File No: STD/1574 & STD/1602

January 2017

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

STD/1574: Chemical A in NAFOL Linear Alcohols, Distn. Residues STD/1602: Chemical B in NAFOL Linear Alcohols, Distn. Residues

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 and Energy.

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:

Street Address: Level 7, 260 Elizabeth Street, SURRY HILLS NSW 2010, AUSTRALIA.

Postal Address: GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.

TEL: + 61 2 8577 8800 FAX: + 61 2 8577 8888 Website: www.nicnas.gov.au

Director NICNAS

TABLE OF CONTENTS

SUMMARY	
CONCLUSIONS AND REGULATORY OBLIGATIONS	3
ASSESSMENT DETAILS	
1. APPLICANT AND NOTIFICATION DETAILS	
2. IDENTITY OF CHEMICAL	
3. COMPOSITION	
4. PHYSICAL AND CHEMICAL PROPERTIES	
5. INTRODUCTION AND USE INFORMATION	7
6. HUMAN HEALTH IMPLICATIONS	
6.1. Exposure Assessment	
6.1.1. Occupational Exposure	8
6.1.2. Public Exposure	
6.2. Human Health Effects Assessment	
6.3. Human Health Risk Characterisation	
6.3.1. Occupational Health and Safety	9
6.3.2. Public Health	
7. ENVIRONMENTAL IMPLICATIONS	
7.1. Environmental Exposure & Fate Assessment	
7.1.1. Environmental Exposure	
7.1.2. Environmental Fate	
7.1.3. Predicted Environmental Concentration (PEC)	
7.2. Environmental Effects Assessment	
7.2.1. Predicted No-Effect Concentration	
7.3. Environmental Risk Assessment	
APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES	
APPENDIX B: TOXICOLOGICAL INVESTIGATIONS	
B.1. Acute toxicity – oral	
B.2. Acute toxicity – dermal	
B.3. Irritation – skin	
B.4. Irritation – eye	
B.5. Skin sensitisation	
B.6. Repeat dose toxicity	
B.7. Repeat dose toxicity	
B.8. Genotoxicity – bacteria	
B.9. Genotoxicity – in vitro	
B.1. Genotoxicity – in vitro	
B.10. Developmental toxicity	
APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS	
C.1. Ecotoxicological Investigations	
C.2.1. Acute toxicity to fish	
C.2.2. Acute toxicity to aquatic invertebrates	
C.2.3. Algal growth inhibition test	
C.2.4. Inhibition of microbial activity	
BIBLIOGRAPHY	26

SUMMARY

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

		USE
- ·	< 100 tonnes per annum (each	Processing aid in paper manufacturing
	chemical)	8
*		
ohols, Distn.		
	ADE NAME CHEMICALS	ADE NAME CHEMICALS VOLUME TD/1574: emical A in FOL Linear phols, Distn. Residues TD/1602: emical B in FOL Linear phols, Distn.

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available information, the notified chemicals are not recommended for classification according to the *Globally Harmonised System of 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 chemicals are not considered to pose an unreasonable risk to the health of workers.

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

Environmental risk assessment

On the basis of their low toxicity to aquatic life and the assessed use pattern, the notified chemicals are not considered 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 safe work practices to minimise occupational exposure during handling of the notified chemicals as introduced in the neat form:
 - Avoid eye contact

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 chemicals 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 chemicals in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

Emergency procedures

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

Regulatory Obligations

Secondary Notification

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

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

- (1) Under Section 64(2) of the Act; if
 - the function or use of the chemicals has changed from a processing aid in paper manufacturing, or is likely to change significantly;
 - the amount of chemical being introduced has increased, or is likely to increase, significantly;
 - the chemicals have begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the chemicals 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 (M)SDS of products containing the notified chemicals provided by the notifier were 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(S)

Cintox Australia Pty Ltd (ABN: 63 122 874 613)

Suite 1, Level 2, 38-40 George Street

PARRAMATTA NSW 2150

NOTIFICATION CATEGORY

STD/1574: Standard: Chemical other than polymer (more than 1 tonne per year) - Group assessment STD/1602: Standard: Chemical other than polymer (more than 1 tonne per year) - Group assessment

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication: chemical name, CAS number, molecular weight, analytical data, impurities, import volume, and identity of recipients.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed for all physico-chemical endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

STD/1574: EU REACH (2015), USA (2016), Canada (2015), Korea (2016)

STD/1602: EU REACH (2013)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

NAFOL Linear Alcohols, Distn. Residues (contains STD/1574 and STD/1602 notified chemicals)

MOLECULAR WEIGHT

STD/1574: < 1,000 Da

STD/1602: < 1,000 Da

ANALYTICAL DATA

Reference NMR and GC-MS spectra were provided for each notified chemical.

3. COMPOSITION

DEGREE OF PURITY STD/1574: 100% STD/1602: 100%

4. PHYSICAL AND CHEMICAL PROPERTIES

STD/1574

APPEARANCE AT 20 °C AND 101.3 kPa: Greyish to yellowish solid pastilles

Property	Value	Data Source/Justification
Melting Point	66.4-69.4 °C	Measured
Boiling Point	269.8 °C at 101.3 kPa	Measured
Density	$900.7 \text{ kg/m}^3 \text{ at } 20 ^{\circ}\text{C}$	Measured
Vapour Pressure	$< 3.69 \times 10^{-6}$ kPa at 20 °C	Measured
Water Solubility	$< 1.0 \times 10^{-3} \text{ g/L at } 20 ^{\circ}\text{C}$	Measured
Hydrolysis as a Function of	Not determined	The notified chemical may contain
pH		hydrolysable functionalities. However, significant hydrolysis is not expected at
		environmental pH due to its low water

Property	Value	Data Source/Justification
		solubility
Partition Coefficient (n-octanol/water)	$\log Pow > 6.5$ at 40 °C	Measured
Adsorption/Desorption	$\log K_{oc} > 5.63$ at 40 °C	Measured
Dissociation Constant	Not determined	No dissociable functionalities
Particle Size	Mean diameter > 1mm	Measured
Flash Point	Not determined	Expected to be > 200 °C based on measured flash point for STD/1602
Flammability	Not highly flammable	Measured
Autoignition Temperature	368 °C	Measured
Explosive Properties	Predicted negative	Based on the chemical structure
Oxidising Properties	Predicted negative	Based on the chemical structure

STD/1602

APPEARANCE AT 20 °C AND 101.3 kPa: Greyish to yellowish solid pastilles

Property	Value	Data Source/Justification
Melting Point	52.5-54.6 °C	(M)SDS
Boiling Point	378 °C at 101.3 kPa	Measured
Density	909.4 kg/m 3 at 20 °C	Measured
Viscosity		Measured
Vapour Pressure	$< 5 \times 10^{-3}$ kPa at 20 °C	Measured
Water Solubility	1.7×10 ⁻⁴ g/L at 20 °C	Measured
Hydrolysis as a Function of pH	Not determined	The notified chemical may contain hydrolysable functionalities. However,
r		significant hydrolysis is not expected at environmental pH due to its low water solubility.
Partition Coefficient (n-octanol/water)	Not determined	Expected to partition to oil phase similar to STD/1574
Adsorption/Desorption	Not determined	Expected to partition to sediment or sludge from water similar to STD/1574
Dissociation Constant	Not determined	No dissociable functionalities
Particle Size	Not determined	Expected to have mean diameter > 1 mm similar to STD/1574
Flash Point	235 °C at 102.1 kPa	Measured
Flammability	Not highly flammable	Measured
Autoignition Temperature	333 °C	Measured
Explosive Properties	Not determined	Not expected to be explosive based on the chemical structure
Oxidising Properties	Not determined	Not expected to be oxidising based on the chemical structure

DISCUSSION OF PROPERTIES

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

Reactivity

The notified chemicals are 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 chemicals are 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 chemicals will not be manufactured in Australia. The notified chemicals will be imported into Australia in neat form, or as components of formulation products at $\leq 20\%$ concentration for use in paper manufacturing.

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

STD/1574

Year	1	2	3	4	5
Tonnes	50-100	50-100	50-100	50-100	50-100
STD/1602					
Year	1	2	3	4	5
Tonnes	50-100	50-100	50-100	50-100	50-100

PORT OF ENTRY

Melbourne and Sydney

TRANSPORTATION AND PACKAGING

The notified chemicals will be shipped to Australia in neat form (100%) as pastilles in 20 kg polyethylene bags or 500 kg polyethylene Bigbags, or as a component of formulations at \leq 20% concentration in 1000 L IBC containers, and will be transported by road to the notifier storage facilities, or directly to the customers' blending facilities. After blending and formulation of the neat notified chemicals, the finished products in 1000 L IBC containers or the imported formulation products containing the notified chemicals will be transported by road to the paper manufacturing sites.

USE

The notified chemicals will be used as viscosity increasing agents, emulsion stabilisers, and binders in a foam inhibitor and pulp deaerator product for paper manufacturing.

OPERATION DESCRIPTION

Blending

At the customers' blending sites, the neat notified chemicals will be weighed and transferred manually from the import containers into on-site blending tanks. The notified chemicals will typically be blended in a closed and computer-controlled system with other components into finished products containing the notified chemicals at \leq 20% concentration. The finished products will be automatically filled in 1000 L IBC tanks and then stored for shipment to end users.

Paper Manufacturing

At the paper manufacturing sites, the blended or imported formulated products containing the notified chemicals will be pumped directly from the containers into fibre suspensions in paper manufacturing stream. Within the pulp and paper mill, wood chip is subject to high temperature and mechanical action which separates and evenly distributes fibres forming a suspension containing 5% solids. This is diluted to form a 1% solids fibre suspension with recycled process water. The notified chemicals will be incorporated into the paper at 0.01% concentration. Water drained from the paper pulp will be recycled and reused to dilute incoming wood fibre suspensions.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	Exposure Duration	Exposure Frequency
	(hours/day)	(days/year)
Transport and storage	4-8	12
Plant blending operators	8	12
Plant manufacturing operators	8	300

EXPOSURE DETAILS

Transport and storage workers may come into contact with the neat notified chemicals or products containing the notified chemicals at $\leq 20\%$ concentration, only in the unlikely event of an accident.

At the blending sites, operators may have dermal and/or ocular exposure to the neat notified chemicals during blending, filling operations and quality control analysis. Inhalation exposure is not expected as aerosols are unlikely to be generated during the operations, and the chemicals are not expected to vaporise.

End users may be exposed to the notified chemicals at $\leq 20\%$ concentration at paper manufacturing facilities. Occupational exposure may occur during transfer of the products containing the notified chemicals, and during connection and disconnection of transfer lines. Exposure from incidental splashes, drips, and spills, and cleaning and maintenance of equipment may also occur.

Workers exposure is expected to be minimised by the use of a closed and computer-controlled system during the blending process and the use of PPE such as gloves, eye protection and protective clothing, in addition to the use of local ventilation at the blending facilities.

Once the notified chemicals are incorporated into paper fibres and dried, no significant exposure is expected to occur from handling the manufactured paper products.

6.1.2. Public Exposure

The notified chemicals will be for industrial use only. However, the public may come into contact with papers treated with the notified chemicals. No significant exposure is expected to occur as the notified chemicals will be incorporated into the dried paper fibres and will be present at a very low concentration (0.01%).

6.2. Human Health Effects Assessment

No toxicity data were submitted for the notified chemical from STD/1602. However, based on its structural similarity, the notified chemical from STD/1574 is considered to be an analogue to the notified chemical in STD/1602. The results from toxicological investigations conducted on the notified chemical from STD/1574 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	LD50 > 2000 mg/kg bw; low toxicity
Rat, acute dermal toxicity	LD50 > 2020 mg/kg bw; low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – adjuvant test	no evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days	NOEL > 1000 mg/kg bw/day
Rat, repeat dose oral toxicity – 90 days	NOEL > 1000 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – <i>in vitro</i> chromosomal aberration	non genotoxic
Genotoxicity -in vitro mammalian cell gene mutation test	non genotoxic
Rat, prenatal developmental toxicity	NOEL = 1000 mg/kg bw/day (maternal and foetal)

Toxicokinetics

Based on the low water solubility and highly lipophilic nature of the notified chemicals, dermal absorption is expected to be limited.

Acute toxicity

The notified chemicals are expected to be of low acute oral and dermal toxicity based on studies conducted in rats with the notified chemical from STD/1574. Based on the results from these studies, the notified chemicals are expected to be of low acute oral and dermal toxicity.

Irritation and sensitisation

The notified chemical from STD/1574 was found to be non-irritating to skin but very slightly irritating to eyes, based on studies conducted in rabbits. In the eye irritation study, very slight conjunctival irritation (redness; Grade 1) was observed in one animal up to the 48 hour observation period. No signs of irritation were observed in the other two test animals.

The notified chemical from STD/1574 was determined to be a non-sensitising in a guinea pig maximisation test.

Based on the results from these studies, the notified chemicals are expected to be non-irritating to skin, very slightly irritating to eyes and non-sensitising.

Repeated dose toxicity

In a 28-day and 90-day repeated dose oral (gavage) toxicity studies in rats, the No Observed Effect Level (NOEL) for the notified chemical from STD/1574 was established as 1000 mg/kg bw/day, based on the absence of treatment related effects at any dose level tested.

The notified chemicals are therefore expected to be of low systemic toxicity from repeated exposure.

Mutagenicity/Genotoxicity

The notified chemical from STD/1574 tested negative in a bacterial reverse mutation assay, an *in vitro* chromosomal aberration test using Chinese hamster ovary cells and an *in vitro* cell gene mutation test using mouse lymphoma cells. Based on the results from these studies, the notified chemicals are not expected to be genotoxic.

Developmental toxicity

A prenatal developmental toxicity study was conducted with the notified chemical from STD/1574 in rats. There were no treatment related mortalities or effects on pregnancy parameters. There were no treatment related foetal malformations and no statistically significant foetal variations. The NOEL was established at 1000 mg/kg bw/day for maternal and foetal toxicity, based on the absence of treatment related effects at any dose level tested.

Health hazard classification

Based on the available information, the notified chemicals are not recommended for classification according to the *Globally Harmonised System of 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 studies conducted with the notified chemical from STD/1574, the notified chemicals are of low hazard, presenting only as very slight eye irritants.

Workers handling the notified chemicals in the neat form during reformulation into finished products will be most at risk of slight eye irritation effects. However, worker exposure is expected to be minimised by the use of closed automated systems during the blending process, and the use of PPE including eye protection. The notified chemicals are not expected to present a risk at other times based on the low use concentrations.

Overall, based on the low hazard, the notified chemicals are not considered to pose an unreasonable risk to the health of workers

6.3.2. Public Health

No significant exposure to the notified chemicals is expected by the public. Furthermore the notified chemicals are of low hazard. Therefore, when used in the proposed manner, the notified chemicals are not considered to pose an unreasonable risk to public health.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The imported notified chemicals will be blended or reformulated into finished products in Australia. At the blending sites, up to 0.5% of the total import volume of the notified chemicals is estimated to be released to environment due to accidental spills. These spills are expected to be collected for reuse or be disposed of to landfill.

Residues in the import containers, accounting for 0.2% of the total import volume, are expected to be washed to sewer via the on-site waste water treatment plants or be disposed of to landfill along with the empty containers. Some liquid spills during the filling operation are expected to be collected by adsorbent material and disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

The notified chemicals will be used as an additive agent for paper manufacturing. At the paper manufacturing sites, releases of the notified chemicals could occur from spills and leaks during connection/disconnection of pumping equipment and transfer lines. This will account for 1% of the import volume. Residues in empty containers will account for a further 1% of the total import volume. These residues are expected to be rinsed and the rinsate will be recycled into the process stream.

It is estimated that 1% of notified chemicals will be discharged into effluent during paper manufacturing process. The notifier indicates that the daily use of the notified chemicals is approximately 77 kg; therefore, the daily release of the notified chemicals into effluent is 0.77 kg.

RELEASE OF CHEMICAL FROM DISPOSAL

All waste water from the manufacturing site is expected to be discharged to surface waters through on-site sewage treatment. The maximum concentration of the notified chemicals in mill effluent is indicated to be 0.015 mg/L.

It is assumed that 50% of the used paper to which the notified chemicals are applied will end up in landfill and the remainder will undergo paper recycling processes.

7.1.2. Environmental Fate

No environmental fate data were submitted. The notified chemicals are expected to be biodegradable under environmental conditions. However, the biodegradation rate is expected to be slower due to the low bioavailability when carbon chain is greater than 16. The notified chemicals are expected to be stable to hydrolysis in the environmental pH range of 4–9.

It is assumed that 50% of the waste paper will be recycled domestically. During recycling processes, waste paper is repulped using a variety of chemical agents, which, amongst other things, enhance detachment of inks and coatings from the fibres. Notified chemicals in waste water from paper recycling are expected to be removed from water column by partitioning to sludge or sediment due to their high adsorption/desorption coefficient (low Koc > 5.63) and low water solubility. Therefore, only a low proportion of the notified chemicals are expected to remain in the effluent water from both on-site waste water treatment plants and municipal water treatment plants to which treated effluent from paper recycling facilities may be discharged. Sludge (containing the notified chemicals) generated during the recycling process is expected to be sent to landfill for disposal or agricultural land for remediation. The notified chemicals are not expected to be mobile in soil due to their high adsorption/desorption coefficient (low Koc > 5.63) and low water solubility.

The notified chemicals have potential to be bioaccumulative based on the measured $\log Pow > 6.5$. However, significant bioaccumulation in aquatic life is not expected as the notified chemicals are expected to be readily

biodegradable. In water, landfill or soil, the notified chemicals are expected to undergo degradation by biotic and abiotic processes to form water and oxides of carbon eventually.

7.1.3. Predicted Environmental Concentration (PEC)

Release of the notified chemicals from paper manufacturing process

Waste water from paper manufacturing processes is expected to be treated on-site before being released to public sewer. The notifier indicated that the daily use of the notified chemicals is approximately 77 kg and 1% of notified chemicals will be discharged into waste water effluent. Therefore, the daily release of the notified chemicals into effluent is 0.77 kg assuming that there is no removal of the notified chemicals at on-site waste water treatment plants.

The waste water containing the notified chemicals released to sewer is expected to be further treated at the public sewage treatment plant (STP). For a conservative scenario, it is assumed that waste water will be released to a moderately-sized STP (daily average water flow is 358 ML, Eastern Treatment Plant, Victoria). The resultant Predicted Environmental Concentration (PEC) in river in a site basis is calculated as following:

$$PEC_{site} = 0.77 \text{ kg/day} \div 358 \text{ ML/day} = 2.15 \text{ µg/L}$$

Release of the notified chemicals from paper recycling process

It is assumed that 50% of the used paper containing the notified chemicals will be subjected to paper recycling. Therefore, half amount of the total import volume of the notified chemicals (up to 100 tonnes) are expected to be released to waste water from paper recycling processes.

For the worst case scenario, it is assumed that there is no removal of the notified chemicals at the sewage treatment plants. Therefore, the resultant predicted environmental concentration (PEC) in sewage effluent on a nationwide basis is estimated as follows:

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import Volume	200,000	kg/year
Proportion expected to be released to sewer	50%	
Annual quantity of chemical released to sewer	100,000	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	384.62	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:	85.04	$\mu g/L$
PEC - Ocean:	8.50	μg/L

Based on the calculation above, the combined Predicted Environmental Concentration (PEC) in river will be

$$PEC_{river} = 85.04 \mu g/L + 2.15 \mu g/L = 87.19 \mu g/L$$

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be $1000~L/m^2/year$ (10~ML/ha/year). The notified chemicals in this volume are assumed to infiltrate and accumulate in the top 10 cm of soil (density $1500~kg/m^3$). Using these assumptions, irrigation with a concentration of $87.19~\mu g/L$ may potentially result in a soil concentration of approximately $5.81\times 10^{-1}~mg/kg$. Assuming accumulation of the notified chemicals in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemicals in the applied soil in 5 and 10 years may be approximately 2.905~mg/kg and 5.81~mg/kg, respectively.

7.2. Environmental Effects Assessment

No ecotoxicity data were submitted for the notified chemical from STD/1602. However, based on its structural similarity, the notified chemical from STD/1574 is considered to be an analogue to the notified chemical in STD/1602.

The results from ecotoxicological investigations conducted on the notified chemical from STD/1574 are summarised in the table below. Details of these studies can be found in Appendix C.

	D 1,	1
Endpoint	Result	Assessment Conclusion
Fish Toxicity (96 hours)	LL50 > 100 mg/LWAF*	Not harmful to fish up to the water solubility
Daphnia Toxicity (48 hours)	EL50 > 100 mg/L WAF	Not harmful to aquatic invertebrates up to the
		water solubility
Algal Toxicity (72 hours)	EL50 > 100 mg/L WAF	Not harmful to algae up to the water solubility
Inhibition of Bacterial	EC50 > 1000 mg/L	Not inhibitory to micro-organisms respiration
Respiration (3 hours)	_	•

^{*}WAF, water accommodation fractions

Under the Globally Harmonised System of Classification and Labeling of Chemicals (United Nations, 2009) the notified chemicals are not expected to be harmful to aquatic life up to their water solubility. Therefore, the notified chemicals are not formally classified for their acute and chronic classification under the GHS.

7.2.1. Predicted No-Effect Concentration

It is not considered necessary to calculate the PNEC since the notified chemicals are not expected to be harmful to aquatic organisms.

7.3. Environmental Risk Assessment

The PNEC for the notified chemicals are not calculated as the notified chemicals are not expected to be harmful to aquatic organisms. Therefore, the Risk Quotient (Q = PEC/PNEC) has not been calculated.

The notified chemicals are not expected to be harmful to aquatic life up to their water solubility. Therefore, although the notified chemicals have potential to be discharged to the aquatic environment, the notified chemicals are unlikely to reach ecotoxicologically significant concentrations. Additionally, due to the expected rapid biodegradation, the notified chemicals are not expected to be bioaccumulative.

Therefore, on the basis of their low toxicity and low potential for bioaccumulation, the notified chemicals are not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

STD/1574

Melting Point 66.4-69.4 °C

Method OECD TG 102 Melting Point/Melting Range.

Remarks Capillary method Test Facility LAUS GmbH (2009a)

Boiling Point 269.8 °C at 101.3 kPa

Method OECD TG 103 Boiling Point.

EC Council Regulation No 440/2008 A.2 Boiling Temperature.

Remarks SIWOLOBOFF method Test Facility LAUS GmbH (2009b)

Density $900.7 \text{ kg/m}^3 \text{ at } 20 \text{ }^{\circ}\text{C}$

Method OECD TG 109 Density of Liquids and Solids.

Remarks Pycnometer method Test Facility LAUS GmbH (2009c)

Vapour Pressure < 3.69×10⁻⁶ kPa at 20 °C

Method OECD TG 104 Vapour Pressure. Remarks Effusion method (weight loss).

Test Facility LAUS GmbH (2009d)

Water Solubility $< 1 \times 10^{-3} \text{ g/L at } 20 \text{ °C}$

Method OECD TG 105 Water Solubility.

Remarks Flask Method. Test Facility Wildlife (2010a)

Partition Coefficient (n-

log Pow > 6.5 at 40 °C

octanol/water)

Method OECD TG 117 Partition Coefficient (n-octanol/water).

Remarks HPLC Method. The test substance was a reaction mixture and was eluted as two peaks on the

evaporative light scattering detector. Both peaks have longer retention time than DDT, one of the reference standards with log Pow = 6.5. Therefore, the log Pow for the test substance

expected to be > 6.5.

Test Facility Wildlife (2010b)

Adsorption/Desorption

 $\log K_{oc} > 5.63$ at 40 °C

- screening test

Method OECD TG 121 estimation of the adsorption coefficient (K_{oc}) on soil and on sewage sludge

using high performance liquid chromatography.

Remarks The test substance was a reaction mixture product and was eluted as several peaks on the

evaporative light scattering detector. All the peaks were eluted out after the highest K_{oc}

reference standard. Therefore, all the observed peaks have a measured log Koc > 5.63.

Test Facility Wildlife (2010c)

Particle Size Mean diameter > 1 mm

Method OECD TG 110 Particle Size Distribution/Fibre Length and Diameter Distributions.

Remarks No test details provided. The medium diameter of the test substance (pastilles) was reported

to exceed 1 mm. Respirable dust with diameters $\leq 4\mu m$ was stated by the study authors to

be unlikely due to the waxy behaviour of the test substance

Test Facility Sasol (2010a)

Flammability Not highly flammable

Method EC Council Regulation No 440/2008 A.10 Flammability (Solids).

Remarks No deviation from the study protocols.

Test Facility LAUS GmbH (2010)

Autoignition Temperature 368 °C

Method Relative Self-Ignition Temperature for Solids.

Remarks DIN 51794 Method Test Facility Sasol (2010b)

Explosive Properties Predicted negative

Method EC Council Regulation No 440/2008 A.14 Explosive Properties.

Remarks Based on its chemical structure, the test substance is not expected to have explosive

properties

Test Facility Sasol (2010c)

Oxidizing Properties Predicted negative

Method Oxidizing Properties (Solids).

Remarks The test substance is present in the reduced form (alcohols) and has no oxidative properties

Test Facility Sasol(2010d)

STD/1602

Boiling Point 378 °C at 101.3 kPa

Method ASTM D1120-94. Remarks Ebulliometer method Test Facility Sasol (2011a)

Density $909.4 \text{ kg/m}^3 \text{ at } 20 \text{ }^{\circ}\text{C}$

Method DIN EN ISO 1183-1 Method A

Remarks Buoyancy method Test Facility Sasol (2011b)

Water Solubility $1.7 \times 10^{-4} \,\mathrm{g/L}$ at 20 °C

Method OECD TG 105 Water Solubility.

Remarks The test reliability is undetermined as only study summary is available.

Test Facility CHELAB (2012a)

Viscosity 6.0 unit mPa s (dynamic) at 80 °C

Method ASTM D 7042-04 Viscosity of Liquids.

Remarks Stabinger Viscometer

Test Facility Sasol (2011c)

Vapour Pressure < 5×10⁻³ kPa at 20 °C

Method (NFT 20-048 - Determination of Vapour Pressure of solids and liquids within range from

10⁻¹ to 10⁵ Pa (Static method)

Test Facility CHELAB (2012b)

Flash Point 235 °C at 102.1 kPa

Method EC Council Regulation No 440/2008 A.9 Flash Point.

Remarks Open cup Test Facility Sasol (2011d)

Autoignition Temperature 333 °C

Method Relative Self-Ignition Temperature for Solids.

Remarks DIN 51794 Method Test Facility Sasol (2011e)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE Notified chemical (STD/1574)

METHOD OECD TG 425 Acute Oral Toxicity: Up-and-Down Procedure.

Species/Strain Rat/Sprague-Dawley

Vehicle Corn oil

Remarks - Method No significant protocol deviations

RESULTS

Group	Number and Sex	Dose	Mortality
	of Animals	mg/kg bw	
1	5F	2000	0/5
LD50	> 2000 mg/kg bw		
Signs of Toxicity	2 2	were salivation,	crusting around the muzzle and

polyuria in one animal, which were no longer evident by Day 2.

Effects in Organs

No gross abnormalities

Remarks - Results There was no effect on bodyweight gain.

CONCLUSION The notified chemical (STD/1574) is of low toxicity via the oral route.

TEST FACILITY Stillmeadow (2009a)

B.2. Acute toxicity – dermal

TEST SUBSTANCE Notified chemical (STD/1574)

METHOD OECD TG 402 Acute Dermal Toxicity.

Species/Strain Rat/Sprague-Dawley

Vehicle Moistened with deionised water

Type of dressing Semi-occlusive.

Remarks - Method No significant protocol deviations

RESULTS

Group	Number and Sex of Animals	Dose mg/kg bw	Mortality
1	5M/5F	2020	0/10
LD50 Signs of Toxicity - Local	> 2020 mg/kg bw No signs of dermal irritation	on	

Signs of Toxicity - Local No signs of dermal irritation Signs of Toxicity - Systemic No clinical signs of toxicity Effects in Organs No gross abnormalities

Remarks - Results There was no effect on bodyweight gain, with the exception of two

females that lost weight slightly during Week 1, but gained weight during

Week 2.

CONCLUSION The notified chemical (STD/1574) is of low toxicity via the dermal route.

TEST FACILITY Stillmeadow (2009b)

B.3. Irritation – skin

TEST SUBSTANCE Notified chemical (STD/1574)

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.

EC Council Regulation No 440/2008 B.4 Acute Toxicity (Skin Irritation).

EC Directive 2004/73/EC B.4 Acute Toxicity (Skin Irritation).

Species/Strain Rabbit/New Zealand White

Number of Animals 3

Vehicle Moistened with deionised water

Observation Period 72 hours Type of Dressing Semi-occlusive.

Remarks - Method No significant protocol deviations

RESULTS

Remarks - Results No signs of irritation were noted in any test animal during the study.

CONCLUSION The notified chemical (STD/1574) is non-irritating to the skin.

TEST FACILITY Stillmeadow (2009c)

B.4. Irritation – eye

TEST SUBSTANCE Notified chemical (STD/1574)

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.

Species/Strain Rabbit/New Zealand White

Number of Animals 3 Observation Period 72 hours

Remarks - Method No significant protocol deviations

RESULTS

Remarks - Results One animal displayed very slight conjunctival irritation (redness; Grade 1)

up to the 48 hour observation period. No signs of irritation were observed

in the other two animals during the study period.

CONCLUSION The notified chemical (STD/1574) is slightly irritating to the eye.

TEST FACILITY Stillmeadow (2009d)

B.5. Skin sensitisation

TEST SUBSTANCE Notified chemical (STD/1574)

METHOD OECD TG 406 Skin Sensitisation – Maximisation test

Species/Strain Guinea pig/Hartley-Albino

PRELIMINARY STUDY Maximum Non-irritating Concentration:

intradermal: 2% topical: 5%

MAIN STUDY

Number of Animals Test Group: 10M/10F Control Group: 5M/5F

Vehicle

Positive control Not conducted in parallel with the test substance, but had been conducted

previously in the test laboratory using α -hexylcinnamaldehyde.

INDUCTION PHASE Induction Concentration:

intradermal: 4% topical: 10%

Signs of Irritation All test animals displayed very slight to slight erythema at intradermal

induction. After topical induction slight erythema was observed in two test animals. All other test animals showed no signs of irritation. All control animals displayed very slight to slight erythema after intradermal and

topical induction.

CHALLENGE PHASE

Challenge topical: 10%

Remarks - Method No significant protocol deviations

RESULTS

Remarks - Results No signs of irritation were noted after challenge in test and control

animals.

CONCLUSION There was no evidence of reactions indicative of skin sensitisation to the

notified chemical (STD/1574) under the conditions of the test.

TEST FACILITY Stillmeadow (2009e)

B.6. Repeat dose toxicity

TEST SUBSTANCE Notified chemical (STD/1574)

METHOD OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.

Species/Strain Rat/Wistar CRL:WI (Han)

Route of Administration Oral – gavage

Exposure Information Total exposure days: 28 days

Dose regimen: 7 days per week

Post-exposure observation period: None

Vehicle 1% Carboxymethylcellulose with 0.2% Tween 80

Remarks - Method No significant protocol deviations

RESULTS

Group	Number and Sex	Dose	Mortality
	of Animals	mg/kg bw/day	
control	5M/5F	0	0/10
low dose	5M/5F	100	1/10
mid dose	5M/5F	300	0/10
high dose	5M/5F	1000	0/10

Mortality and Time to Death

One animal died in the low dose group during the orbital sinus sampling, prior to termination on Day 29. The death was not considered to be treatment related. No other mortalities were noted during the study.

Clinical Observations

There were no treatment related clinical signs of toxicity. Body weights and food consumption were unaffected.

Laboratory Findings - Clinical Chemistry, Haematology, Urinalysis

There were no treatment related haematology, coagulation and clinical chemistry changes. There were no treatment related changes in the urinalysis data.

Effects in Organs

There were no necropsy or histology findings attributed to treatment.

Remarks – Results

The test substance was well tolerated with no obvious evidence of toxicity being noted at dose levels up to 1000 mg/kg bw/day.

CONCLUSION

The No Observed Effect Level (NOEL) was established as 1000 mg/kg bw/day in this study, based on no treatment related effects noted at any dose level tested.

TEST FACILITY Charles River (2010a)

B.7. Repeat dose toxicity

TEST SUBSTANCE Notified chemical (STD/1574)

METHOD OECD TG 408 Repeated Dose 90-Day Oral Toxicity Study in Rodents.

Species/Strain Rat/Wistar CRL:WI (Han)

Route of Administration Oral – gavage

Exposure Information Total exposure days: 90 days
Dose regimen: 7 days per week

Post-exposure observation period: 28 days

Vehicle 1% Carboxymethylcellulose with 0.2% Tween 80

Remarks - Method No significant protocol deviations

RESULTS

Group	Number and Sex	Dose	Mortality
	of Animals	mg/kg bw/day	
control	10M/10F	0	0/10
low dose	10M/10F	100	0/10
mid dose	10M/10F	300	0/10
high dose	10M/10F	1000	0/10
control recovery	5M/5F	0	0/5
high dose recovery	5M/5F	1000	0/5

Mortality and Time to Death

There was one unscheduled death during the study. A male animal from the high dose recovery group was found dead on Day 3 of dosing. The cause of death was considered to be related to dosing and not attributable to the test substance. The animal was replaced with a reserve animal.

Clinical Observations

There were no treatment related clinical signs of toxicity and there were no test substance related changes in bodyweight and food consumption.

Laboratory Findings - Clinical Chemistry, Haematology, Urinalysis

There were no differences in haematology, coagulation, clinical chemistry or urinalysis parameters that were considered to be related to treatment.

Effects in Organs

No test substance related macroscopic or microscopic findings were noted.

Remarks - Results

The test substance was well tolerated with no obvious evidence of toxicity being noted at dose levels up to 1000 mg/kg bw/day.

CONCLUSION

The No Observed Effect Level (NOEL) was established as 1000 mg/kg bw/day in this study, based on no treatment related effects at any dose level tested.

TEST FACILITY Charles River (2010b)

Genotoxicity - bacteria **B.8.**

Notified chemical (STD/1574) TEST SUBSTANCE

METHOD OECD TG 471 Bacterial Reverse Mutation Test.

Plate incorporation procedure (Test 1)/Pre incubation procedure (Test 2)

Species/Strain S. typhimurium: TA1535, TA1537, TA98, TA100

E. coli: WP2uvrA

Metabolic Activation System S9 fraction from Aroclor 1254 induced rat liver Concentration Range in a) With metabolic activation: 6-2000 µg/plate Main Test b) Without metabolic activation: 6-2000 μg/plate

Vehicle DMSO

Remarks - Method The solubility of the test substance restricted the maximum concentration

tested to 2000 µg/plate

RESULTS

Metabolic	Metabolic Test Substance Concentration (μg/plate) Resulting in:				
Activation	Cytotoxicity in	Cytotoxicity in	Precipitation	Genotoxic Effect	
	Preliminary Test	Main Test			
Absent					
Test 1	> 2000	> 2000	2000	Negative	
Test 2		> 2000	2000	Negative	
Present					
Test 1	> 2000	> 2000	2000	Negative	
Test 2		> 2000	2000	Negative	

Remarks - Results No evidence of mutagenic activity was obtained with any strain in any

CONCLUSION The notified chemical (STD/1574) was not mutagenic to bacteria under the

conditions of the test.

TEST FACILITY Charles river (2009)

B.9. Genotoxicity – in vitro

TEST SUBSTANCE Notified chemical (STD/1574)

METHOD OECD TG 473 In vitro Mammalian Chromosome Aberration Test.

Species/Strain Chinese hamster

Cell Type/Cell Line Ovary cells (CHO 10 B₄)

S9 fraction from Aroclor 1254 induced rat liver Metabolic Activation System

Vehicle

Remarks - Method No significant protocol deviations. Test 1 also served as the preliminary

cytotoxicity test.

Metabolic Activation	Test Substance Concentration (µg/mL)	Exposure Period	Harvest Time
Absent			
Test 1	0.78, 1,56, 3.13, 6.25, 12.5, 25, 50*, 100*, 200*	6 h	24 h
Test 2	50*, 100*, 200*	22 h	24 h
Present			
Test 1	0.78, 1,56, 3.13, 6.25, 12.5, 25, 50*, 100*, 200*	6 h	24 h
Test 2	50*, 100*, 200*	6 h	24 h

^{*}Cultures selected for metaphase analysis.

RESULTS

Metabolic	Tes	st Substance Concentra	ition (μg/mL) Resultin	g in:
Activation	Cytotoxicity in	Cytotoxicity in	Precipitation	Genotoxic Effect
	Preliminary Test	Main Test		
Absent				
Test 1	> 200	> 200	> 200	Negative
Test 2		> 200	> 200	Negative
Present				
Test 1	> 200	> 200	> 200	Negative
Test 2		> 200	> 200	Negative

Remarks - Results

No statistically significant increase in the number of cells with aberrations was observed at any concentration, with and without metabolic activation.

In an extra assessment of polyploidy carried out on the cultures treated in the absence of metabolic activation and harvested at 48 h, there was also no increase in the number of polyploidy cells.

The positive and vehicle controls gave satisfactory responses confirming the validity of the test system.

CONCLUSION

The notified chemical (STD/1574) was not clastogenic to Chinese hamster ovary cells treated *in vitro* under the conditions of the test.

TEST FACILITY Charles River (2010c)

B.1. Genotoxicity – in vitro

TEST SUBSTANCE Notified chemical (STD/1574)

METHOD OECD TG 476 In vitro Mammalian Cell Gene Mutation Test.

Species/Strain Mouse

Cell Type/Cell Line Lymphoma cells/L5178Y

Metabolic Activation System S9 fraction from Aroclor 1254 induced rat liver

Vehicle DMS0

Remarks - Method No significant protocol deviations

Metabolic	Test Substance Concentration (µg/mL)*	Exposure	Expression	Selection
Activation		Period	Time	Time
Absent				
Test 1	25, 50, 100, 200	4	$\sim 48 \ h$	9-12 days
Test 2	25, 50, 100, 200	24	$\sim 48 \ h$	9-12 days
Present				
Test 1	25, 50, 100, 200	4	$\sim 48 \text{ h}$	9-12 days
Test 2	25, 50, 100, 200	4	$\sim 48 \ h$	9-12 days

^{*}All cultures selected for metaphase analysis.

RESULTS

Metabolic	Te.	st Substance Concentra	ation (µg/mL) Resultin	g in:
Activation	Cytotoxicity in Preliminary Test	Cytotoxicity in Main Test	Precipitation	Genotoxic Effect
Absent				
Test 1	> 200	> 200	200	Negative
Test 2	> 200	> 200	200	Negative
Present				
Test 1	> 200	> 200	200	Negative
Test 2		> 200	200	Negative

Remarks - Results No evidence of mutagenic activity was observed in any assay.

The positive and vehicle controls gave satisfactory responses confirming

the validity of the test system

CONCLUSION The notified chemical (STD/1574) was not clastogenic to mouse

lymphoma L5178Y cells treated in vitro under the conditions of the test.

TEST FACILITY Charles River (2010d)

B.10. Developmental toxicity

TEST SUBSTANCE Notified chemical (STD/1574)

METHOD OECD TG 414 Prenatal Development Toxicity Study

Species/Strain Rats/Sprague-Dawley

Route of Administration Oral – gavage

Exposure Information Exposure days: day 6 through to day 19 of gestation

Post-exposure observation period: none

Vehicle 1% Carboxymethylcellulose with 0.2% Tween 80

Remarks - Method No significant protocol deviations

RESULTS

Group	Number of Animals	Dose	Mortality
		mg/kg bw/day	
1	24F	0	0/24
2	24F	100	0/24
3	24F	300	0/24
4	24F	1000	0/24

Mortality and Time to Death

There were no mortalities during the study.

Effects on Dams

There were no effects of treatment on body weight gain, food consumption performance or clinical signs.

Effects on Foetus

The incidence of embryo-foetal deaths and mean foetal weights did not suggest any obvious effect of treatment.

The type and distribution of foetal abnormalities and variants did not suggest any obvious effect of treatment.

Remarks - Results

Under the conditions of the study, the test substance had no obvious effects on pregnancy, incidence of embryotoxicity or foetal abnormalities.

CONCLUSION

The No Observed Effect Level (NOEL) was established as 1000 mg/kg bw/day in this study for both maternal and foetal toxicity, based on no treatment related effects noted at any dose level tested.

TEST FACILITY Charles River (2010e)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE the notified chemical (STD/1574)

METHOD OECD TG 203 Fish, Acute Toxicity Test – static

Species Pimephales promelas

Exposure Period 96 hours Auxiliary Solvent None

Water Hardness 140-144 mg CaCO₃/L Analytical Monitoring Not applicable

Remarks – Method The test solution was prepared as water accommodation fractions (WAFs)

due to low water solubility of the test substance. The WAF was prepared by adding the weighed amount of test substance into water followed by stirring for 48 hours. The mixture was allowed to stand for 1 hour and then the solution was decanted from mid-depth into the test chamber through a

spigot.

The test was conducted according to the test guideline above with no

significant deviation from the protocol.

RESULTS

Concentration WAF mg/L		Number of Fish	Mortality			
Nominal	Actual		24 h	48 h	72 h	96 h
Control	-	10	0	0	0	0
100	Not determined	10	0	0	0	0

LL50 > 100 WAF mg/L at 96 hours. NOEL 100 WAF mg/L at 96 hours.

Remarks – Results All validity criteria for the test are satisfied. All test fish appeared normal

without any mortality during the test period at the nominal WAF loading

rate of 100 mg/L.

CONCLUSION The notified chemical (STD/1574) is not harmful to fish

TEST FACILITY Wildlife (2010d)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE The notified chemical (STD/1574)

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

Species Daphnia magna
Exposure Period 48 hours
Auxiliary Solvent None

Water Hardness 136 mg CaCO₃/L Analytical Monitoring Not applicable

Remarks - Method The test solution was prepared as water accommodation fractions (WAFs)

due to low water solubility of the test substance. The WAF was prepared by adding the weighed amount of test substance into water followed by stirring for 48 hours. The mixture was allowed to stand for 1 hour and then the solution was decanted from mid-depth into the test chamber through a

spigot.

The test was conducted according to the test guideline above with no

significant deviation from the protocol.

RESULTS

Concentra	tion WAF mg/L	Number of D. magna	Number Ir	nmobilised
Nominal	Actual		24 h	48 h
Control	-	30	0	0
100	Not determined	30	0	0
EL50 NOEL		> 100 WAF mg/L at 48 hours 100 WAF mg/L at 48 hours		
Remarks - Results		All validity criteria for the test were normal without any mortality during loading rate of 100 mg/L.		1 11
Conclusion		The notified chemical (STD/1574) is	not harmful to aqua	atic invertebrates

C.2.3. Algal growth inhibition test

TEST FACILITY

TEST SUBSTANCE The notified chemical (STD/1574)

METHOD OECD TG 201 Alga, Growth Inhibition Test

Wildlife (2010e)

Species Pseudokirchneriella subcapitat

Exposure Period 72 hours

Concentration Range Nominal: Control, 100 mg/L Actual: Not determined

Auxiliary Solvent None
Water Hardness Not reported
Analytical Monitoring Not applicable

Remarks - Method The test solution was prepared as water accommodation fractions (WAFs)

due to low water solubility of the test substance. The WAF was prepared by adding the weighed amount of test substance into water followed by stirring for 48 hours. The mixture was allowed to stand for 1 hour and then the solution was decanted from mid-depth into the test chamber through a

spigot.

The test was conducted according to the test guideline above with no

significant deviation from the protocol.

RESULTS

Bior	nass	Gra	pwth
EL50	NOEL	EL50	NOEL
WAF mg/L at 72 h	WAF mg/L at 72 h	WAF mg/L at 72h	WAF mg/L at 72 h
> 100	> 100	> 100	> 100

Remarks - Results All validity criteria for the test are satisfied.

There were no signs of adherence of cells to the test chambers or noticeable aggregations or flocculation in the negative control or in any treatment groups. There were no noticeable changes in cell morphology at the

nominal WAF loading rate of 100 mg/L.

CONCLUSION The notified chemical (STD/1574) is not harmful to algae

TEST FACILITY Wildlife (2010f)

C.2.4. Inhibition of microbial activity

TEST SUBSTANCE The notified chemical (STD/1574)

METHOD OECD TG 209 Activated Sludge, Respiration Inhibition Test.

Inoculum Activated sludge

Exposure Period 3 hours

Concentration Range Nominal: Control, 10, 30, 100 and 1000 mg/L

Actual: Not determined

Remarks – Method The test was conducted according to the test guideline above with no

significant deviation from the protocol

RESULTS

EC50 > 1000 mg/L

Remarks – Results All validity criteria for the test are stratified.

The difference between the two control respiration rates was 10.6 - 11.8%,

meeting the validation criterion of less than 15% difference limit.

The 3,5-dichlorophenol reference group was determined to have an EC50 = 19.5 mg/L, within the 5 to 30 mg/L range considered acceptable for the

test.

CONCLUSION The notified chemical (STD/1574) is not inhibitory to micro-organisms

respiration activity

TEST FACILITY Wildlife (2010g)

BIBLIOGRAPHY

- Charles River (2009) [Notified chemical: STD/1574]: Testing for Mutagenic Activity with *Salmonella typhimurium* TA 1535, TA 100, TA 1537 and TA 98 and *Escherichia coli* WP2*uvr*A (Study No. 787718, November, 2009). Edinburgh, UK, Charles River (Unpublished report submitted by the notifier).
- Charles River (2010a) [Notified chemical: STD/1574]: A 28 Day Oral (Gavage) Toxicity Study in Rats (Study No. 459926, July, 2010). Edinburgh, UK, Charles River (Unpublished report submitted by the notifier).
- Charles River (2010b) A 90 Day Toxicity Study of [Notified chemical STD/1574] by Oral (Gavage) in Rats with a 28 Day Recovery Period. Edinburgh, UK, Charles River (Unpublished report submitted by the notifier).
- Charles River (2010c) [Notified chemical: STD/1574]: Chromosomal Aberrations Assay with Chinese Hamster Ovary Cell Cultures *In Vitro* (Study No. 787723, January, 2010). Edinburgh, UK, Charles River (Unpublished report submitted by the notifier).
- Charles River (2010d) [Notified chemical: STD/1574]: Mouse Lymphoma Mutation Study (Study No. 787739, January, 2010). Edinburgh, UK, Charles River (Unpublished report submitted by the notifier).
- Charles River (2010e) [Notified chemical: STD/1574]: Developmental Toxicity Study in Rats (Study No. 495257, July, 2010). Edinburgh, UK, Charles River (Unpublished report submitted by the notifier).
- CHELAB (2012a) Water Solubility (Study No. 11.076290.0001, July, 2012). Resana, Italy, CHELAB SrL (Unpublished report submitted by the notifier).
- CHELAB (2012b) Vapour Pressure (Study No. 11.076290.0001, July, 2012). Resana, Italy, CHELAB SrL (Unpublished report submitted by the notifier).
- LAUS GmbH (2009a) Determination of the Melting point of [notified chemical: STD/1574] according to OECD 102 resp. EU A.1. (Study No. 09091001G904, December, 2009). Kirrweiler, Germany, LAUS GmbH (Unpublished report submitted by the notifier).
- LAUS GmbH (2009b) Determination of the Boiling point of [notified chemical: STD/1574] according to OECD 103 resp. EU A.2 (Study No. 09091001G906, December, 2009). Kirrweiler, Germany, LAUS GmbH (Unpublished report submitted by the notifier).
- LAUS GmbH (2009c) Determination of the Density of [notified chemical: STD/1574] according to OECD 109 resp. EU A.3 (Study No. 09091001G914, December, 2009). Kirrweiler, Germany, LAUS GmbH (Unpublished report submitted by the notifier).
- LAUS GmbH (2009d) Determination of the Vapour Pressure of [notified chemical: STD/1574] according to OECD 104 resp. EU A.4 (Study No. 09091001G952, December, 2009). Kirrweiler, Germany, LAUS GmbH (Unpublished report submitted by the notifier).
- LAUS GmbH (2010) Determination of the Flammability of [notified chemical: STD/1574] according to EU A.10 (Study No. 09091001G934, May, 2010). Kirrweiler, Germany, LAUS GmbH (Unpublished report submitted by the notifier).
- NOHSC (2004) Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.
- Sasol (2010a) REACH Physico-Chemical Data Report 7.14 Granulometry (Study No. 6703, April, 2010). Brunsbuttel, Germany, Sasol Germany Gmbh (Unpublished report submitted by the notifier).
- Sasol (2010b) REACH Physico-Chemical Data Report 7.12 Ignition Temperature (Study No. 6073, April, 2010). Brunsbuttel, Germany, Sasol Germany Gmbh (Unpublished report submitted by the notifier).
- Sasol (2010c) REACH Physico-Chemical Data Report 7.11 Explosive Properties (Study No. 6704, April, 2010). Brunsbuttel, Germany, Sasol Germany Gmbh (Unpublished report submitted by the notifier).
- Sasol (2010d) REACH Physico-Chemical Data Report 7.13 Oxidising Properties (Study No. 6702, April, 2010). Brunsbuttel, Germany, Sasol Germany Gmbh (Unpublished report submitted by the notifier).
- Sasol (2011a) REACH Physico-Chemical Data Report 7.3 Boiling Point (Study No. 8365, December, 2011). Brunsbuttel, Germany, Sasol Germany Gmbh (Unpublished report submitted by the notifier).
- Sasol (2011b) REACH Physico-Chemical Data Report 7.4 Relative Density (Study No. 8366, December, 2011). Brunsbuttel, Germany, Sasol Germany Gmbh (Unpublished report submitted by the notifier).

Sasol (2011c) REACH Physico-Chemical Data Report 7.17 Viscosity (Study No. 8370, December, 2011). Brunsbuttel, Germany, Sasol Germany Gmbh (Unpublished report submitted by the notifier).

- Sasol (2011d) REACH Physico-Chemical Data Report 7.9 Flash Point (Study No. 8367, December, 2011). Brunsbuttel, Germany, Sasol Germany Gmbh (Unpublished report submitted by the notifier).
- Sasol (2011e) REACH Physico-Chemical Data Report 7.12 Ignition Temperature (Study No. 8369, December, 2011). Brunsbuttel, Germany, Sasol Germany Gmbh (Unpublished report submitted by the notifier).
- Stillmeadow (2009a) [Notified chemical STD/1574]: Final Report Acute Oral Toxicity Study (UDP) in Rats OECD 425 (Study No. 13292-09, November, 2009). Sugar Land, Texas, USA, Stillmeadow Inc. (Unpublished report submitted by the notifier).
- Stillmeadow (2009b) [Notified chemical STD/1574]: Final Report Acute Dermal Toxicity Study in Rats OECD 402 (Study No. 13293-09, October, 2009). Sugar Land, Texas, USA, Stillmeadow Inc. (Unpublished report submitted by the notifier).
- Stillmeadow (2009c) [Notified chemical STD/1574]: Final Report Acute Dermal Irritation Study in Rabbits OECD 402 (Study No. 13295-09, October, 2009). Sugar Land, Texas, USA, Stillmeadow Inc. (Unpublished report submitted by the notifier).
- Stillmeadow (2009d) [Notified chemical STD/1574]: Final Report Acute Eye Irritation Study in Rabbits OECD 405 (Study No. 13294-09, October, 2009). Sugar Land, Texas, USA, Stillmeadow Inc. (Unpublished report submitted by the notifier).
- Stillmeadow (2009e) [Notified chemical STD/1574]: Final Report Guinea Pig Maximization Test for Topically Applied Test Substance OECD 406 & OPPTS 870.2600 (Study No. 13296-09, November, 2009). Sugar Land, Texas, USA, Stillmeadow Inc. (Unpublished report submitted by the notifier).
- SWA (2012) Code of Practice: Managing Risks of Hazardous Chemicals in the Workplace, Safe Work Australia, http://www.safeworkaustralia.gov.au/sites/swa/about/publications/pages/managing-risks-of-hazardous-chemicals-in-the-workplace.
- 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 >.
- Wildlife (2010a) [Notified chemical: STD/1574]: Determination of Water Solubility by the Shake Flask Method (Project No. 527E-129, February, 2010). Easton, Maryland, USA, Wildlife International, Ltd. (Unpublished report submitted by the notifier).
- Wildlife (2010b) [Notified chemical: STD/1574]: Estimation for n-Octanol/Water Partition Coefficient using High Performance Liquid Chromatography (HPLC) (Project No. 527C-102, January, 2010). Easton, Maryland, USA, Wildlife International, Ltd. (Unpublished report submitted by the notifier).
- Wildlife (2010c) [Notified chemical: STD/1574]: Estimation of Adsorption Coefficient using High Performance Liquid Chromatography (HPLC) (Project No. 527C-101, January, 2010). Easton, Maryland, USA, Wildlife International, Ltd. (Unpublished report submitted by the notifier).
- Wildlife (2010d) [Notified chemical: STD/1574]: A 96-Hour Static Acute Toxicity Test with the Fathead Minnow (*Pimephales promelas*) (Project No. 527A-103, January, 2010). Easton, Maryland, USA, Wildlife International, Ltd. (Unpublished report submitted by the notifier).
- Wildlife (2010e) [Notified chemical: STD/1574]: A 48-Hour Static Acute Toxicity Test with the Cladoceran (*daphnia magna*) (Project No. 527A-102, January, 2010). Easton, Maryland, USA, Wildlife International, Ltd. (Unpublished report submitted by the notifier).
- Wildlife (2010f) [Notified chemical: STD/1574]: A 72-Hour Toxicity Test with the Freshwater Alga (*Pseudokirchneriella subcapita*ta) (Project No. 527A-101, January, 2010). Easton, Maryland, USA, Wildlife International, Ltd. (Unpublished report submitted by the notifier).
- Wildlife (2010g) [Notified chemical: STD/1574]: An Activated sludge Respiration Inhibition Test (Project No. 527E-127, January 2010). Easton, Maryland, USA, Wildlife International, Ltd. (Unpublished report submitted by the notifier).