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June 2010

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Sartomer CD420

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

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANTS
Hewlett Packard (ABN: 74 004 394 763)
353 Burwood Highway,
Forest Hill, VIC 3131

AND

CPI GRAPHICS (ABN: 54 004 081 501)
41-45 Mills Road
Breaside, VIC 3195

AND

INTERNATIONAL SALES AND MARKETING (ABN: 36 467 259 314)
260-262 Highett Road
Highett, VIC 3190

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 and structural formulae, molecular weight, spectral data, purity, identity and % weight of toxic or hazardous impurities/non-hazardous impurities and identity and % weight of additives/adjuvants.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
PHYSICAL CHEMICAL PROPERTIES
Boiling point, Vapour pressure, Water solubility, Partition coefficient, Dissociation constant, Flash point and Flammability limits.
TOXICITY
Acute oral toxicity, Acute dermal Toxicity, Acute Inhalation Toxicity, Skin Irritation, Eye Irritation, Skin Sensitisation, Repeated Dose Toxicity, Induction of Point Mutations, Induction of Germ Cell Damage, and Chromosome Damage.
ECOTOXICITY
Fish, Acute Toxicity; Daphnia sp., Acute Immobilisation/Reproduction; Algal growth inhibition; Bioaccumulation and Biodegradation.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
CEC Permit No 728, CEC Permit No 746

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Sartomer CD 420
SR 420

3. COMPOSITION

DEGREE OF PURITY >95%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Liquid

Property	Value	Data Source/Justification
Boiling Point	234.38 ± 9.00°C at 101.3 kPa	Calculated by ACD I-Lab Service.
Density	930 kg/m^3 at 25°C	MSDS
Vapour Pressure	8.24×10^{-3} kPa at 25°C	Calculated
Water Solubility	1.0×10^{-2} g/L	Calculated
Hydrolysis as a Function of pH	Not determined	Not expected to hydrolyse at environmental pH (4-9)
Partition Coefficient (n-octanol/water)	log Pow = 4.29	Calculated
Adsorption/Desorption	log K_{oc} = 2.65 and 3.23	Calculated
Dissociation Constant	Not determined	No dissociable functions
Particle Size	N/A	The notified chemical is in liquid form
Flash Point	86°C at 101.3 kPa	Analogue 1 data
Flammability	Upper: 0.9 % Lower: 5.0 %	Analogue 1 data
Autoignition Temperature	93°C	MSDS
Explosive Properties	No explosive properties	Based on its structural information, the notified chemical is not expected to be explosive.

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

Reactivity
The notified chemical is intended to react in use. It is not stable in the presence of strong oxidizers, strong reducers, free radical initiators, inert gases, oxygen scavengers. Hazardous polymerisation may occur on depletion of inhibitor. Conditions to avoid: high temperatures, localized heat sources, oxidizing conditions, freezing conditions, direct sunlight, ultraviolet radiation, inert gas blanketing.

Dangerous Goods classification
Based on the physical-chemical data provided in the above table the notified chemical cannot be classified according to the Australian Dangerous Goods Code (NTC, 2007). However the data above does not address all Dangerous Goods endpoints. Therefore consideration of all endpoints should be undertaken before a final decision on the Dangerous Goods classification is made by the introducer of the chemical.

The close analogue 1 is classed as combustible liquid according to the National Fire Protection Association (NFPA) and giving a flammability rating of 2, while analogue 2 is classified as Flammable liquid. According to the reactivity of the notified chemical and the flammability of the close analogue the notified chemical requires Storage in accordance with the *National Standard for the Storage and Handling of Workplace Dangerous Goods* [NOHSC:1015(2001)] for C1 combustible liquids.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported as a component of inkjet printing inks in 5L plastic bottles at a concentration of up to 30%.

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

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

PORT OF ENTRY
SYDNEY AND MELBOURNE.

IDENTITY OF RECIPIENTS
CPI Graphics, Hewlett-Packard Australia Pty Ltd and International Sales & Marketing Pty Ltd

TRANSPORTATION AND PACKAGING
The notified chemical will be imported in 5L plastic bottles at a concentration of up to 30%. It will be transported from port of entry to the notifier's warehouse facilities or directly to the customers (printing industries).

USE
The notified chemical is intended for use as a UV curing agent in inks. It will be imported as a component of formulated inkjet printing inks at up to 30% concentration. The formulated inks will be used by industrial printers for digital printing of large format images such as posters, banners etc.

OPERATION DESCRIPTION
The notified chemical will not be manufactured, reformulated or repackaged in Australia. The inks containing the notified chemical at up to 30% will be used in industrial printers for the digital printing of large format images on a variety of substrates.

The ink bottles will be manually connected to the printing machines via an inlet and attached to a flexible tube which supplies the ink head. Ink will be automatically injected into printing machines.

While printers are running, printer operators monitor the operation, keep the substrate feeders stocked, attend to substrate jams, and will carry out the quality control work as required.

After printing, the notified chemical will be fixed (UV-cured) with other ink ingredients into the substrate matrix.

Any residual ink within printing equipment will be wiped clean using rags and solvents. Printer operators wear gloves during these tasks. Rags and dirty solvents are normally disposed of by the printing company through licensed waste disposal contractors.

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)*
Transport and storages	10-20	4-8	200
Service technicians	200	0.5	5
Printer operators	> 1000	8	200
Wholesale printer supplies	> 1000	8	200

EXPOSURE DETAILS

Dermal exposure of transport, warehousing and wholesale workers to the imported notified chemical will occur only in the event of an accident where the packaging is breached.

The most likely route of exposure of service technicians is dermal as they will come in contact with the notified chemical during printer maintenance. Inhalation exposure is unlikely due to the low vapour pressure of the

notified chemical (8.24×10^{-3} kPa). Printer maintenance personnel will wear disposable gloves and safety glasses.

Printer operators will have limited exposure to the notified chemical, as the process is mainly automated. Dermal and ocular exposure is possible during the replacement of ink bottles (manual process) and cleaning residual ink from printers. Inhalation exposure will be limited due to the low vapour pressure of the notified substance and because of local exhaust ventilation employed in areas surrounding printing machines.

After application to the substrate, the ink containing the notified chemical is UV-cured (chemically reacted) and hence the notified chemical will not be bioavailable.

6.1.2. Public exposure

The printer inks containing the notified chemical will not be sold to the public. After application to the substrate and cured, the notified chemical is expected to remain bound to the substrate print matrix and will not be available for exposure.

6.2. Human health effects assessment

No toxicity data were submitted for the notified chemical. Toxicity information on some analogue chemicals were submitted. The analogue data are summarised in the table below.

Endpoint	*Result and Conclusion*				
	Analogue 1*	Analogue 2	Analogue 3	Analogue 4	Analogue 5*
Rat, acute oral toxicity	LD50 >5000 mg/kg bw; low toxicity	LD50 >3000 mg/kg bw; low toxicity	LD50 >9000 mg/kg bw; low toxicity	LD50 >5000 mg/kg bw; low toxicity	LD50 >8000 mg/kg bw; low toxicity
Rat, acute dermal toxicity	LD50 > 7500 mg/kg bw; low toxicity	LD50 > 1500 mg/kg bw; low toxicity	LD50 >5000 mg/kg bw; low toxicity	LD50 > 5000 mg/kg bw; low toxicity	LD50 > 2500 mg/kg bw; low toxicity
Rat, acute inhalation toxicity	LC50 >1.4 mg/L/8 hour;	LC50 >10.3 mg/L/4 hour;	LC50 >30 mg/L/4 hour;	Not available	Not available
Rabbit, skin irritation	severely irritating	Not available	moderate irritating	slightly irritating	Not available
Rabbit, eye irritation	irritating	Not available	moderate irritating	slightly irritating	Not available
Guinea pig, skin sensitisation	evidence of sensitisation	Not available	evidence of sensitisation	no evidence of sensitisation	evidence of sensitisation
Mouse, skin sensitisation – Local lymph node assay	evidence of sensitisation	weak sensitiser	evidence of sensitisation	Not available	Not available
Rat, repeat dose <Inhalation> toxicity – 90 days.	NOAEL = 23 mg/kg bw/day. LOAEL = 0.225 mg/L (68 mg/kg bw/day)	NOAEL = 84 (male) and 111 (female) mg/kg bw/day	Not available	Not available	Not available
Mutagenicity – bacterial reverse mutation	non mutagenic	non mutagenic	non mutagenic	non mutagenic	
Genotoxicity – in vitro <Mammalian Chromosomal Aberration test>	non genotoxic	Not available	Not available	Not available	Not available
Genotoxicity – in vivo <in vivo cytogenetic assay-clastogenicity>	non genotoxic	Not available	Not available	Not available	Not available
Carcinogenicity	evidence of carcinogenicity through dermal route (>21%)	no evidence of carcinogenicty	no evidence of carcinogenicty	no evidence of carcinogenicty	

* Closely resembles the notified chemical

Health hazard classification
Based on the analogue data provided, the notified chemical is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phrases:
Xi; R36/38: Irritating to eyes and skin.
R43: May cause sensitisation by skin contact.

6.3. Human health risk characterisation

6.3.1. Occupational health and safety
The notified chemical has not been tested for any toxicological properties but based on analogue data, it is likely to be a skin and eye irritant and a skin sensitiser.

These hazards are expected during handling of ink products containing up to 30% of the notified chemical, particularly during manual replacement of ink containers, cleaning of ink residuals and servicing the printing machine.

All printing operations involving the notified chemical should take place under local exhaust ventilation. Printer operators and servicing personnel should wear PPE to minimise skin and eye exposure during handling the ink products containing the notified chemical at up to 30%.

Overall the risk to workers can be considered acceptable if above controls are in place.

6.3.2. Public health
The inks containing the notified chemical at up to 30% will not be sold to the public. No exposure is expected from the dried printed materials. Therefore, risk to the public from the notified chemical is not expected.

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 into Australia as a component of a final product in ready-to-use 5 L ink bottles. No manufacturing and reformulation of the notified chemical will take place in Australia. Environmental release of the notified chemical is unlikely to occur during importation, storage and transportation.

RELEASE OF CHEMICAL FROM USE
The ready-to-use 5 L ink bottles will be designed to prevent leakage and will not be opened during transport, use, installation or replacement. Therefore, release of toner containing the notified chemical to the environment is not expected under normal conditions of use. If leakage or spillage does occur, the toner will be physically contained with absorbent material and disposed of to landfill. 5 L ink bottles will be contained within the printer until the contents are consumed and then they will be removed and sent for recycling or disposed of to landfill. Approximately 0.1% of the ink containing the notified chemical will remain in spent 5 L ink bottles.

RELEASE OF CHEMICAL FROM DISPOSAL
The majority of the notified chemical is expected to be disposed of to landfill and is expected to remain associated with the substrates (e.g. plastic and paper) to which it has been applied. Of the 5% notified chemical applied to paper, half of this amount is expected to be recycled. During recycling processes, waste paper is repulped using a variety of chemical agents which, amongst other things, enhance detachment of ink from the fibres.

7.1.2 Environmental fate

Due to its high volatility, the notified chemical's potential for persistence in air and long range transport was assessed using "AOP Program (v1.92)". This estimates the half-life of the notified chemical in air, based on a 12 hour day, as being 5.9 h, which indicates that the notified chemical is expected to react rapidly with OH-radicals and therefore will not have the potential for long-range transport.

Based on results of a biodegradation study of an analogue of the notified chemical, provided with this notification, the notified chemical is expected to be readily biodegradable and therefore not expected to persist in the environment. The notified chemical is not anticipated to bioaccumulate since it is expected to be readily biodegradable. The fraction of the notified chemical applied to paper will be cured and is not expected to be bioavailable.

For details of the environmental fate studies refer to Appendix C.

7.1.3 Predicted Environmental Concentration (PEC)

PECs (ocean and river) have been calculated assuming that 5% of the total imported notified chemical will be applied to paper and half of this amount will be recycled. A worst case continental model has been assumed in which none of the notified chemical entering waste water treatment plants is removed from the effluents. It is expected the PECs will be less than the calculated values since most of the notified chemical will be adsorbed to sediment due to its hydrophobicity.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	10,000	kg/year
Proportion expected to be released to sewer	2.5%	
Annual quantity of chemical released to sewer	250	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	0.68	kg/day
Water use	200	L/person/day
Population of Australia (Millions)	21.161	million
Removal within STP	0%	
Daily effluent production:	4,232	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.16	µg/L
PEC - Ocean:	0.02	µg/L

7.2. Environmental effects assessment

The results from ecotoxicological investigations conducted on an analogue (different to ones provided for health end points) of 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	LC50 (96 h) = 0.67 mg/L	Very toxic to fish
Daphnia Toxicity – Acute	EC50 (48 h) = 0.40 mg/L	Very toxic to aquatic invertebrates
Daphnia Toxicity – Chronic (reproduction)	Study 1: LOEC (21 d) = 0.13 mg/ L NOEC (21 d) < 0.13 mg/L	At least harmful to aquatic invertebrates with long lasting effects
	Study 2: NOEC (14 d) = 0.51 mg/L	Harmful to aquatic invertebrates with long lasting effects
Algal Toxicity	E_rC_{50} (96 h) = 2.13 mg/L NOEC (96 h) = 1.70 mg/L	Toxic to algae

Under the Globally Harmonised System of Classification and Labelling of Chemicals (United Nations, 2009) the notified chemical is acutely toxic to algae, acutely very toxic to fish and aquatic invertebrates. As there were incomplete data for the chronic endpoints for all three trophic levels of the analogue of the notified chemical, the most stringent classification for the long term effects of the analogue of the notified chemical was applied and this was based on the most sensitive acute endpoint and the log Pow. Therefore the notified chemical is classified very toxic to aquatic invertebrates with long lasting effects.

7.2.1 Predicted No-Effect Concentration

The lowest endpoint from ecotoxicological studies of an analogue to the notified chemical was used to calculate the PNEC. An assessment factor of 500 was used since ecotoxicity results for three acute trophic endpoints and one chronic endpoint were available for an analogue chemical which had minor structural differences to the notified chemical.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
NOEC (Daphnia Chronic)	< 0.13	mg/L
Assessment Factor	500	
PNEC:	< 0.26	µg/L

7.3. Environmental risk assessment

The risk quotients (Q = PEC/PNEC) are tabulated below.

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	< 0.16	< 0.26	0.622
Q - Ocean	< 0.02	< 0.26	0.062

The risk quotient for aquatic exposure is calculated to be < 1 based on the above calculated PEC and PNEC values and is an upper limit based on the expectation that most of the notified chemical will be adsorbed to sludge and sediment in STPs. The Q value of < 1 indicates the notified chemical is not expected to pose an unacceptable risk to the aquatic environment from its proposed use pattern.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the analogue data provided, the notified chemical is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phrases:
Xi; R36/38: Irritating to eyes and skin.
R43: May cause sensitisation by skin contact.

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 2009) 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***
Eye irritation	2	Causes eye irritation
Skin irritation	2	Causes skin irritation
Skin sensitisation	1A	May cause sensitisation by skin contact
Aquatic toxicity	Acute category 1	Very toxic to aquatic life
	Chronic category 1	Very toxic to aquatic life with long lasting effects

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 PEC/PNEC ratio and the reported use pattern, the notified chemical is not expected to pose a risk to the environment.

Recommendations

REGULATORY CONTROLS
Hazard Classification and Labelling

- Safe Work Australia should consider the following health hazard classification for the notified chemical:
  - R36/38: Irritating to eyes and skin
  - R43: May cause sensitisation by skin contact.

- The following risk phrases are recommended in the workplace on products/mixtures containing the notified chemicals:
  - Concentration ≥ 20% : R36/R38, R43
  - ≥1% Concentration < 20% : R43

Health Surveillance

- As the notified chemical presents a skin sensitisation health hazard, employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of sensitisation.

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical:
  - Local exhaust ventilation should be in place during all operations involving handling of the notified chemical.

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical:
  - Avoid contact with eyes and skin.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical during handling of ink products containing up to 30% of the notified chemical, particularly during manual replacement of ink containers, cleaning of ink residuals and servicing the printing machine:
  - Gloves.
  - Safety glasses.
  - Protective clothing.

  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 to landfill.

Storage

- The following precautions should be taken regarding storage of the notified chemical:
  - Storage in accordance with the *National Standard for the Storage and Handling of Workplace Dangerous Goods* [NOHSC:1015(2001)] for C1 combustible liquids.

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 inkjet printing ink use up to 30%, 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 products containing the notified chemical provided by the notifier were reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Vapour Pressure 8.24×10^{-3} kPa at 25°C

Method	MPBVP (v1.43)
Remarks	EPI Suite 4.00
Test Facility	US EPA (2009)

Water Solubility 1.0×10^{-2} g/L

Method	WSKOW (v1.41)
Remarks	EPI Suite 4.00
Test Facility	US EPA (2009)

Partition Coefficient (n-octanol/water) log Pow = 4.29

Method	KOWWIN (v1.67)
Remarks	EPI Suite 4.00
Test Facility	US EPA (2009)

Adsorption/Desorption – screening test log K_{oc} = 2.65 and 3.23

Method	KOCWIN (v2.00)
Remarks	Calculated from MCI (Molecular Connectivity Index) and Log Pow respectively. EPI Suite 4.00.
Test Facility	US EPA (2009)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Analogue of the notified chemical
METHOD	OECD TG 301 D Ready Biodegradability: Closed Bottle Test.
Inoculum	Unknown
Exposure Period	28 days
Auxiliary Solvent	Unknown
Analytical Monitoring	Unknown
Remarks - Method	The analysis of this study is based on summary information presented in a reliable internationally peer reviewed data set for an analogue of the notified chemical.

RESULTS

Test substance		*Sodium Benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
5	72	5	56
15	100	15	74
28	100	28	>83

Remarks - Results	The reference substance was degraded >60% by day 14, indicating a valid test. Since the raw data were not available, it was not possible to determine if the other validity criteria were satisfied. However, the authors of the summary considered the study to be valid without restriction and we therefore consider that the test was valid.
CONCLUSION	The test substance, and by inference the notified chemical, is considered to be readily biodegradable
TEST FACILITY	Exempt Information

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Analogue of the notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test – Flow Through
Species	*Pimephales promelas* (fathead minnow)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	186-187 mg $CaCO_3$/L
Analytical Monitoring	GC/MS
Remarks – Method	The analysis of this study is based on summary information presented in a reliable internationally peer reviewed data set for an analogue of the notified chemical. Standard protocol guidelines were followed with no significant deviations reported. The LC50 and NOEC were determined using the trimmed Spearman-Karber method and TOXSTAT, respectively.

RESULTS

Concentration mg/L			*Mortality*					
Nominal	*Mean Measured*	*Number of Fish*	*3 h*	*6h*	*24 h*	*48 h*	*72 h*	*96 h*
0	NC	20	0	0	0	0	0	0
0.35	0.09	20	0	0	0	0	0	0
0.62	0.15	20	0	0	0	0	0	0
1.12	0.34	20	0	0	0	1	1	1
2.01	0.82	20	0	0	0	7	13	13
3.45	1.75	20	0	0	1	20	20	20

NC = not calculated. All measurements of the control sample were <0.04 mg/L, which was the detection limit of the analytical method.

LC50	0.67 mg/L at 96 hours (based on mean measured test concentrations)
NOEC	0.34 mg/L at 96 hours (based on mean measured test concentrations)
Remarks – Results	All validation criteria for the study were satisfied except that the mean measured concentrations of the test substance were 26-50% of the nominal concentrations. The measured concentrations should preferably be at least 80% of the nominal concentrations. In accordance with test guidelines, the measured concentrations were used to determine the study endpoints.

CONCLUSION The test substance, and by inference the notified chemical, is considered to be very toxic to fish

TEST FACILITY Exempt Information

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Analogue of the notified chemical

METHOD OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test - Static

Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	193 - 197 mg $CaCO_3$/L
Analytical Monitoring	Conducted with an unknown method
Remarks - Method	The analysis of this study is based on summary information presented in a reliable internationally peer reviewed data set for an analogue of the notified chemical. Standard protocol guidelines were followed with no significant deviations reported.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual**		*24 h*	*48 h*
0	<0.04	20	0	0
0.5	0.24	20	0	5
1.0	0.53	20	2	13
2.0	1.21	20	5	20
4.0	2.78	20	15	20
8.0	7.40	20	20	20

*Mean of the 0, 24 and 48 h concentrations

EC50	0.40 mg/L at 48 hours (based on mean of 0, 24 and 48 h concentrations)
NOEC	< 0.24 mg/L at 48 hours
Remarks - Results	All validation criteria for the study were satisfied.

CONCLUSION The test substance, and by inference the notified chemical, is considered

to be very toxic to invertebrates

TEST FACILITY Exempt Information

C.2.3. Chronic toxicity to aquatic invertebrates (Study 1)

TEST SUBSTANCE Analogue of the notified chemical

METHOD OECD TG 202 part 2 "*Daphnia sp.*, Reproduction Test" – Semi Static (1993)

Species	*Daphnia magna*
Exposure Period	21 d
Auxiliary Solvent	None
Water Hardness	127 - 170 mg $CaCO_3$ /L
Analytical Monitoring	Solid/liquid extraction GC/MS
Remarks - Method	The analysis of this study is based on summary information presented in a reliable internationally peer reviewed data set for an analogue of the notified chemical. The EC50 (immobilisation) was determined using the trimmed Spearman-Karber method and the EC50 (reproduction)*, was determined using a point estimation technique.

*50% inhibition of the mean number of young produced per female compared to the control organism reproduction

RESULTS

Test Day 21			
Concentration (mg/L)		*Cumulative Percentage Immobilised* [a]	*Mean Number of Offspring Released per original female* [d]
Nominal	*Actual* [b]		
0	0	5	162.6
0.25	0.13	5	133.6
0.5	0.29	5	138.6
1	0.51	8	138.4
2	1.06	10	74.9
4	2.40	90[c]	< 1

[a] N=40
[b] Based on measured mean for Day 3, 16 and 21.
[c] Value significantly different from the control value at $p \leq 0.05$
[d] Calculated from N=30. First brood released on day 7.

EC50 (immobilisation)	1.61 mg/L [e]
EC50 (reproduction)	1.02 mg/L [e]
NOEC (immobilisation)	1.06 mg/L [e]
NOEC (reproduction)	< 0.13 mg/L [e]

[e] At 21 d, based on mean measured concentrations

Remarks - Results All validation criteria for the study were satisfied. A reproduction NOEC was not calculated. Therefore based on the LOEC of 0.13 mg/L the NOEC was determined to be <0.13 mg/L and hence indicates that the test substance, and by inference the notified chemical, should be categorised as at least harmful to aquatic invertebrates with long lasting effects. Based on the NOEC result for immobilisation, the test substance, and therefore the notified chemical, cannot be classified for long-term hazard.

CONCLUSION The test substance, and by inference the notified chemical, is considered to be at least harmful to aquatic invertebrates with long lasting effects

TEST FACILITY Exempt Information

C.2.4. Chronic toxicity to aquatic invertebrates (Study 2)

TEST SUBSTANCE	Analogue of the notified chemical
METHOD	OECD TG 202 part 2 "*Daphnia sp.*, Reproduction Test" – Semi Static (1993)
Species	*Daphnia magna*
Exposure Period	14 d
Auxiliary Solvent	None
Water Hardness	128 - 169 mg $CaCO_3$ /L
Analytical Monitoring	Solid/liquid extraction GC/MS
Remarks - Method	The analysis of this study is based on summary information presented in a reliable internationally peer reviewed data set for an analogue of the notified chemical. The EC50 (immobilisation) was determined using the trimmed Spearman-Karber method. The EC50 (reproduction)*, was determined using a point estimation technique.

*50% inhibition of the mean number of young produced per female compared to the control organism reproduction

RESULTS

Test Day 14			
Concentration (mg/L)		*Cumulative Percentage Immobilised* [a]	*Mean Number of Live Young Released per original female*[d]
Nominal	*Actual*[b]		
0	0	3	66.9
0.25	0.11	5	43.2
0.5	0.28	8	52.6
1	0.51	0	59.3
2	1.09	3	28.0
4	2.50	68[c]	<1

[a] N=40
[b] Mean values from Day 2 initial and Day 3 final measurements.
[c] Value significantly different from the control value at $p \leq 0.05$
[d] Calculated from N=30. First brood released on day 7.

EC50 (immobilisation)	1.99 mg/L [e]
EC50 (reproduction)	0.97 mg/L [e]
NOEC (immobilisation)	1.09 mg/L [e]
NOEC (reproduction)	0.51 mg/L [e]

[e] At 14 d, based on mean measured concentrations

Remarks - Results	All validation criteria for the study were satisfied.
CONCLUSION	The test substance, and by inference the notified chemical, is considered to be harmful to aquatic invertebrates with long lasting effects
TEST FACILITY	Exempt Information

C.2.5. Algal growth inhibition test

TEST SUBSTANCE	Analogue of notified chemical	
METHOD	OECD TG 201 Alga, Growth Inhibition Test - Static	
Species	*Pseudokirchneriella subcapitata*	
Exposure Period	96 hours	
Concentration Range	Nominal:	0.0, 0.7, 1.3, 2.7, 5.3 and 10.6 mg/L
	Actual:	<0.04, 1.13, 1.70, 2.66, 5.22 and 9.39 mg/L
Auxiliary Solvent	None	
Water Hardness	Unknown	
Analytical Monitoring	GC/MS	
Remarks - Method	The analysis of this study is based on summary information presented in a	

reliable internationally peer reviewed data set for an analogue of the notified chemical.

RESULTS

E_rC_{50} mg/L at 96 h	NOEC mg/L at 96 h
2.13	1.70

Remarks - Results

The increase in the mean algal biomass in the inoculum control within 72 hours was a factor of 7.4 which is less than the minimum 16 fold factor required by the test guideline. The lower than expected growth rate was thought to be due to the use of vessels which did not allow air exchange or introduction of ambient CO_2, which are both essential for algal propagation. Based on the dose response of algal growth inhibition this study was considered valid.

CONCLUSION

The test substance, and by inference the notified chemical, is toxic to algae.

TEST FACILITY

Exempt Information

BIBLIOGRAPHY

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.

NTC (National Transport Commission) 2007 Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG code), 7th Edition, Commonwealth of Australia

United Nations (2009) Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 3rd revised edition. United Nations Economic Commission for Europe (UN/ECE), <http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html >.

US EPA (2009) Estimations Programs Interface Suite™ for Microsoft® Windows, v 4.00. United States Environmental Protection Agency. Washington, DC, USA.