File No: STD/1448

November 2013

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Priolube 1973

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 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.

For the purposes of subsection 78(1) of the Act, this Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This 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:

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Director
NICNAS

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SUMMARY

The following details will be published in the NICNAS *Chemical Gazette:*

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
STD/1448	Croda Singapore Pte Ltd (Trading as Croda Australia)	Priolube 1973	ND*	< 100 tonnes per annum	Synthetic lubricant base fluid

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
As only limited toxicity data were provided for the notified chemical, the notified chemical cannot be classified according to the *Globally Harmonised System for the Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

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

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

Environmental risk assessment
On the basis of the assessed use pattern, the notified chemical is not expected to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES
Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified chemical during reformulation:
  - Enclosed, automated processes, where possible

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced and during reformulation:
  - Avoid contact with skin
  - Avoid inhalation of aerosols/mists

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

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

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Disposal

- The notified chemical should be disposed of in accordance with local regulations for recycling, re-use or recovery of calorific content.

Storage

- The following precautions should be taken by users regarding storage of the notified chemical:
  - Avoid direct contact with strong oxidising agents

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by physical 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(2) of the Act; if
  - the function or use of the chemical has changed from being a synthetic lubricant base fluid, or is likely to change significantly;
  - the amount of chemical being introduced has increased, 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.

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

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Croda Singapore Pte Ltd (Trading as Croda Australia) (ABN: 34 088 345 457)
Suite 102, 447 Victoria Street
WETHERILL PARK NSW 2164

NOTIFICATION CATEGORY
Standard (Reduced fee notification): Chemical other than polymer (more than 1 tonne per year) – similar to a chemical that has been previously assessed by NICNAS (File No.: NA/636)

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: chemical name, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, impurities, additives/adjuvants, import volume, use details, identity of manufacturer and analogue details.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: all physico-chemical endpoints, acute dermal toxicity, acute inhalation toxicity, skin irritation, eye irritation, skin sensitisation, repeat dose toxicity, induction of point mutations, genotoxic damage *in vivo* and chromosome damage *in vitro*

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Priolube 1973

MOLECULAR WEIGHT
> 500 Da

ANALYTICAL DATA
Reference IR spectra were provided

3. COMPOSITION

DEGREE OF PURITY > 99%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Light-yellow liquid

Property	Value	Data Source/Justification
Pouring Point/Freezing Point	< -36 °C	SDS
Boiling Point	> 200 °C	SDS
Density	900 kg/m^3	SDS
Vapour Pressure	< 0.1 kPa at 20 °C	SDS
Water Solubility	Not determined	Expected to be low based on the predominantly hydrophobic structure of the notified chemical
Hydrolysis as a Function of pH	Not determined	Contains potentially hydrolysable functionalities. However, significant hydrolysis is not expected under environmental conditions due to its limited water solubility.
Partition Coefficient (n-octanol/water)	Not determined	Expected to partition from water to octanol phase based on its predominately hydrophobic nature
Adsorption/Desorption	Not determined	Expected to partition into the organic component in soils and sediments, and become associated with these materials
Dissociation Constant	Not determined	Not contain any dissociable functionalities
Flash Point	> 250 °C	SDS
Flammability	Not determined	Not expected to be highly flammable based on flash point
Autoignition Temperature	Not determined	Not expected to undergo autoignition based on flash point
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidative properties

DISCUSSION OF PROPERTIES

Reactivity

The notified chemical is expected to be stable under normal conditions of use. The SDS of the notified chemical states that the chemical should avoid contact with strong oxidising agents.

Physical hazard classification

Based on the submitted physico-chemical data depicted in the above table, the notified chemical is not recommended for hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

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 neat as a liquid at > 99% purity for reformulation and as a component of ready-to-use additive packages at concentrations < 40%.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 50	< 50	< 100	< 100	< 100

PORT OF ENTRY

Perth, Melbourne, Sydney and Brisbane

TRANSPORTATION AND PACKAGING

The notified chemical (> 99% purity) will be imported in 200 L drums, 1,000 L intermediate bulk containers (IBCs) or 10 – 20 tonne ISO tanks. The ready-to-use additive packages containing the notified chemical at concentrations < 40% will be imported in 200 L steel drums. Both the notified chemical and the additive packages will be transported by road and rail in original packages for distribution nationwide.

USE

The notified chemical is a base liquid for synthetic lubricants used at concentrations < 40%.

OPERATION DESCRIPTION

Reformulation

The notified chemical will be reformulated at the customer's site by blending with oils and other additives to form finished lubricants.

When imported in IBCs or ISO tanks, the notified chemical will be loaded into blending vessels by operators equipped with flexible transfer hoses and pumps. After the transfer of the notified chemical, the hoses and pumps will normally be flushed and disconnected. Where the notified chemical is imported in drums, it will be loaded into the blending vessels by the operators either manually or with the help of mechanical devices. Spear pumps may also be used in the transfer.

The blending processes will occur at > 50 °C in either blending tanks or via continuous static mixture, most likely in enclosed automated systems with adequate ventilation and appropriate engineering controls. The finished lubricants containing the notified chemical at < 40% will be tested for quality control purposes and then packaged into 200 L steel drums with automated processes.

Cleaning and maintenance of the blending vessels and filling lines will occur from time to time

The finished lubricants containing the notified chemical at < 40% will be stored and distributed nationwide via road and rail for end use.

End use

The imported or reformulated finished lubricants containing the notified chemical at < 40% concentration, packaged in steel drums, will be loaded to lubricant reservoirs of the machinery during original manufacture or during follow-up services, either through automated systems or manually. The end use of the products containing the notified chemical is for industrial applications only including stern-tube lubricants for ships and hydraulic fluids.

At the end of the use cycle, it is expected that the finished products containing the notified chemical will be drained from the lubricant reservoirs of the machinery and collected for disposal.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport	2	8
Storage	1	10
Reformulation	4	10
Cleaning and maintenance	3	6
Quality control	2	10
End users	2	200

EXPOSURE DETAILS

Transport and Storage

Transport and storage workers are not expected to be exposed to the notified chemical except in the unlikely event of an accidental rupture of the containers.

Reformulation, Packaging and Testing

During reformulation, procedures involved in the handling of the notified chemical and products containing it will occur in industrial areas with adequate ventilation and appropriate engineering controls. The blending processes are expected to take place in enclosed automated systems, reducing the potential for workers to be exposed to the notified chemical. Dermal and ocular exposure to the notified chemical at > 99% concentration may occur during the charging of blending vessels, equipment cleaning and maintenance. Dermal and ocular exposure may occur to the notified chemical at < 40% concentration during packaging and quality control testing. Inhalation exposure is not expected given the low vapour pressure of the notified chemical unless aerosols or mists are formed.

PPE including coveralls, impervious gloves, and safety goggles are expected to be worn by workers to minimise exposure during reformulation and packaging.

End Use

Dermal and ocular exposure to the notified chemical at < 40% concentration may occur during the charging, topping up and maintenance activities. Inhalation exposure is not expected given the low vapour pressure of the notified chemical. PPE including coveralls, impervious gloves, and safety goggles are expected to be worn by workers to minimise exposure.

6.1.2. Public Exposure

The notified chemical and the products containing it are expected to be used in industrial settings only. Therefore, given the proposed use pattern, public exposure is not expected except in the event of accidental release.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified chemical or its analogues are summarised in the following table. For full details of the acute oral toxicity study that was not summarised in NA/636, refer to Appendix B.

Endpoint	*Result and Assessment Conclusion*	*Test Substance*
Rat, acute oral toxicity	LD50 > 2,000 mg/kg bw; low toxicity	Notified chemical
Rat, acute dermal toxicity [a]	LD50 > 2,000 mg/kg bw; low toxicity	Analogue 2
Rat, acute dermal toxicity [a]	LD50 > 2,000 mg/kg bw; low toxicity	Analogue 3
Rabbit, skin irritation [a]	slightly irritating	Analogue 2
Rabbit, skin irritation [a]	slightly irritating	Analogue 3

Rabbit, eye irritation [a]	non-irritating	Analogue 3
Guinea pig, skin sensitisation – adjuvant test [a]	no evidence of sensitisation	Analogue 3
Rat, repeat dose oral toxicity – 28 days [a]	NOEL = 1,000 mg/kg bw/day	Analogue 3
Mutagenicity – bacterial reverse mutation [a]	non mutagenic	Analogue 1 [b]
Mutagenicity – bacterial reverse mutation [a]	non mutagenic	Analogue 3
Genotoxicity – in vitro chromosomal aberration assay in human lymphocytes [a]	non genotoxic	Analogue 3

a. Studies were summarised in NA/636
b. Analogue 1 is the chemical previously assessed in NA/636

Toxicokinetics, metabolism and distribution.
No data was provided for the notified chemical or its analogues on toxicokinetics. Based on the use patterns provided, the main uptake route for the users of the notified chemical is expected to be dermal absorption. The notified chemical has limited water solubility with a molecular weight > 500 Da and this may reduce the dermal absorption potential for the notified chemical.

Acute toxicity.
An acute oral toxicity study on the notified chemical showed that the chemical is of low toxicity via the oral route. No clinical signs of toxicity were observed. Acute oral toxicity studies conducted on Analogues 1, 2 and 3 also showed low toxicity (NA/636).

An acute dermal toxicity study was not provided for the notified chemical. Studies on Analogues 2 and 3 in rats showed low acute dermal toxicity with LD50 > 2,000 mg/kg bw (NA/636).

No data was provided for the notified chemical or its analogues on acute inhalation toxicity. The notified chemical has a low vapour pressure; hence inhalation exposure is not expected unless aerosols or mists are formed.

Based on the available information, the notified chemical is of low acute oral and dermal toxicity.

Irritation and sensitisation.
No skin and eye irritation studies were provided for the notified chemical.

Skin irritation studies on Analogues 2 and 3 in rabbits showed the analogue chemicals to be slightly irritating to the skin (NA/636). The notified chemical has a structure alert for skin irritation, however the potential for irritation is expected to be limited by the molecular weight (> 500 Da) and low water solubility. Based on the available information, the notified chemical may be slightly irritating to the skin.

An eye irritation study on Analogue 3 in rabbits showed the analogue chemical to be non-irritating.

No data on skin sensitisation was provided for the notified chemical. A study on Analogue 3 using guinea pigs indicated that the analogue chemical was not a skin sensitiser (NA/636).

Based on the available information, the notified chemical is slightly irritating to the skin, non-irritating to the eye and is not expected to have potential for skin sensitisation.

Repeated Dose Toxicity.
A repeat dose oral toxicity study was not provided for the notified chemical. A 28-day repeat dose oral toxicity study on Analogue 3 using rats dosed up to 1,000 mg/kg bw/day showed that the analogue chemical did not exhibit any significant organ toxicity to both male and female rats under the conditions of the study. A NOEL of the analogue chemical was estimated as > 1,000 mg/kg bw/day in the study based on the highest dose used (NA/636).

Based on the available information, the notified chemical is not expected to cause systemic toxicity.

Mutagenicity/Genotoxicity.
No mutagenicity/genotoxicity data on the notified chemical was provided. Analogues 1 and 3 were not mutagenic in bacterial reverse mutation assays. An *in vitro* chromosomal aberration assay on Analogue 3 using human lymphocytes also did not show evidence of genotoxicity for the analogue chemical (NA/636).

Based on the available information, the notified chemical is not expected to be genotoxic.

Health hazard classification
As only limited toxicity data on the notified chemical were provided, the chemical cannot be classified according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
Based on the available information, the notified chemical is expected to be of low hazard presenting only as a possible slight skin irritant. Acute inhalation toxicity is not known, however inhalation exposure is only expected where aerosols or mists are formed.

Reformulation workers would be most at risk of irritating effects when handling the notified chemical as introduced at > 99% concentration. The expected use of PPE should minimise this risk. Furthermore, the use of automated enclosed processes during reformulation and packaging should minimise any potential for inhalation exposure to aerosols or mists.

Risks from exposure to the notified chemical during end-use is not expected when handling finished lubricants containing the notified chemical at < 40% concentration.

Therefore, when used under the occupational settings described, the risk of the notified chemical to the health of workers is not expected to be unreasonable.

6.3.2. Public Health
The notified chemical and the finished products containing it are intended for industrial application only, hence public exposure is not expected. Therefore, when used in the proposed manner, the risk of the notified chemical to the health of the public is not expected to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE
The notified chemical will be imported as a component of lubricant formulations or as raw material used for preparation of lubricants in Australia. The products containing the notified chemical will be transported in original packages for distribution nationwide. No environmental release of the notified chemical is expected during transport and storage except in the case of accidental spills or leaks. Small quantities of the notified chemical may be released to the environment during the reformulation processes as spills and leaks from the connection and disconnection of transfer hoses. Any spills and leaks of the notified chemical are expected to be re-used to the extent practicable, or are expected to be collected with absorbent material and disposed of to landfill.

RELEASE OF CHEMICAL FROM USE
The end use of the products containing the notified chemical is for industrial applications only including stern-tube lubricants for ships and hydraulic fluids. As the products will be used by well trained professional staff, the release of the notified chemical from its use is expected to be limited. Any wastes produced from spills during use and servicing activities are expected to be collected and disposed of in accordance with local regulations.

RELEASE OF CHEMICAL FROM DISPOSAL
The empty containers will be cleaned and reconditioned by suppliers or approved contractors with any wastes disposed of in accordance with local regulations. At the end of its useful life, used products containing the notified chemical are expected to be drained from the lubricant reservoirs of the machinery and be collected and disposed of in accordance with local regulations.

7.1.2. Environmental Fate

The notified chemical was determined to have 78.5% degradation on average over 28 days although the test results indicated it does not meet the 10-day window for it to be classified as readily biodegradable. This means the notified chemical can be considered as inherently biodegradable. Based on its low molecular weight and hydrophobic properties, the notified chemical has potential to bioaccumulate. However, the notified chemical is not expected to be bioavailable to aquatic organisms due to its estimated low water solubility, limited potential for release to aquatic compartments and rapid degradability. For the details of the environmental fate study please refer to Appendix C.

Most of the notified chemical will be thermally decomposed during use, recycling or refinement. Small amounts of the notified chemical are expected to be sent to landfill as residues in empty containers or as a component of waste lubricants. The notified chemical is expected to be degraded by thermal decomposition in industrial facilities or via abiotic or biotic pathways in landfill to form water and oxides of carbon.

7.1.3. Predicted Environmental Concentration (PEC)

The notified chemical is not expected to be present in significant concentrations in the aquatic environment because of the very low potential for direct release to surface waters when used as lubricants for industrial applications only. A Predicted Environmental Concentration (PEC) has therefore not been calculated.

7.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on the notified chemical are summarised in the table below. The tests for toxicity effects of the notified chemical on daphnia and algae were conducted on the water accommodation fractions (WAF) of the test substance. Details of these studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	LC50 (96 h) > limit of water solubility	Not harmful to fish up to the limit of its water solubility
Daphnia Toxicity	EL50 (48 h) > 2,000 mg/L (WAF)	Not harmful to aquatic invertebrates up to the limit of water solubility
Algal Toxicity	E_rL50 (72 h) > 2,000 mg/L (WAF)	Not harmful to algae up to the limit of water solubility

The notified chemical was determined to be not acutely harmful to fish, aquatic invertebrates and algae up to its limit of solubility in water and it is expected to rapidly biodegrade in the environment. Therefore, it is not classified for acute or long-term aquatic hazards under the Globally Harmonised System of Classification and Labelling of Chemicals (United Nations, 2009).

7.2.1. Predicted No-Effect Concentration

A Predicted No-Effect Concentration (PNEC) was not considered necessary since the PEC has not been calculated.

7.3. Environmental Risk Assessment

A Risk Quotient is unable to be quantified as a PEC and PNEC were not calculated. There is no significant aquatic release of the notified chemical anticipated based on its reported use pattern. The notified chemical is expected to rapidly biodegrade and is not expected to be bioavailable. Ecotoxicity results indicate the notified chemical is not harmful to aquatic life up to the limit of its solubility in water. Therefore, the notified chemical is not expected to pose an unreasonable risk to the environment based on its assessed use pattern and low hazard.

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 401 Acute Oral Toxicity.
Species / Strain	Rat / Bor: WISW (SPF cbp)
Vehicle	None.
Remarks - Method	No significant protocol deviations

RESULTS

Group	*Number and Sexof Animals*	*Dose (mg/kg bw)*	*Mortality*
1	10 (5 M/5 F)	2,000	0/10

LD50	> 2,000 mg/kg bw
Signs of Toxicity	No abnormal clinical signs were observed. Body weight gains were normal in all test animals.
Effects in Organs	No test substance related findings were noted.
Remarks - Results	Urinary retention and uterus hydrometra were observed separately in two animals. Lung hyperemias were found in two animals. Authors stated that these effects might due to the sacrificing procedures or to the animal individual variation.

CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	IBR (1993)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test
Inoculum	Activated sludge
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	CO_2 measurement
Remarks - Method	Test conducted in accordance with the test guideline above. No significant deviation from the protocol was reported.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
2	1	5	≥ 60
9	32.5		
15	55		
21	71.5		
28	78.5	28	94

Remarks - Results	The test validity criteria were met. The positive control was found to degrade 94% within 28 days and the 10-day window for ready biodegradability was met. The test substance was determined to have ≥ 60% biodegradation in the two repeated tests. However, the 10-day window for the notified chemical to be considered readily biodegradable, as required by the test guidelines, was not met.
CONCLUSION	The notified chemical is considered to be inherently degradable
TEST FACILITY	Institut Fresenius (2003)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test - Static
Species	Golden orfe (*leuciscus idus melanotus L.)*
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	Not applicable
Remarks – Method	Ten fish were exposed to the test media at the saturated concentrations for the test substance. The test was conducted in accordance with the test guideline above. No significant deviation from the protocol was reported.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality (%)*			
Nominal	*Actual*		*24 h*	*48 h*	*72 h*	*96 h*
control	-	10	0	0	0	0
10000	-	10	0	0	0	0

LC50	> limit of water solubility at 96 hours.

Remarks – Results	The results were based on nominal concentrations as the actual concentration of the test substance was not determined during the fish toxicity test. No mortality or any abnormal behaviour was observed for the tested fish during the 96 hour exposure time period.
CONCLUSION	The notified chemical is not harmful to fish up to the limit of its water solubility
TEST FACILITY	IWL (1993)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 202 *Daphnia* sp. Acute Immobilisation Test – semi-static.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	231mg $CaCO_3$/L
Analytical Monitoring	Not applicable
Remarks - Method	The test preparations were prepared by the water accommodation fraction (WAF) method. A stock solution at 2,000 mg/L was prepared by addition of appropriate test substance in fresh water algal culture medium, followed with 20 hours stirring and 4 hours settling. The aqueous layer was removed for testing. This resultant 2,000 mg/L WAF stock solution was diluted with difference volumes of water to prepare the desired concentrations for the test. The study was performed in compliance with international codes of good laboratory practice (GLP). Following the preliminary study, the definitive test was conducted in accordance with the test guideline above. No significant deviation from the protocol was reported.

RESULTS

Loading rate mg/L(WAF)		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0	-	20	0	0
125	-	20	0	0
250	-	20	0	0
500	-	20	0	0
1000	-	20	0	0
2000	-	20	0	0

EL50	> 2,000 mg/L WAF at 48 hours
NOEL	2,000 mg/L WAF at 48 hours
Remarks - Results	The WAF test media were prepared from a single stock solution, highest concentration of 2,000 mg/L, instead of by dilution of a series of WAF stock solutions at the corresponding concentrations.
CONCLUSION	The notified chemical is not harmful to aquatic invertebrates up to the limit of its water solubility.
TEST FACILITY	CEIL (2004a)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified chemical

METHOD	OECD TG 201 Alga, Growth Inhibition Test.
Species	*Pseudokirchneriella subcapitata*
Exposure Period	72 hours
Concentration Range	Nominal: 0, 125, 250, 500, 1000, 2000 mg/L Actual: Not determined
Auxiliary Solvent	None
Water Hardness	12 mg $CaCO_3$/L
Analytical Monitoring	Not applicable
Remarks - Method	The test preparations were prepared by the water accommodation fraction (WAF) method. A stock solution at 2,000 mg/L was prepared by addition of appropriate test substance in fresh water algal culture medium, followed with 20 hours stirring and 4 hours settling. The aqueous layer was removed for testing. This resultant 2,000 mg/L WAF stock solution was diluted with different volumes of water to prepare the desired concentrations for the test. The study was performed in compliance with international codes of good laboratory practice (GLP). Following the preliminary study, the definitive test was conducted in accordance with the test guideline above. No significant deviation from the protocol was reported.

RESULTS

Biomass		*Growth*	
E_bL50	*NOE_bL*	*E_rL50*	*NOE_rL*
mg/L WAF at 72 h	*mg/L WAF*	*mg/L WAF at 72 h*	*WAF mg/L*
> 2,000	-	> 2,000	-

Remarks - Results	The WAF test media were prepared from a single stock solution, highest concentration of 2,000 mg/L, instead of by dilution of a series of WAF stock solutions at the corresponding concentrations.
CONCLUSION	The notified chemical is not harmful to algae up to the limit of its water solubility.
TEST FACILITY	CEIL (2004b)

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