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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Chemical in CodeStream LMC 410

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (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.

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

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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/1588	DS Chemport (Australia) Pty Ltd	Chemical in CodeStream LMC 410	Yes	≤ 3 tonnes per annum	Component of inks/coatings

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified chemical is recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the following table.

Hazard classification	*Hazard statement*
Eye Irritation (Category 1)	H318 – Causes serious eye damage

Based on the available information, the notified chemical is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004), with the following risk phrase:

R41: Risk of serious damage to eyes

The environmental hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS) is presented below. Environmental classification under the GHS is not mandated in Australia and carries no legal status but is presented for information purposes.

Hazard classification	*Hazard statement*
Acute Category 1	H400 – Very toxic to aquatic life
Chronic Category 3	H412 – Harmful to aquatic life with long lasting effects

Human health risk assessment
Provided that the recommended controls are being adhered to, 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 PEC/PNEC ratio and the reported use pattern, the notified chemical is not considered to pose an unreasonable risk to the environment.

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- The notified chemical should be classified as follows:
  - Eye Irritation (Category 1): H318 – Causes serious eye damage

The above should be used for products/mixtures containing the notified chemical, if applicable, based on the concentration of the notified chemical present and the intended use/exposure scenario.

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 formulation, printing or laser treatment:
  - Use of enclosed automated systems, where possible
  - Local exhaust ventilation if aerosols or dusts are generated

- 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 during formulation, printing or laser treatment:
  - Avoid contact with eyes and skin
  - Clean up spills promptly

- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical during formulation, printing or laser treatment:
  - Impervious gloves, coveralls and goggles
  - Respiratory protection if aerosols or dusts are emitted and not minimised by engineering controls

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

- A copy of the (M)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 of 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

- Where reuse or recycling are not appropriate, dispose of the notified chemical in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

Storage

- The handling and storage of the notified chemical should be in accordance with the Safe Work Australia Code of Practice for *Managing Risks of Hazardous Chemicals in the Workplace* (SWA, 2012) or relevant State or Territory Code of Practice.

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(1) of the Act; if
- The ink/coating containing the notified chemical is used on packaging that is in contact with food

or

(2) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from component of inks/coatings, 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.

(Material) Safety Data Sheet
The (M)SDS of a product containing the notified chemical provided by the notifier was reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT
DS Chemport (Australia) Pty Ltd (ABN: 68 006 335 048)
41 Jesica Road
CAMPBELLFIELD VIC 3061

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, analytical data, degree of purity, impurities, additives/adjuvants and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: adsorption/desorption, particle size, autoignition temperature, explosive property, oxidising property, reactivity, skin irritation and acute inhalation toxicity.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
ECHA (2015)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
CodeStream LMC 410 (product containing the notified chemical)

MOLECULAR WEIGHT
> 500 Da

ANALYTICAL DATA
Reference HPLC and IR spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 90%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: odourless white powder

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Measured. The notified chemical decomposes before melting.
Boiling Point	Not determined	Measured. The notified chemical decomposes before boiling.
Density	1,320 kg/m^3 at 20 °C	Measured
Vapour Pressure	0.27 kPa at 25 °C 0.38 kPa at 20 °C	Measured
Water Solubility	0.09 g/L at 20 °C	Measured
Hydrolysis as a Function of pH	$t_{½}$ > 1 year at pH 4, 7 and 9	Measured
Partition Coefficient (n-octanol/water)	log Pow = 2.86 ± 0.06 at 24 °C	Measured

Adsorption/Desorption	Not determined	Expected to partially adsorb to soil and sediment based on molecular weight and structure
Dissociation Constant	pKa = 8.2 at 20 °C	Measured
Particle Size	Not determined	The notified chemical will be imported in an aqueous dispersion mixture
Flash Point	210 °C	Measured
Flammability	Not flammable	Measured
Autoignition Temperature	Not determined	Introduced in aqueous solution
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidising properties

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

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

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 of 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. The notified chemical will be imported as a raw material at a concentration of up to 40% and in formulation 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	< 2	< 2	< 3	< 3	< 3

PORT OF ENTRY
Melbourne, Sydney, Brisbane and Perth

IDENTITY OF MANUFACTURER/RECIPIENTS
DS Chemport (Australia) Pty Ltd

TRANSPORTATION AND PACKAGING
The notified chemical at < 40% concentration will be imported in 20 L closed-top plastic containers or 1000 L intermediate bulk containers by sea. The containers will be distributed by road to the sites of reformulation and end-use. The notified chemical may also be imported in laser markable inks/coatings at < 30% concentration.

USE
The notified chemical will be used in laser markable inks/coatings for commercial printing on paper, corrugate cardboard and polymer film. The finished coated material will be used as packaging and labels for a variety of products for both industrial and consumer use. The final concentration of the notified chemical in laser markable inks/coatings will be <30%.

OPERATION DESCRIPTION
The notified chemical will not be manufactured in Australia. It will be imported in to Australia as raw material at < 40% concentration for reformulation, or in laser markable inks/coatings concentration for industrial use at < 30%.

Reformulation
When the notified chemical is reformulated in Australia, the raw material will be transferred to the mixing tank, either manually or using a metered pump. The reformulation facilities are expected to be automated closed systems with local exhaust ventilation. The inks/coatings produced will be tested for quality control and then packaged into 20L containers for transportation to the end-use site. The final concentration of the notified chemical in end-use ink/coating will be < 30%.

End-use
Laser markable inks/coatings containing the notified chemical at < 30% concentration will be used by industries in flexographic printing on cardboard and plastic substrates. The 20L containers containing the products will be transported to the site of application, where they will be transferred via a hose and pump into the printing press coating station pan. At the end of printing/coating cycle, the product remaining in the printing pan will be pumped back into the container for later use. Once the printing/coating process is finished, the equipment will be rinsed and the rinsate will be collected in containers and recycled.

At a later stage, which may be at another site, sections of the dried ink/coating will be activated by laser or other heat source, to produce markings on the substrates.

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 and storage of formulated product	3	10
Process operator (formulation)	2-3	25
Quality control	1-2	4-5
Applicator of formulation (printing)	8	60

EXPOSURE DETAILS
Transport and storage
Transport and storage workers are unlikely to be exposed to the notified chemical (at < 40%) except in the event of an accidental release due to spills or leaks.

Reformulation
Dermal and ocular exposure to the notified chemical at up to 40% may occur when process operators are transferring the raw material containing the notified chemical into mixing vessels for blending and during the transfer of end-use product into the containers. Quality control workers may also be exposed to the notified chemical at up to 40% via dermal and ocular route during testing of product samples for quality control. Inhalation exposure is unlikely due to the physical state (liquid) of the imported formulation containing the notified chemical but may occur during blending and transfer if aerosols are generated.

End-use
Dermal and ocular exposure to the notified chemical at up to 30% may occur during transfer of the coating into the printing machine. Inhalation exposure is not expected due to the physical state of the coating. Aerosols might be generated during printing processes and when the ink/coating is activated by laser.

The notifier advised that control measures such as the use of automated systems, local exhaust ventilation and personal protecting equipment (PPE) (including impervious gloves, coveralls, goggles and respiratory protection if required) will reduce exposure to the notified chemical during reformulation, testing and application.

The notified chemical or its breakdown products may also be released into the air during activation of the coating by laser or other heat source. Dermal, oral or inhalation exposure of workers may occur at this stage, unless engineering controls or PPE are used to reduce exposure.

6.1.2. Public Exposure

The laser-markable ink/coating products containing the notified chemical at less than 30% concentration are for industrial use only and will not be available to general public. The public may come into contact with the substrates on which the ink or coating is applied. However, once the coating is applied and cured, the notified chemical will be bound within the print matrix and is not expected to be bioavailable.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified chemical and/or mixtures containing the notified chemical are summarised in the following table. For full details of the studies, refer to Appendix B.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity (30.2% solution)	LD50 > 2,000 mg/kg bw; low toxicity (solution)
Rat, acute dermal toxicity	LD50 > 2,000 mg/kg bw; low toxicity
Rabbit, eye irritation	severely irritating
Guinea pig, skin sensitisation – Magnusson and Kligman Maximisation test (38% solution) *	no evidence of sensitisation (solution)
Rat, repeat dose oral toxicity – 90 days. †	NOAEL = 10 mg/kg bw/day
Mutagenicity – bacterial reverse mutation*	non mutagenic
Genotoxicity – in vitro Mammalian chromosome aberration test†	non genotoxic

* – Study conducted on mixture containing 85% notified chemical
† – Study conducted on mixture containing 80% notified chemical

Toxicokinetics, metabolism and distribution

No studies on toxicokinetics, metabolism and distribution were provided. Dermal absorption may occur based on the partition coefficient (log Pow = 2.86 ± 0.06 at 24°C), however may be limited by the high molecular weight (> 500 Da).

Acute toxicity

A dermal toxicity study in rats conducted on the notified chemical suggested the chemical is of low toxicity via the dermal route.

Based on the study report for acute oral toxicity, it is likely that the dosage was based on the 30.2% solution rather than the notified chemical itself. If so, the dosage tested was 604 mg/kg of notified chemical rather than 2000 mg /kg, and the chemical was not acutely toxic at this dose. Therefore no conclusions can be made from this study regarding the chemical's acute toxicity at higher doses.

Irritation and sensitisation

No skin irritation study was provided on the notified chemical. However, the results of the skin sensitisation study in guinea pigs and the acute dermal toxicity study in rats suggest that the chemical is likely to be non-irritating to the skin.

An eye irritation study in rabbits found the notified chemical to be severely irritating to the eyes.

No evidence of skin sensitisation was observed in a guinea pig maximisation test carried out using the notified chemical.

Repeated dose toxicity

In an undated 90-day repeated dose oral toxicity study on rats, a mixture containing 80% of the notified chemical was administered at 0.1, 1, 10 and 100 mg/kg bw/day. The most significant effect was mortality of 5% (1/20) and 10% (2/20) in male and female rats respectively in the high dose (100 mg/kg bw/day) group. Mortality occurred in the lower dose groups but according to the study authors, the deaths were attributed to errors in oral gavage and were consider not to be test substance related.

In the high dose group, significant reduction in body weight gain was recorded in male rats, and deterioration of fur condition in both males and females. Changes were observed in other parameters such as relative organ weights, biochemical and haematological parameters and histopathology, but were either non dose related, or considered to be within the normal range. They were therefore not considered by the study authors to be caused by administration of the test item. Autopsy results showed occasional inflammation of lungs in animals from all test groups including control.

A NOAEL of 10 mg/kg bw/day was established by the study authors, based on adverse effects in the 100 mg/kg bw/day test group. Although the deaths at the high dose (100 mg/kg bw/day) suggest that classification may be warranted, there is uncertainty whether the deaths were caused by administration of the notified chemical, or whether lung infections occurred. The presence of lung inflammation in all groups, and the absence of significant other adverse effects in organs and body systems at 100 mg/kg bw/day suggest that this could be a factor. Therefore a hazard classification has not been applied for this endpoint.

Mutagenicity/Genotoxicity
The notified chemical was found to be non-mutagenic in a reverse bacterial mutation study and non-clastogenic in an *in vitro* mammalian chromosome aberration test conducted using human lymphocytes.

Health hazard classification
Based on the available information, the notified chemical is recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the following table.

Hazard classification	*Hazard statement*
Eye Irritation (Category 1)	H318 – Causes serious eye damage

Based on the available information, the notified chemical is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004), with the following risk phrase(s):

R41: Risk of serious eye damage

It is noted that the notified chemical is also classified by the notifier for acute toxicity (category 4): H302 Harmful if swallowed.

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
The notified chemical is a severe eye irritant and may have adverse effects at low concentrations after repeated exposure. Workers with potential exposure to the notified chemical (at ≤ 40% concentration) include reformulation, quality control, print machine operators and equipment maintenance workers. Exposure is most likely to occur via the dermal route, although ocular and inhalation exposure to the notified chemical may also occur. Dermal, oral and inhalation exposure to the notified chemical or its breakdown products may also occur if these are released from the ink/coating during laser or heat activation.

Control measures such as use of enclosed/automated processes along with local exhaust ventilation are expected to be employed at most stages to reduce exposure. Workers are also expected to wear personal protective equipment (PPE) such as impervious gloves, coveralls and goggles or face shields that would further reduce exposure.

The risk to workers is not considered to be unreasonable if such controls are in place.

6.3.2. Public Health
The product containing the notified chemical is for industrial use only and will not be available to public. The public may come in contact with the dried coated material. However, once cured, the notified chemical will be bound within the print matrix and is not expected to be bioavailable. Hence, public exposure to the notified chemical is not expected, and the risk to health of the public is not considered 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 into Australia as a component of a raw material for reformulation into finished commercial laser markable coatings. No significant release of the notified chemical is expected from transportation and storage, except in the unlikely event of accidental spills or leaks. It is estimated by the notifier

that a maximum of 1% (or up to 30 kg) of the notified chemical may be released from accidental spills and leaks. In the event of spills, the product containing the notified chemical is expected to be collected with adsorbents, and disposed of to landfill in accordance with local government regulations.

The reformulation process will involve blending operations that will be highly automated, and is expected to occur within a fully enclosed environment. Therefore, significant release of the notified chemical from this process to the environment is not expected. The process will be followed by automated filling of the formulated products into containers suitable for distribution. Wastes containing the notified chemical generated during reformulation include equipment wash water, empty import containers, and spilt materials. It is estimated by the notifier that a maximum of 2% (or up to 60 kg) of the notified chemical may be released as container residue and spilt materials. Wastes may be collected and released to sewers in a worst case scenario, or disposed of to landfill in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE

The majority of the notified chemical will be used as a component of commercial laser markable coatings for printing onto paper and paperboard (90% of the total import volume, or 2,700 kg). A minor amount of commercial coatings containing the notified chemical will be used for printing onto plastic films (10% of the total import volume, or 300 kg). The printing process will be largely automated, and the notified chemical is expected to be stable within an inert coating matrix on printed substrates once cured. Therefore, environmental release of the notified chemical during use is expected to be limited to accidental spills and leaks and cleaning of printing equipment. It is estimated by the notifier that up to 1% of the annual import volume (or 30 kg) may be released as a result of spills and equipment cleaning. Spilt material and solid wastes from cleaning will be collected and disposed of to landfill in accordance with local government regulations.

RELEASE OF CHEMICAL FROM DISPOSAL

The notified chemical will be used in commercial laser markable coatings for printing onto paper, paperboard and plastic films. The majority of the notified chemical is expected to share the fate of the printed articles to which it is bound, and is expected to be disposed of to landfill at the end of their useful life.

Of the 90% import volume of the notified chemical applied to paper and paperboard, it is assumed that half of this amount is expected to be disposed of to landfill, and the remainder will undergo paper recycling processes. Empty containers containing residues of the notified chemical will be disposed of to landfill in accordance with local government regulations. Hence, the majority of the notified chemical is expected to be disposed of to landfill, with a potential for some release to sewer through paper recycling processes. During paper recycling processes, waste paper is pulped using a variety of chemical treatments which, amongst other things, will enhance ink detachment from the fibres.

7.1.2. Environmental Fate

The majority of the notified chemical in commercial laser markable coatings will be bound within the coating matrix, and will share the fate of the printed articles. The majority of the notified chemical is expected to enter the environment from disposal of printed articles to which the coating containing the notified chemical is bound. Based on the results of a ready biodegradability study, the notified chemical is considered readily biodegradable (84% in 28 days). For details of the environmental fate study, please refer to Appendix C. The notified chemical is not expected to be bioaccumulative based on its ready biodegradability and low partition coefficient (log P_{OW} = 2.86 ± 0.06).

Potentially 90% of the notified chemical could be disposed of to landfill as part of printed waste paper and paperboard. However, approximately 50% of the paper and paperboard substrates to which the coating containing the notified chemical is applied are expected to be recycled. During the de-inking process, the notified chemical is unlikely to be released into the supernatant waters. Based on its low water solubility and anionic properties, during recycling the majority of the cured coating containing the notified chemical is expected to adsorb to sludge and sediment. Sewage sludge will eventually be disposed of to landfill, or re-used for soil remediation. In landfill and in surface waters, the notified chemical is expected to eventually degrade through biotic and abiotic processes to form water and oxides of carbon and zinc.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has been calculated to assume a worst case scenario, with half of the paper and paperboard substrates containing the notified chemical undergoing recycling (i.e. 3,000 kg import volume × 90% printed onto paper substrates × 50% = 1,350 kg). It is assumed that the notified chemical will be released into sewers during recycling, with no removal during recycling or STP processes. As the notified chemical bound to paper and paperboard substrates is to be processed at paper recycling facilities located

throughout Australia, it is anticipated that such releases will occur over 260 working days per annum into the Australian effluent volume.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	3,000	kg/year
Proportion expected to be released to sewer	45%	
Annual quantity of chemical released to sewer	1,350	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	5.19	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	0%	
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	1.148	µg/L
PEC - Ocean:	0.115	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1,000 L/m^2/year (10 ML/ha/year). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1,500 kg/m^3). Using these assumptions, irrigation with a concentration of 1.15 µg/L may potentially result in a soil concentration of approximately 7.65 µg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of the notified chemical in the applied soil in 5 and 10 years may be approximately 38.27 µg/kg and 76.54 µg/kg, respectively.

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*
Acute toxicity		
Fish	96 h LC50 = 4.2 mg/L*	Toxic to fish
Daphnia	48 h EC50 = 0.095 mg/L*	Very toxic to aquatic invertebrates
Algae	72 h EC50 = 4.2 mg/L	Toxic to algae
Chronic toxicity		
Fish	14 d NOEC = 3.2 mg/L	Not harmful to fish
Daphnia	21 d NOEC = 0.32 mg/L	Harmful to aquatic invertebrates

* – Study conducted on mixture containing 85% notified chemical

Based on the above acute ecotoxicological endpoints, the notified chemical is expected to be very toxic to aquatic invertebrates, and toxic to fish and algae. Therefore, under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009), the notified chemical is formally classified as "Acute Category 1; Very toxic to aquatic life". Based on the above chronic ecotoxicological endpoints and its ready biodegradability, the notified chemical is formally classified as "Chronic Category 3; Harmful to aquatic life with long lasting effects" under the GHS.

7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) has been calculated from the most sensitive endpoint for aquatic invertebrates. A safety factor of 50 was used given acute ecotoxicological endpoints are available for three trophic levels, and chronic ecotoxicological endpoints are available for two trophic levels.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (*Daphnia*, 48 h)	0.095	mg/L
Assessment Factor	50	
Mitigation Factor	1.00	
PNEC:	1.90	µg/L

7.3. Environmental Risk Assessment

The Risk Quotient (Q = PEC/PNEC) has been calculated based on the predicted PEC and PNEC.

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q – River	1.148	1.90	**0.604**
Q – Ocean	0.115	1.90	**0.060**

The Risk Quotients for discharge of treated effluents containing the notified chemical to the aquatic environment indicates that the notified chemical is unlikely to reach ecotoxicologically significant concentrations in surface waters, based on its maximum annual importation quantity. The notified chemical is readily biodegradable, and is expected to have a low potential for bioaccumulation. On the basis of the PEC/PNEC ratio, maximum annual importation volume, and assessed use pattern in commercial laser markable coatings, the notified chemical is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point/Freezing Point Not determined

Method OECD TG 102 Melting Point/Melting Range.
Remarks The microscopic melting point method was used. The test substance decomposed at 197.8°C before reaching melting point.
Test Facility Hodogaya (2012a)

Boiling Point Not determined

Method OECD TG 103 Boiling Point.
Remarks The differential scanning calorimeter (DSC) method was used and the test was conducted twice. An endothermic peak at around 80 C was assumed to result from moisture evaporation. Other endothermic peaks observed around 230-240 C and around 413 C were attributed to thermal decomposition. The test substance decomposed before reaching boiling point.
Test Facility Hodogaya (2012b)

Density 1,320 kg/m^3 at 20 °C

Method OECD TG 109 Density of Liquids and Solids.
Remarks Pycnometer method. Test conducted twice.
Test Facility Hodogaya (2012c)

Vapour Pressure 0.27 kPa at 20 °C
0.38 kPa at 25 °C

Method EC Council Regulation No 440/2008 A.4 Vapour Pressure.
Remarks Isoteniscope method.
Test Facility LAB (2010)

Water Solubility 0.09 g/L at 20 °C

Method OECD TG 105 Water Solubility.
Remarks Flask Method
Test Facility Confidential (2012)

Hydrolysis as a Function of pH $t_{½}$ > 1 year at pH 4, 7 and 9

Method OECD TG 111 Hydrolysis as a Function of pH.

pH	*T (°C)*	$t_{½}$
4	25	> 1 year
7	25	> 1 year
9	25	> 1 year

Remarks After 5 days under the accelerated conditions of 50 °C the rate of hydrolysis of the notified substance was less than 10% at pH 4, 7 and 9. This is equivalent to a half life of > 1 year at 25°C. Therefore, it can be concluded that under the conditions of the test, the notified chemical is hydrolytically stable at pH 4, 7 and 9.
Test Facility Brixham (2010)

Partition Coefficient (n-octanol/water) log Pow = 2.86 ± 0.06 at 24 °C

Method OECD TG 117 Partition Coefficient (n-octanol/water).
EC Council Regulation No 440/2008 A.8 Partition Coefficient.
Remarks Flask Method. Calculated as the ratio between solubility in n-octanol and solubility in

water.
Test Facility TNO (1994)

Dissociation Constant pKa = 8.2 at 20 °C

Method OECD TG 112 Dissociation Constants in Water.
Remarks Titration Method
Test Facility CiToxLAB (2013)

Flash Point 210 °C

Method EC Council Regulation No 440/2008 A.9 Flash Point.
Remarks A Cleveland open tester was used.
Test Facility Fukuoka (1987)

Solid Flammability Not flammable

Method EC Council Regulation No 440/2008 A.10 Flammability (Solids).
Remarks In the preliminary screening test the test substance ignited very briefly with a yellow flame and black smoke. The flame extinguished on removal of the ignition source. Therefore no further testing was required. Based on the study, the authors did not classify the substance as a readily combustible under UN Class 4, Division 4.1.
Test Facility Chilworth (2011)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE: 30.2% notified chemical

METHOD: Method similar to OECD TG 401 Acute Oral Toxicity.
- Species/Strain: Rat/Crj:CD(SD)
- Vehicle: Purified water
- Remarks - Method: No significant deviations from the OECD TG 401 guidelines. The test substance was administered by oral gavage.
Based on the wording of the study report, it is assumed that the animals were dosed with 2,000 mg/kg of the dispersion containing 30.2% notified chemical. However it is also possible that the dosage was adjusted to account for the concentration of the chemical in the dispersion.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5M & 5F	2,000	0/10

- LD50: > 2,000 mg/kg bw
- Signs of Toxicity: None reported
- Effects in Organs: None reported
- Remarks - Results: Test animals administered with the test substance showed mucous faeces containing white material. Two days after administration, no symptoms were observed. Dirt on the abdomen of one female rat was observed during a period from 3 to 6 hours after administration.

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

TEST FACILITY: Hita (1992)

B.2. Acute toxicity – dermal

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 402 Acute Dermal Toxicity – Limit Test.
- Species/Strain: Rat/CRL:(WI)
- Vehicle: Dampened with water to ensure good contact with skin
- Type of dressing: Semi-occlusive
- Remarks - Method: No deviations from the OECD guidelines.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5M & 5F	2,000	0/10

- LD50: > 2,000 mg/kg bw
- Signs of Toxicity - Local: None reported
- Signs of Toxicity - Systemic: None reported
- Effects in Organs: None reported
- Remarks - Results: A slight body weight loss was observed in one female test rat between days 7 and 14. No other treatment related effects on body weight or weight gain were observed.

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

TEST FACILITY CiToxLAB (2015)

B.3. Irritation – eye

TEST SUBSTANCE Notified chemical

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain Rabbit/New Zealand White
Number of Animals 3 (male)
Observation Period 21 days
Remarks - Method No significant deviations from the OECD guidelines. 100 mg of test substance was administered as single dose in left eye and the right eye served as control. The treated eye was rinsed with physiological saline solution one hour after treatment.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect (days)*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	3.00	3.00	2.33	3	> 21	1
Conjunctiva: chemosis	4.00	3.00	1.67	4	< 15	0
Conjunctiva: discharge	3.00	3.00	2.67	3	> 21	1
Corneal opacity	2.33	1.67	1.67	3	< 21	0
Iridial inflammation	0.00	0.00	0.00	0	-	-

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

Remarks - Results Initial pain reaction was observed in all animals. The effects observed were not fully reversible within 21 days. No other systemic effects were observed.
One animal showed reduction in body weight which was considered by the study author not to be treatment related.

CONCLUSION The notified chemical is severely irritating to the eye.

TEST FACILITY LAB (2011)

B.4. Skin sensitisation

TEST SUBSTANCE Mixture containing 85% notified chemical (38% solution)

METHOD OECD TG 406 Skin Sensitisation – Magnusson and Kligman Maximisation Test.
Species/Strain Guinea pig/albino Dunkin-Hartley
PRELIMINARY STUDY Maximum Non-irritating Concentration:
intradermal: 5%
topical: 100%
MAIN STUDY
Number of Animals Test Group: 20 Control Group: 10
Vehicle Distilled water
Positive control Not conducted in parallel with the test substance, but had been conducted previously in the test laboratory using 2,4-Dinitrochlorobenzene.
INDUCTION PHASE Induction Concentration:
intradermal: 5% (w/v)
topical: 100%
Signs of Irritation Yes

CHALLENGE PHASE

1st challenge	topical: 75% and 50%
Remarks - Method	No significant deviations from the OECD guidelines. Procedure used is based on method described by Magnusson and Kligman (1970). Concentrations of the test substance for induction and challenge were chosen on the basis of preliminary tests. Challenges with the 75% and 50% of the test substance were performed at the same time, on different sites on each animal.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after challenge:*	
		24 h	*48 h*
Test Group	50%	0	0
	75%	0	0
Control Group	-	0	0

Remarks - Results	One test animal from the control group was found dead on day 9.

CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the test substance under the conditions of the test.
TEST FACILITY	SafePharm (1992a)

B.5. Repeat dose toxicity

TEST SUBSTANCE	Mixture containing 80% notified chemical
METHOD	Similar to OECD TG 408 Repeated Dose 90-Day Oral Toxicity Study in Rodents.
Species/Strain	Rats/KBL:Wistar
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 90 days Dose regimen: 7 days per week
Vehicle	0.5% Tragacanth solution
Remarks - Method	The study results did not provide information on individual animals. They contained specific results for each aspect of the test, conclusions and group data. No method details were provided to authenticate whether the study was conducted according the OECD guidelines.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
Control	20F & 20M	0	0/40
I	20F & 20M	0.1	1M
II	20F & 20M	1	0/40
III	20F & 20M	10	1M
IV	20F & 20M	100	1M & 2F

Mortality and Time to Death

The deaths occurred at various stages of the study. The deaths in group IV were attributed to the general decline in health due to the dose of test substance administered. It was assumed that the specific cause of death in this group was infection-related congestion of the lung, related to the decline in health. The deaths in group I and III were attributed by the study authors to errors in gavage.

Clinical Observations

Deterioration of the condition of fur was observed in test animals from group IV. Significant reduction in weight gain was noted in male rats from test group IV. No reduction in food and water intake was observed in

any test groups.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Haematology

Male rats from test groups I to III showed significant increase in red blood cells and all male rats exposed to the test substance showed increased haemoglobin levels. In females, only the number of red blood cells increased, in groups III and IV only, with no change in haemoglobin and other haematocrit values.

Clinical chemistry

Significant reduction in albumin/globulin ration was observed in test animals from group III and IV. Small increases in bilirubin levels were reported in male rats from group IV. Reductions in electrolyte levels (sodium, potassium and chloride) were noted in test animals from group IV. Though significant changes in serum biochemistry were noted, the changes were not significant when compared to historical control data in the laboratory and hence the changes were considered to be normal by the study authors.

Urinalysis

Increase in urine volume was noted for rats from group IV. No other significant changes were reported.

Effects in Organs

Inflammation of the lung was occasionally noted in all groups, including the control.

Increase in relative weight of organs such as brain, liver, kidneys, adrenal gland and testis was noted in male rats and in kidneys and adrenal gland in female rats. However these changes were not clearly dose related.

Histopathology

Various histopathological changes were noted in test animals from various groups, however most of these were not dose related, occurred also in controls, and some were isolated effects. Animals exposed to the test substance showed pyknosis and fatty degeneration of liver cells. However the incidence of these effects was not dose related.

Remarks – Results

Apart from the mortalities, the study authors did not definitely attribute the other effects to treatment, as most were isolated, not dose related or within the historical ranges.

CONCLUSION

The No Observed Adverse Effect Level (NOAEL) was established as 10 mg/kg bw/day in this study, based on the clinical and biochemical changes and mortality observed in test animals from 100 mg/kg bw/day exposure group.

TEST FACILITY	Seisan (undated)

B.6. Genotoxicity – bacteria

TEST SUBSTANCE	Mixture containing 85% notified chemical
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. Plate incorporation procedure
Species/Strain	*S. typhimurium*: TA1538, TA1535, TA1537, TA98, TA100
Metabolic Activation System	S9 mix from Aroclor 1254 induced rat liver
Concentration in Main Test	Test 1: 8, 40, 200, 1,000 and 5,000 µg/plate Test 2: 312.5, 625, 1,250, 2,500 and 5,000 µg/plate
Vehicle	Distilled water
Remarks - Method	No significant deviations from the OECD guidelines. Concentrations were chosen on the basis of a preliminary study. Positive controls: With metabolic activation: 2-aminoanthracene (TA1535); benzo(a)pyrene (TA1538, TA1537, TA98 TA100) Without metabolic activation: *N*-Ethyl-*N'*-nitro-*N*-nitrosoguanidine (TA1535 & TA100); 9-Aminoacridine (TA1537); 4-Nitro-o-phenylene-

diamine (TA1538); 4-Nitroquinoline-1-oxide (TA98).

The mixture was provided in a diluted form, however the concentration was taken into account when calculating the dosage

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 5,000 µg	> 5,000 µg	> 5,000 µg	Negative
Test 2	> 5,000 µg	> 5,000 µg	> 5,000 µg	Negative
Present				
Test 1	> 5,000 µg	> 5,000 µg	> 5,000 µg	Negative
Test 2	> 5,000 µg	> 5,000 µg	> 5,000 µg	Negative

Remarks - Results

In both tests, no biologically relevant increases in the frequency of revertant colonies were obtained in the presence or absence of metabolic activation. No visible thinning of the background lawn of non-revertant cells was observed.

Positive controls performed as expected confirming the validity of the assay.

CONCLUSION

The test material was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY

SafePharm (1992b)

B.7. Genotoxicity – in vitro

TEST SUBSTANCE

Mixture containing 85% notified chemical

METHOD

OECD TG 473 In vitro Mammalian Chromosome Aberration Test (as in 1981 Guidelines).

Species/Strain: Human
Cell Type/Cell Line: Lymphocytes
Metabolic Activation System: S9 fraction from Aroclor 1254 induced rat liver
Vehicle: Distilled water
Remarks - Method: No significant deviations from the OECD guidelines. Vehicle controls and positive controls (ethyl methanesulphonate and cyclophosphamide) were run concurrently with the notified chemical.
The mixture was provided in a diluted form, however the concentration was taken into account when calculating the dosage.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Expression Time*	*Selection Time*
Absent				
Test 1	1.95, 3.9, 7.8, 15.63, 31.25*, 62.5*, 125* & 250	20h		20h
Present				
Test 1	1.95, 3.9, 7.8, 15.63, 31.25, 62.5*, 125* & 250*	4h	16h	20h
Test 2	1.95, 3.9, 7.8, 15.63*, 31.25*, 62.5*, 125 & 250	4h	26h	30h

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*		
	Cytotoxicity	*Precipitation**	*Genotoxic Effect*
Absent			
Test 1	≥ 250	-	Negative
Present			
Test 1	> 250	-	Negative
Test 2	≥ 125	-	Negative

*No comments regarding precipitation were made in the test report.

Remarks - Results

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

TEST FACILITY SafePharm (1992c)

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: CO2 Evolution Test.
Inoculum	Activated sewage sludge
Exposure Period	28 days (extended to 36 days*)
Auxiliary Solvent	None
Analytical Monitoring	Theoretical Carbon Dioxide ($ThCO_2$)
Remarks - Method	The test was conducted in accordance with the test guideline above, with no significant deviations in protocol reported.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
6	1	6	72
14	14	14	107
22	51	22	101
28	84	28	97
36*	97		

* Corrected for the last gas wash

Remarks - Results	All validity criteria for the test were satisfied. The percentage degradation of the reference compound surpassed the threshold level of 60% by 6 days (72%), and attained 97% degradation in 28 days. Therefore, the tests indicate the suitability of the inoculums. The degree of degradation of the test substance was 84% after 28 days, and attained the threshold level of 60% within the 10-day window. Therefore, the test substance is considered to be readily biodegradable according to the OECD (301 B) guideline.
CONCLUSION	The notified chemical is readily biodegradable.
TEST FACILITY	SafePharm (1995)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Mixture containing 85% notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test – Semi-static.
Species	*Oncorhynchus mykiss* (rainbow trout)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	100 mg $CaCO_3$/L
Analytical Monitoring	HPLC
Remarks – Method	The test was conducted in accordance with the test guideline above, with no significant deviations in protocol reported.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality (%)*				
Nominal	*Actual*		*3 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control	Control	10	0	0	0	0	0
3.2	2.58	10	0	0	0	0	0
5.6	5.01	10	0	0	30	100	100

10	8.98	10	0	100	100	100	100
18	14.4	10	0	100	100	100	100
32	29.8	10	0	100	100	100	100

LC50	4.2 mg/L (95% CI 3.2-5.6 mg/L) at 96 hours.
NOEC	3.2 mg/L at 96 hours.
Remarks – Results	All validity criteria for the test were satisfied. The test solutions were renewed every 24 hours during the 96 h test period. The actual concentrations of the test substance were measured at 0 and 24 hours during the 96 h test period. The measured nominal concentrations were within 20% difference of the actual concentrations. The 96 h LC50 and NOEC for fish was determined to be 4.2 mg/L and 3.2 mg/L, respectively, based on nominal concentrations.
CONCLUSION	The test substance is considered to be toxic to fish.
TEST FACILITY	SafePharm (1994a)

C.2.2. Chronic toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 204 Fish, Prolonged Toxicity Test: 14-Day Study – Semi-static.
Species	*Brachydanio rerio* (zebra fish)
Exposure Period	14 days
Auxiliary Solvent	Dimethyl sulfoxide (DMSO)
Water Hardness	227 mg $CaCO_3$/L
Analytical Monitoring	None
Remarks – Method	The definitive test was conducted at the nominal concentrations of 0.56, 1.0, 1.8, 3.2, 5.6, and 10 mg/L of the test substance. The test was conducted in accordance with the test guideline above, with no significant deviation in protocol reported.

RESULTS

Nominal Concentration mg/L	*Number of Fish*	*Mortality*			
		2 d	*7 d*	*11 d*	*14 d*
Control	20	0	0	0	0
Solvent control	20	0	0	0	0
0.56	20	0	0	0	0
1.0	20	0	0	0	0
1.8	20	0	0	0	0
3.2	20	0	0	0	0
5.6	20	5	25	40	40
10	20	100	ND	ND	ND

ND: Not determined

NOEC	3.2 mg/L at 14 days.
Remarks – Results	All validity criteria for the test were satisfied. The test solutions were renewed every two days during the 14 d test period. The actual concentrations of the test substance were not measured during the 14 d test period. The 14 d NOEC for fish was determined to be 3.2 mg/L, based on nominal concentration.
CONCLUSION	The notified chemical is not considered to be harmful to fish on a chronic basis.
TEST FACILITY	TNO (1990a)

C.2.3. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Mixture containing 85% 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	270 mg $CaCO_3$/L
Analytical Monitoring	HPLC
Remarks - Method	A total of 20 daphnids were used. The test was conducted in accordance with the test guideline above, with no significant deviation in protocol reported.

RESULTS

Concentration mg/L		*Number of D. magna*	*Cumulative Immobilised (%)*	
Nominal	*Actual*		*24 h*	*48 h*
Control	Control	20	0	0
0.018	ND	20	0	0
0.032	0.0291	20	0	0
0.056	ND	20	0	0
0.10	0.0953	20	0	60
0.18	ND	20	0	100
0.32	0.295	20	0	100
0.56	ND	20	25	100
1.0	0.84	20	65	100

ND: Not determined

EC50	0.095 mg/L (95% CI 0.083-0.11 mg/L) at 48 hours
NOEC	0.056 mg/L at 48 hours
Remarks - Results	All validity criteria for the test were satisfied. The test solutions were not renewed during the 48 h test period. The actual concentrations of the test substance were measured at the start and end of the 48 h test period. As the measured concentrations were within 20% difference of the nominal concentrations, the nominal were used. The 48 h EC50 and NOEC for daphnids were determined to be 0.095 mg/L and 0.056 mg/L, respectively, based on nominal loading concentrations.
CONCLUSION	The test substance is considered to be very toxic to aquatic invertebrates.
TEST FACILITY	SafePharm (1994b)

C.2.4. Chronic toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction test – Semi-static.
Species	*Daphnia magna*
Exposure Period	21 days
Auxiliary Solvent	Dimethyl sulfoxide (DMSO)
Water Hardness	227 mg $CaCO_3$/L
Analytical Monitoring	None
Remarks - Method	The definitive test was conducted at the nominal concentrations of 0.056, 0.10, 0.18, 0.32, 0.56, 1.0, 1.8, and 3.2 mg/L of the test substance. A total of 20 daphnids were used. The test was conducted in accordance with the test guideline above, with no significant deviation in protocol reported.

RESULTS

	Nominal Test Concentration (mg/L)									
	Control	*Solvent control*	*0.056*	*0.10*	*0.18*	*0.32*	*0.56*	*1.0*	*1.8*	*3.2*
Adult survival (%)	92.5	100	100	97.5	97.5	100	97.5	95	35	2.5
Total no. offspring released by survived *Daphnia*	134.0	135.9	131.1	140.7	140.5	122.7	80.5	19.8	2.7	0
± SD	12.9	9.7	7.5	6.8	12.6	8.8	12.9	5.1	2.8	0

SD = Standard deviation

EC50	0.61 mg/L at 21 days
NOEC	0.32 mg/L at 21 days
Remarks - Results	All validity criteria for the test were satisfied. The test solutions were renewed three times per week during the 21 d test period. The actual concentrations of the test substance were not measured during the 21 d test period. The 21 d EC50 and NOEC were determined to be 0.61 mg/L and 0.32 mg/L, respectively, based on nominal concentrations.

CONCLUSION The notified chemical is considered to be harmful to aquatic invertebrates on a chronic basis.

TEST FACILITY TNO (1990b)

C.2.5. Algal growth inhibition test

TEST SUBSTANCE Notified chemical

METHOD OECD TG 201 Freshwater Alga and Cyanobacteria, Growth Inhibition Test.

Species	*Scenedesmus subspicatus* (green alga)
Exposure Period	72 hours
Concentration Range	Nominal: 0.4-6.4 mg/L Actual: 0.324-5.61 mg/L
Auxiliary Solvent	Dimethylformamide (DMF)
Water Hardness	Not reported
Analytical Monitoring	HPLC
Remarks - Method	The test was conducted in accordance with the test guideline above, with no significant deviation in protocol reported.

RESULTS

Biomass		*Growth*	
EC50 *mg/L at 72 h*	*NOEC* *mg/L*	*EC50* *mg/L at 24 h*	*NOEC* *mg/L*
3.5	1.6	4.2	1.6

Remarks - Results	All validity criteria for the test were satisfied. The actual concentrations of the test substance were measured at the start and end of the 72 h test period. As the measured concentrations were within 20% difference of the nominal concentrations, the nominal were used. The 72 h EC50 and NOEC were determined to be 4.2 mg/L and 1.6 mg/L, respectively, based on nominal concentrations.

CONCLUSION The notified chemical is considered to be toxic to algae.

TEST FACILITY SafePharm (1996)

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