, Ohio, USA (Unpublished report provided by the notifier).

Charles River Laboratories (2007b) CP4579: A primary skin irritation study in rabbits. Final Report No: LMT00065, September 2007 for Chevron Energy Technology Company, Richmond, USA. Charles River Laboratories, Spencerville, Ohio, USA (Unpublished report provided by the notifier).

Charles River Laboratories (2007c) CP4579: A primary eye irritation study in rabbits. Final Report No: LMT00064, July 2007 for Chevron Energy Technology Company, Richmond, USA. Charles River Laboratories, Spencerville, Ohio, USA (Unpublished report provided by the notifier).

Charles River Laboratories (2007d) CP4579: A dermal sensitisation study in guinea pigs. Final Report No: LMT00066, November 2007 for Chevron Energy Technology Company, Richmond, USA. Charles River Laboratories, Spencerville, Ohio, USA (Unpublished report provided by the notifier).

Charles River Laboratories (2008) CP4579: An acute dermal toxicity study in rats. Final Report No: LMT00063, March 2008 for Chevron Energy Technology Company, Richmond, USA. Charles River Laboratories, Spencerville, Ohio, USA (Unpublished report provided by the notifier).

Clovance Laboratories Inc. (2007a). CP4579: Chromosomal aberrations in cultured human peripheral blood lymphocytes. Final Report September 2007, Study No: 6183-142 for Chevron Energy Technology Company, Richmond, USA. Clovance Laboratories Inc., Virginia, USA (Unpublished report provided by the notifier).

Clovance Laboratories Inc. (2007b). CP4579: In Vivo Mouse Bone Marrow Micronucleus Assay. Final Report September 2007, Study No: 6183-143 for Chevron Energy Technology Company, Richmond, USA. Clovance Laboratories Inc., Virginia, USA (Unpublished report provided by the notifier).

Integrated Laboratory Technology (2008) CP4579: Physical and chemical properties. Final Report, June 2008 for Chevron Energy Technology Company. Integrated Laboratory Technology. 100 Chevron Way, Richmond, CA 94802, USA (Unpublished report provided by the notifier).

SafePharm Laboratories Ltd. (2007a) CP4579: Assessment of ready biodegradability; CO_2 evolution test. Final Report November 2007, Project Number: 0703/0369 for Chevron Energy Technology Company, Richmond, USA. SafePharm Laboratories Ltd., Derbyshire, UK (Unpublished report provided by the notifier).

SafePharm Laboratories Ltd. (2007b) CP4579: Acute toxicity to rainbow trout (*Oncorhynchus mykiss*). Final Report September 2007, Project Number: 0703/0365 for Chevron Energy Technology Company, Richmond, USA. SafePharm Laboratories Ltd., Derbyshire, UK (Unpublished report provided by the notifier).

SafePharm Laboratories Ltd. (2007c) CP4579: Acute toxicity to *Daphnia magna*. Final Report December 2007, Project Number: 0703/0366 for Chevron Energy Technology Company, Richmond, USA. SafePharm Laboratories Ltd., Derbyshire, UK (Unpublished report provided by the notifier).

SafePharm Laboratories Ltd. (2007d) CP4579: Algal inhibition test. Final Report November 2007, Project Number: 0703/0367 for Chevron Energy Technology Company, Richmond, USA. SafePharm Laboratories Ltd., Derbyshire, UK (Unpublished report provided by the notifier).

SafePharm Laboratories Ltd. (2007e). CP4579: *Salmonella Typhimurium* and *Escherichia Coli*/Mammalian-Microsome Reverse Mutation Assay. Final Report September 2007, Project Number: 0703/0364 for for Chevron Energy Technology Company, Richmond, USA. SafePharm Laboratories Ltd., Derbyshire, UK (Unpublished report provided by the notifier).

SafePharm Laboratories Ltd. (2008) CP4579: Determination of adsorption coefficient and auto-ignition temperature (liquids & gases). Final Report May 2008, Project Number: 0703/0405 for Chevron Energy Technology Company, Richmond, USA. SafePharm Laboratories Ltd., Derbyshire, UK (Unpublished report provided by the notifier).

WIL Research Laboratories, LLC (2008) CP4579: A 28-day repeated dose oral (gavage) toxicity study of CP4579 in rats (with functional observational battery and motor activity determinations). Final Report May 2008, Project Number: WIL-187070 for Chevron Energy Technology Company, Richmond, USA. WIL Research Laboratories, LLC, Ashland, USA (Unpublished report provided by the notifier).