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# NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

# PUBLIC REPORT

# 2-Propanol, 1-amino-, compds. with polyethylene glycol hydrogen sulfate C<sub>12-14</sub>-alkyl ethers

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.

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

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

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Director NICNAS

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# **SUMMARY**

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

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
STD/1506	Diversey	2-Propanol, 1-	Yes	≤ 80 tonnes per	Component of dish
	Australia Pty Ltd	amino-, compds.		annum	washing and laundry
		with polyethylene			detergents, hard
		glycol hydrogen			surface cleaners and
		sulfate C12-14-alkyl			industrial degreasers
		ethers			

# **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 for the Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the table below.

Hazard classification	Hazard statement	
Skin irritation Category 2	H315 - Causes skin irritation	
Eye irritation Category 2A	H319 - Causes serious eye irritation	

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:

R38: Irritating to skin

The environmental hazard classification according to the *Globally Harmonised System for the 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 2)	H401 - Toxic to aquatic life

# Human health risk assessment

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

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

# **Environmental risk assessment**

On the basis of the PEC/PNEC ratio and the assessed 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:
  - Skin irritation Category 2: H315 Causes skin irritation
  - Eye irritation Category 2A: H319 Causes serious eye irritation

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 reformulation:
  - Enclosed, automated processes where possible
- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical during reformulation:
  - Avoid contact with skin and eyes
- 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 reformulation:
  - Coveralls
  - Impermeable gloves
  - Safety goggles

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 for the Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

# Disposal

• The notified chemical should be disposed of to landfill.

# 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 concentration of the chemical exceeds or is intended to exceed 20% in dishwashing liquids, 18% in laundry detergents, 3% in general surface cleaning products and 10% in industrial degreasers;

or

- (2) Under Section 64(2) of the Act; if
  - the function or use of the chemical has changed from a component of dishwashing liquids, laundry detergents, general surface cleaning products and industrial degreasers, 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 the notified chemical and a product containing the notified chemical 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)

Diversey Australia Pty Ltd (ABN: 92 080 527 117)

29 Chifley Street,

**SMITHFIELD NSW 2164** 

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: analytical data, degree of purity, residual monomers and impurities.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows: melting point, vapour pressure, water solubility, hydrolysis as a function of pH, adsorption/desorption, dissociation constant, particle size, flash point, and all human toxicity endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

EU: REACH (2013)

# 2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

MARLINAT 242/90 M (contains 90% notified chemical)

CAS NUMBER

1187742-72-8

CHEMICAL NAME

2-Propanol, 1-amino-, compds. with polyethylene glycol hydrogen sulfate C<sub>12-14</sub>-alkyl ethers

OTHER NAME(S)

Alcohols, C12-14 (even numbered), ethoxylated (≤ 2.5 moles EO), sulfated, monoisopropanolamine salt

MOLECULAR FORMULA

Unspecified

STRUCTURAL FORMULA

$$H_3C$$
  $(CH_2)_{11-13}$   $OH$   $OH$   $OH$ 

MOLECULAR WEIGHT

451.61-479.67 Da (for n = 2.5)

ANALYTICAL DATA

Reference NMR, FTIR, GC, GC/MS, and UV spectra were provided.

# 3. COMPOSITION

Degree of Purity > 90%

ADDITIVES/ADJUVANTS

Chemical Name 1,2-Propanediol

*CAS No.* 57-55-6 *Weight %* 10

# 4. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20 °C and 101.3 kPa: Clear faint liquid at 20 °C (90% in 1,2-propanediol). Slightly yellow foamy solid (dried notified chemical).

Property	Value	Data Source/Justification
Melting Point/Freezing Point	5 °C at 101.3 kPa	(M)SDS
Boiling Point	> 280 °C at 101.3 kPa	Measured
Density	$1,080 \text{ kg/m}^3 \text{ at } 21 ^{\circ}\text{C}$	Measured
Vapour Pressure	6.049 x 10 <sup>-5</sup> kPa at 25 °C	Calculated on parent acid. Vapour pressure of the salt is expected to be lower.
Water Solubility	Not determined	Expected to be low based on its predominantly hydrophobic nature, however, the notified chemical may be dispersible in water based on its surface activity
Hydrolysis as a Function of pH	Not determined	Not expected to significantly hydrolyse under environmental conditions (pH 4-9)
Partition Coefficient (n-octanol/water)	$\log Pow = 1$ at 23 °C	Measured
Adsorption/Desorption	Not determined	Expected to partition to phase boundaries based on its surfactant properties
Dissociation Constant	Not determined	The notified chemical is a salt and is expected to be ionised in the environment
Particle Size	Not determined	The product is imported and supplied in liquid form.
Flash Point	Not determined	Solid
Solid Flammability	Not flammable	Measured
Autoignition Temperature	270 °C at 101.5 kPa	Measured
Explosive Properties	Not determined	Contains no structural alerts for explosive properties.
Oxidising Properties	Not determined	Contains no structural alerts for 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 for the Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia.

### 5. INTRODUCTION AND USE INFORMATION

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

The notified chemical will be imported into Australia at 90% concentration (in 1,2-propanediol) or as a component of formulated products (at  $\leq$  20% concentration).

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

Year	1	2	3	4	5
Tonnes	40	50	60	70	80

PORT OF ENTRY Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS Diversey Australia Pty Ltd

# TRANSPORTATION AND PACKAGING

The notified chemical will be imported into Australia at 90% concentration in 205 L drums or as a component of formulated products, by sea. Commercial dishwashing products containing the notified chemical (at  $\leq$  20% concentration) will be imported in 1.5 L sealed plastic pouches, which are designed to fit into a wall-mounted dispenser. The notified chemical or products containing the notified chemical will then be transported by road throughout Australia to local formulators and end users.

#### USF

The notified chemical will be used as a component of detergents and general cleaning products (proposed usage concentration: 20% in dishwashing liquids, 18% in laundry detergents, 3% in general surface cleaning products and 10% in industrial degreasers).

### OPERATION DESCRIPTION

### Reformulation

The reformulation process will involve typical liquid blending and bottle filling operations. The process will be fully automated, enclosed and bunded. Workers will load the notified chemical at 90% concentration into the mixing tank through transfer lines and pumping equipment. The mixing process will be in closed tanks. The final formulated products containing the notified chemical (at  $\leq$  20% concentration) will be automatically packaged into containers suitable for end use and transported to retailers.

# Commercial dishwashing

Workers will install the pouch of the hand dish washing product which contains the notified chemical (at  $\leq$  20% concentration) into a wall-mounted dispenser above the sink. The dish washing liquid will then be directly dispensed into the sink which will be filled with water (typically 15 mL of dish washing product for a 40 L water/sink). The workers will wash the dishes using a scrubber/brush or sponge/scourer. The water containing the notified chemical will be drained and the dishes will be rinsed with water.

# Industrial degreasing

Workers will dilute the degreaser product containing the notified chemical (at  $\leq$  10% concentration) in water in a bucket. The solution will be then manually poured into the wash fluid port on industrial parts washing machines (e.g. in automotive transmission and engine repair shops). Workers will place the industrial parts onto the racks within the machine. The washing process will be enclosed and automated. Once the machine has finished the wash cycle, the workers will open the washer and remove the cleaned parts. The spent wash fluid will be pumped from the washer sump into a 205 L drum for disposal by licensed contractors.

# Other end-use activities

End-use products (including household dishwashing liquids, general surface cleaners and fabric washing products) containing the notified chemical (at  $\leq 20\%$  concentration) may be used by consumers and professionals (such as cleaners).

### 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 warehouse workers	2-3	24
Reformulation workers	4-8	200
Professional kitchen workers	8-12	300
Workers involved in degreasing	2-8	200
Retail workers	2-8	300

#### EXPOSURE DETAILS

*Transport and warehouse workers* 

Worker exposure to the notified chemical during the transport and storage of the notified chemical and products containing it is not expected, except in the event of an accident where packaging may be breached.

# Reformulation workers

Dermal and ocular exposure to the notified chemical (at  $\leq$  90% concentration) may occur during reformulation operations, especially when connecting and dosing the notified chemical into the mixer tank. The loading process will be performed under a fume extractor and the mixing process will be carried out in closed tanks under local exhaust ventilation. The notifier has stated that workers will be using personal protective equipment (PPE), such as coveralls, respirator, gloves and eye protection when carrying out these activities.

# Professional kitchen workers

Dermal exposure to the notified chemical (at  $\leq$  20% concentration) may occur when dispensing the dishwashing liquid. The notifier has stated that the use of gloves will be recommended during dispensing operations. Dermal and perhaps ocular exposure to the notified chemical (at 15 ml of dish washing product in 40 L water, approximately 0.0075% concentration) may also occur during dish washing.

### Workers involved in degreasing

Dermal exposure to the notified chemical (at  $\leq 10\%$  concentration) may occur during dilution of the degreaser product and charging of the wash fluid into the washer. The washing process will be enclosed and automated. The notifier has stated that workers will wear PPE, including coveralls, safety glasses and impervious gloves.

# Workers involved in other end-use activities (e.g. professional cleaners)

Exposure to the notified chemical (at  $\leq 20\%$  concentration) in end-use products may occur in the cleaning industry. Such professionals may use some PPE to minimise repeated exposure, and good hygiene practices are expected to be in place. If PPE is used, exposure of such workers is expected to be of a similar or lesser extent than that experienced by consumers using products containing the notified chemical.

### Retail workers

Workers are not expected to be exposed to the notified chemical except in the case of a leak or spill from damaged packing. In the event of a spill, dermal and ocular are likely to be the main routes of exposure. The notifier has stated that during clean-up, workers will be recommended to wear impervious gloves, cotton coveralls and eye protection.

# **6.1.2.** Public Exposure

There will be widespread and repeated exposure of the public to the notified chemical (at  $\leq 20\%$  concentration) through the use of detergents and general cleaning products. The principal route of exposure will be dermal.

Data on typical use patterns of household cleaning product categories in which the notified chemical may be used are shown in the following tables (SDA, 2005). For the purposes of the exposure assessment via the dermal route, Australian use patterns for the various product categories are assumed to be similar to those in

Europe. In the absence of dermal absorption data, the default dermal absorption of 100% was assumed for calculation purposes (European Commission, 2003). An adult bodyweight of 60 kg has been used for calculation purposes.

- Household products (Indirect dermal exposure - from wearing clothes):

Product type	Amount (g/use)	<b>C</b> (%)	Product Retained (%)	Percent Transfer (%)	Daily systemic exposure (mg/kg bw/day)
Laundry liquid	230	18	0.95	10	0.6555

Daily systemic exposure = amount x concentration x product retained x percent transfer x dermal absorption (%)/body weight

- Household products (Direct dermal exposure):

Product type	Frequency (use/day)	<b>C</b> (%)	Contact Area (cm <sup>2</sup> )	Product Use C (g/cm <sup>3</sup> )	Film Thickness (cm)	Time Scale Factor	Daily systemic exposure (mg/kg bw/day)
Laundry liquid	1.43	18	1980	0.01	0.01	0.007	0.0059
Dishwashing liquid	3	20	1980	0.009	0.01	0.03	0.0535
All-purpose cleaner	1	3	1980	1.0	0.01	0.007	0.0693
Total							0.1287

Daily systemic exposure = frequency of use x concentration x body surface contact area x product concentration x film thickness on skin x time scaling factor x dermal absorption (%)/body weight

The worst case scenario estimation using these assumptions is for a person who is a simultaneous user of all products listed in the above tables that contain the notified chemical. This would result in a combined internal dose of 0.7842 mg/kg bw/day.

# 6.2. Human Health Effects Assessment

Endpoint	Analogue	Result and Assessment Conclusion
Rat, acute oral toxicity	A	LD50 > 2000 mg/kg bw; low toxicity
Rat, acute dermal toxicity	A	LD50 > 2000  mg/kg bw; low toxicity
Rabbit, skin irritation	A	irritating
Rabbit, eye irritation	A	irritating
Guinea pig, skin sensitisation – non-adjuvant test	A	no evidence of sensitisation
Rat, repeat dose oral toxicity – 90 days	В	NOAEL = 225  mg/kg bw/day
Mutagenicity – bacterial reverse mutation	A	non mutagenic

Analogues	CAS Name	CAS Number	Trade/other name
A	2-Propanol, 1,1',1"-nitrilotris-, compds. with polyethylene glycol hydrogen sulfate C12- 14-alkyl ethers	174450-50-1	Marlinat 242/90 T
В	Poly(oxy-1,2-ethanediyl), α- sulfo-ω-hydroxy-, C12-14- alkyl ethers, sodium salts	68891-38-3	Sodium lauryl ether sulphate

The notified chemical and the analogue chemicals belong to the same class of anionic surfactants known as alcohol ethoxysulfates (AES). The notified chemical and analogue chemicals differ mainly in the nature of the counterion which is not expected to have a significant contribution on toxicological effects. Therefore the analogue chemicals are considered acceptable to estimate the toxicity of the notified chemical.

Toxicokinetics, metabolism and distribution.

No toxicokinetic data on the notified chemical were submitted.

The notified chemical belongs to the class of anionic surfactants known as alcohol ethoxysulfates (AES). Alcohol ethoxysulfates (AES) are readily absorbed in the gastrointestinal (GI) tract and excreted mainly in the urine (HERA, 2003). The notified chemical is ionic and therefore dermal absorption is expected to be limited. This is supported by the low percutaneous absorption rate of an AES with a C12 alkyl chain and 3 ethoxy units measured in a rat *in vivo* study of  $0.0163 \,\mu\text{g/cm}^2/\text{h}$  (HERA, 2003).

### Acute toxicity.

Analogue A was of low acute oral and dermal toxicity in studies conducted in rats.

### Irritation and sensitisation.

Analogue A was irritating to the skin in the study conducted in rabbits.

In an eye irritation study in rabbits, conjunctival reactions in the form of diffuse crimson reddening were noted with all treated eyes appearing normal between 17 to 24 days. The scores did not meet the criteria for classification of the chemical as an eye irritant according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004). However, the results of the study did warrant classification of the chemical under the GHS as H319 (Category 2A): Causes serious eye irritation. In addition, the notifier has classified the chemical as R41: Risk of serious damage to eyes.

Analogue A was not a skin sensitiser in a guinea pig skin sensitisation study using the Buehler method.

# Repeated dose toxicity.

In a 90 day repeated dose toxicity study, rats were administered analogue B by gavage at 0, 25, 75 and 225 mg/kg bw/day. No mortalities or systemic treatment-related effects were observed in any test group. However, local treatment effects were seen in the forestomach to different degrees in all test groups related to the irritation potential of the analogue chemical. The No Observed (Adverse) Effect Level (NO(A)EL) for systemic toxicity was therefore established as 225 mg/kg bw/day.

### Mutagenicity/Genotoxicity.

Analogue A was not mutagenic in a bacterial reverse mutation test.

# Health hazard classification

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

Hazard classification	Hazard statement
Skin irritation Category 2	H315 - Causes skin irritation
Eye irritation Category 2A	H319 - Causes serious eye irritation

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):

R38: Irritating to skin R36: Irritating to eyes

### 6.3. Human Health Risk Characterisation

### 6.3.1. Occupational Health and Safety

The notified chemical is a skin and eye irritant. There is potential for dermal and ocular exposure of workers to the notified chemical (at  $\leq 90\%$  concentration) during reformulation processes. Exposure should be minimised through the stated use of enclosed, automated processes, local exhaust ventilation and PPE. Other workers, including commercial laundry and kitchen workers, may be exposed to products containing the notified chemical (at  $\leq 20\%$  concentration). These workers may use PPE to lower exposure. The risk of irritant effects from the notified chemical at these concentrations is considered to be low, even in the absence of PPE.

Overall, the risk to workers from exposure to the notified chemical is not considered to be unreasonable, given the toxicological profile of the notified chemical and the expected use of engineering controls and PPE.

#### 6.3.2. Public Health

The public may have dermal or ocular exposure to the notified chemical (at  $\leq$  20% concentration) through the use of detergents and general cleaning products. The risk of irritant effects from the notified chemical at these concentrations is considered to be low, even in the absence of PPE.

The repeat dose toxicity potential was estimated by calculation of the margin of exposure (MoE) of the notified chemical, based on the use of laundry detergent and dish washing liquids and the NOAEL of 225 mg/kg bw/day, which was established in toxicity studies on an analogue chemical. A MoE value of > 100 is considered acceptable to account for intra- and inter-species differences. Using the abovementioned NOAEL, a MoE of 287 was estimated, which is considered acceptable.

Overall, the risk to public health associated with the proposed use of the notified chemical in detergents and general cleaning products 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 not be manufactured in Australia; therefore there will be no release to the environment from these activities. During reformulation, release of the notified chemical may result from residues in empty containers (2% of the total import volume), spills and leaks from transfer and filling (1% of the total import volume), and washings from tanks and equipment cleaning (2% of the total import volume). The residues, along with the empty containers and adsorbed spills, are expected to be disposed of to landfill. Washings are expected to be collected as much as possible to be reused in subsequent batches. Approximately 0.5% of the total import volume of the notified chemical is expected to be released to the on-site waste treatment facility and then discharged to sewer as trade waste.

# RELEASE OF CHEMICAL FROM USE

During use as detergent and general cleaning products, the entire volume of the notified chemical in washings is expected to be released to sewers on a nationwide basis. Residues of the notified chemical in the empty containers (up to 2% of the total import volume) are expected to be disposed of to landfill.

### RELEASE OF CHEMICAL FROM DISPOSAL

The majority of the notified chemical is expected to be released to sewer. A small amount of the notified chemical is likely to be disposed of to landfill when empty containers with residues of detergent or cleaning products are discarded.

# 7.1.2. Environmental Fate

For the details of the environmental fate study, please refer to Appendix C. The product containing the notified chemical (90%) is considered to be readily biodegradable based on a biodegradation study provided. Since the product contains a very high percentage of the notified chemical (90%) and showed a high percentage (> 80%) of biodegradability, the notified chemical is likely to be readily biodegradable in the environment.

The majority of the product containing the notified chemical is expected to be released to sewage treatment plants (STPs). Based on the ready biodegradability of the notified chemical, it was assumed in the SimpleTreat model (European Commission, 2003) that 87% of the notified chemical is expected to be removed by biodegradation during STP processes. Notified chemical remaining in treated sewage effluents is likely to be released to surface waters or applied to land when used for irrigation. Notified chemical in sewage sludge is anticipated be disposed of to landfill or applied to land when sludge is used for soil remediation. Based on its surface activity and biodegradability, the notified chemical is not expected to bioaccumulate.

The notified chemical is expected to degrade in STPs, surface waters, soils and landfill due to its ready biodegradability. The metabolites are expected to further degrade in both the aquatic and terrestrial

compartments through biotic and abitoic processes to form water, oxides of carbon, sulfur, nitrogen and inorganic salts.

### 7.1.3. Predicted Environmental Concentration (PEC)

The calculation for the Predicted Environmental Concentration (PEC) is summarised in the table below. Based on the reported use as a component of liquid detergents and general cleaning products, it is assumed that 100% of the total import volume of the chemical is released to sewer on a nationwide basis over 365 days per year. Applying assumptions in the SimpleTreat model (European Commission, 2003) based on the ready biodegradability of the notified chemical, 87% of the notified chemical is expected to be removed by biodegradation during STP processes (European Commission, 2003).

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	80,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	80,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	219.18	kg/day
Water use	200	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	87%	Mitigation
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	6.3	μg/L
PEC - Ocean:	0.63	μg/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 chemical in this volume is 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  $6.3~\mu g/L$  may potentially result in a soil concentration of approximately  $42~\mu g/kg$ . Assuming accumulation of the notified chemical in soil for 5 and 10~years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10~years may be approximately  $210~\mu g/kg$  and  $420~\mu g/kg$ , respectively.

### 7.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on a product containing the notified chemical (94.4%) are summarised in the table below. Details of the studies of the product can be found in Appendix C.

Endpoint	Result	Assessment Conclusion
Fish Toxicity (96 h)	LC50 = 7.7  mg/L	Toxic to fish
Daphnia Toxicity (48 h)	EC50 = 7.7  mg/L	Toxic to aquatic invertebrates
Algal Toxicity (72 h)	$E_rC50 = 14 \text{ mg/L}$	Harmful to algae

The product containing the notified chemical (94.4%) is expected to be toxic to fish and daphnia, and harmful to algae. On the basis of the acute toxicity data of the product, the product is expected to be toxic to aquatic organisms. Since the product contains a very high percentage of the notified chemical, it is confident that the observed toxicities adequately represent the toxicity of the notified chemical. 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 2; Toxic to aquatic life. Based on the acute toxicity, ready biodegradability and lack of potential for bioaccumulation of the notified chemical, it has not been formally classified under the GHS for long term toxicity.

### 7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) for the notified chemical has been calculated and is presented in the table below. The PNEC is calculated based on the endpoint for the most sensitive species (fish and daphnia) for the notified chemical. Three acute ecotoxicity endpoints for aquatic species from three trophic levels are available. Therefore, an assessment factor of 100 has been used.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50	7.7	mg/L
Assessment Factor	100	
PNEC:	77	μg/L

# 7.3. Environmental Risk Assessment

Based on the above PEC and PNEC values, the following Risk Quotient (Q) has been calculated:

Risk Assessment	PEC μg/L	PNEC µg/L	Q
Q - River:	6.3	77	0.082
Q - Ocean:	0.63	77	0.008

The Risk Quotients (Q = PEC/PNEC) for the notified chemical have been calculated to be < 1 for the river and ocean compartments. Therefore, the notified chemical is unlikely to result in ecotoxicologically significant concentrations in the aquatic environment from the assessed use pattern. The notified chemical is not expected to be bioaccumulative. The notified chemical is considered to be readily biodegradable, thus it is unlikely to persist in surface waters or soils. Therefore, the notified chemical is not expected to pose an unreasonable risk to the aquatic environment from the assessed use pattern.

# **APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES**

**Boiling Point** > 280 °C at 101.3 kPa (with decomposition)

Method Differential Scanning Calorimetry

Remarks Decomposition observed before boiling point was reached. The test was carried on a dried

sample.

Test Facility SASOL (2011a)

**Density**  $1,080 \text{ kg/m}^3 \text{ at } 21 \text{ }^{\circ}\text{C}$ 

Method OECD TG 109 Density of Liquids and Solids.

Remarks Air comparison pycnometer (measuring cylinder). Measured on a dried sample.

Test Facility SASOL (2011b)

**Partition Coefficient (n-**  $\log Pow = 1$  at 23 °C

octanol/water)

Method OECD TG 123: Octanol-Water Partition Coefficients of Surfactants: Slow Stirring/Surface

Tension method

Remarks Two phase titration was done as described per ISO 2271 guidelines. It was observed that the

above test guideline is not outlined for surfactant chemicals. Therefore, the result should be

treated with caution.

Test Facility SASOL (2011c)

Solid Flammability Not flammable

Method EU TG A10 of Annex V of 67/548/EEC

Remarks Flammability (solids). The test substance did not burn in the preliminary test.

Test Facility SASOL (2011d)

**Autoignition Temperature** 270 °C at 101.5 kPa

Method ASTM E 659-78 (2005)

Remarks Dried substance Test Facility SASOL (2012)

# **APPENDIX B: TOXICOLOGICAL INVESTIGATIONS**

# **B.1.** Acute toxicity – oral

TEST SUBSTANCE Analogue A (84%)

METHOD OECD TG 401 Acute Oral Toxicity.

Species/Strain Rat/Wistar Vehicle none

Remarks - Method No significant protocol deviations occurred during the study.

RESULTS

Group	Number and Sex of Animals	Dose mg/kg bw	Mortality
1	2 M, 2 F	2000	0
2	3 M, 3 F	2000	0

LD50 > 2000 mg/kg bw

Signs of Toxicity All animals showed increased activity and pilorection up to four hours

after dosing. No clinical symptoms were noticed from five hours after

and not related to treatment with the test substance. The male rats showed

dosing until the end of the observation period (day 14).

Effects in Organs None

CONCLUSION Analogue A is of low toxicity via the oral route.

TEST FACILITY Hüls (1997a)

# **B.2.** Acute toxicity – dermal

TEST SUBSTANCE Analogue A (84%)

METHOD OECD TG 402 Acute Dermal Toxicity.

Species/Strain Rat/Wistar Vehicle None

Type of dressing Semi-occlusive.

Remarks - Method No significant protocol deviations occurred during the study.

RESULTS

Group	Number and Sex	Dose	Mortality
	of Animals	mg/kg bw	
1	5 M, 5 F	2000	0
I D50	2000 /1 1		
LD50	> 2000 mg/kg bw		
Signs of Toxicity - Local	of the dressings w male and three fe application. Scab f After 6 and 12 da respectively, with a scarred skin, at the	as observed. Inflammation chale rats was observed formation was observed at ays the scab fell off for residual scab observed on end of the observation peri	sites following the removal of the treated skin of four 24 hours after the dermal to 72 hours after application. male rats and female rats, one female rat, with slightly od.
Signs of Toxicity - Systemic	<ul> <li>No systemic clinica</li> </ul>	ıl signs were observed	
Effects in Organs	No macroscopic ab	normalities were observed	on day 14.
Remarks - Results	minimal or no bod	y weight gain observed in	reight loss on day 7, with a all female rats at the end of to be a physiological finding

bodyweight gains throughout the study.

**CONCLUSION** Analogue A is low toxicity via the dermal route.

**TEST FACILITY** Hüls (1997b)

### **B.3.** Irritation – skin

TEST SUBSTANCE Analogue A (84%)

**METHOD** OECD TG 404 Acute Dermal Irritation/Corrosion.

Species/Strain Rabbit/Small white Russian Number of Animals Three female rabbits

Vehicle None Observation Period 14 days

Type of Dressing Semi-occlusive.

Remarks - Method No deviation from protocol was recorded.

### RESULTS

Lesion		ean Sco nimal N	-	Maximum Value	Maximum Duration of Any Effect	Maximum Value at End of Observation Period
	1	2	3		•	
Erythema/Eschar	2.7	2.0	2.3	3	< 10 days	0
Oedema	4.0	2.0	2.3	4	< 10 days	0

<sup>\*</sup> Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

### Remarks - Results

Well-defined erythema with distinct oedema in two animals and severe oedema in the third animal was noted after 24 hours. After 48 hours the signs of irritation remained unchanged in two animals. The third animal showed moderately severe erythema and severe oedema after 48 and 72 hours. Localised skin irritation with well-defined to moderately severe erythema and moderate to severe oedema was observed in the other two animals after 72 hours with slight subcutaneous haemorrhages in one rabbit. Distinct skin irritation and scaling were observed on day 6. After 8 to 10 days, the signs of irritation slowly wore off with detachment of the scales and no signs of irritation were evident on day 14.

**CONCLUSION** Analogue A is irritating to the skin.

**TEST FACILITY** Hüls (1997c)

# **B.4.** Irritation – eye

TEST SUBSTANCE Analogue A (84%)

OECD TG 405 Acute Eye Irritation/Corrosion. **METHOD** 

Species/Strain Rabbit/Small white Russian Three female rabbits

Number of Animals

Observation Period 24 days

Remarks - Method No significant protocol deviations occurred during the study. 0.1 mL of the liquid substance was instilled into one eye of each of three rabbits. After exposure of 24 hours (and at subsequent examinations), a 0.1% fluorescein

solution was instilled into the eyes, followed by flushing with warm

physiological saline.

### RESULTS

Lesion		1ean Score Animal No		Maximum Value	Maximum Duration of Any Effect	Maximum Value at End of Observation Period
	1	2	3			
Conjunctiva: redness	2.7	2.3	2.3	3	< 24 days	0
Conjunctiva:chemosis	1.3	2.0	1.3	2	< 17 days	0
Corneal opacity	1.0	1.7	1.0	2	< 17 days	0
Iridial inflammation	0	1.0	0	1	< 13 days	0

<sup>\*</sup> Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

Remarks - Results

Distinct hyperaemia of some blood vessels with slight swelling in conjunctivae was observed after one hour of the test substance administration. All animals treated eyes showed lachrymation. Conjunctival reactions in the form of diffuse crimson reddening (individual blood vessels not easily discernible) were observed 24 hours after administration. The cornea was slightly opaque and the iris in one animal showed severe hyperaemia. The irritations reactions and signs persisted at 72 hours after administration and white mucosal secretion and haemorrhages on the mucosa and nictitating membrane in all animals were observed after 24 to 72 hours. The signs of irritation slowly started to wear off after 6 days. Slight hair loss on the eyelids of all animals was observed on day 13. All animals were free from the signs of irritation between day 17 and 24.

CONCLUSION

Analogue A is irritating to the eye.

TEST FACILITY

Hüls (1997d)

# **B.5.** Skin sensitisation

TEST SUBSTANCE

Analogue A (84%)

**METHOD** 

Species/Strain PRELIMINARY STUDY OECD TG 406 Skin Sensitisation - < Bühler test>. Guinea pig/Dunkin Hartley, Pirbright white Maximum Non-irritating Concentration:

topical: 25%

MAIN STUDY

Number of Animals INDUCTION PHASE

Test Group: 20 F

Control Group: 10 F

**Induction Concentration:** 

Signs of Irritation

topical: 50%

Very slight skin irritation (very slight erythema and oedema) in 2/20 animals was observed 30 hours after administration of the substance (induction phase I). Slight to well defined erythema with slight oedema in 14/20 animals was observed 30 hours after administration of the substance (induction phase II). As the 14 animals exhibited scaling, the test substance was administered to intact skin for the induction phase III. Very slight erythema and oedema in 4 animals and well defined erythema and oedema in 5 animals and moderate erythema and oedema in 2 animals were observed 30 hours after administration of the substance (induction phase III). One animal exhibited additional necrotic spots on the skin. No sign of skin irritation were observed for the control group treated with the deionised water (vehicle).

CHALLENGE PHASE

challenge

topical: 25%

Remarks - Method

A dose range finding study was initially conducted with 3 animals at concentrations of 5%, 25%, 50% (in deionised water dissolved by heating to approximately 50 °C) and 100% administered on the shaved left and right flanks of the animals (under occlusive patch for 6 hours). After removal of the patch, the administered area was washed with warm water

and dermal reactions were assessed after 30 and 54 hours of the administration. Slight to well defined oedema and erythema were observed in animals administered at 50% and distinct to moderate or severe erythema and oedema in animals administered at 100%. No skin irritation reactions were found in animals administered at 5 or 25%. Based on the results 50% was used for induction phase dose and 25% was used for the challenge dose.

A concurrent positive control study was not run, but had been conducted previously in the test laboratory using 2-mercaptobenzothiazole.

# **RESULTS**

Animal	Challenge Concentration	Number of Animals Showing Skin Reactions after: challenge		
		24 h	48 h	
Test Group	25%	0/20	0/20	
Control Group	25%	0/10	0/10	
Remarks - Results		entration did not show any ere no signs of irritation on		
Conclusion		There was no evidence of reactions indicative of skin sensitisation to analogue chemical under the conditions of the test.		

# **B.6.** Repeat dose toxicity

TEST FACILITY

TEST SUBSTANCE Analogue B (70%)

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

Species/Strain Rats/(Hsd/Win:Wu)
Route of Administration Oral – gavage

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

Hüls (1997e)

Post-exposure observation period: 28 days

Vehicle Aqua dest.

Remarks - Method Full study report not provided.

# RESULTS

Group	Number and Sex	Dose	Mortality
	of Animals	mg/kg bw/day	
control	10M, 10F	0	1
low dose	10M, 10F	25	1
mid dose	10M, 10F	75	1
high dose	10M, 10F	225	0
control recovery	5M, 5F	0	0
mid dose recovery	5M, 5F	75	0
high dose recovery	5M, 5F	225	1

# Mortality and Time to Death

There was no test substance related mortality. However, three female rats died due to bloodletting: one of the control group after 67 applications, one of the mid dose group (75 mg/kg bw/day dose) after 31 applications and one of the high dose recovery group (225 mg/kg bw/day dose) after 32 applications. One female rat of the low dose group (25 mg/kg bw/day dose) was sacrificed after 66 applications due to a traumatic fracture of the

mandibular/maxilla caused by the top cage wire smash.

#### Clinical Observations

No treatment related symptoms were observed in any test group.

No treatment related effects on the mean food consumption and the mean water intake were observed in any test

No deviations of the total body weight gain of the animals were observed in any test group. However, a slight decrease of the total body weight gain in the female high dose recovery group was observed but was reported to be not test substance related.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

There were no significant deviations in clinical chemistry, ophthalmology or haematological findings. The values were similar to the control groups.

# Effects in Organs

There were no significant deviations in any parameter of the absolute organ weights compared to the control groups. However, a decrease in the relative heart weight of female animals of the mid dose group was observed and considered by the study authors to be incidental and within the normal range of historical values.

The macroscopical examination showed no treatment related effects in the low and mid dose groups. Animals of the high dose group (4 males/10) showed treatment related findings of the forestomach, such as mucosal oedema. However the recovery groups did not show any substance related findings.

The microscopical examination showed treatment related effects in the low, mid and high dose groups. The forestomach of the animals of the high dose group showed some lesions such as hyperplasia, submucosal oedema and chronic ulceration. The morphology was consistent with the macroscopical findings. The lesions were in higher frequency and higher degree in males than in females.

The forestomach was evaluated as the target organ and examined in low and mid dose group and recovery groups. In the first two groups 3/10 animals showed small eosinophilic foci in the stratified epithelium of the forestomach. A small number of acute cells were observed amongst the foci.

### Remarks - Results

The effects observed in the forestomach of the rats were reported by the study authors to be a local/irritant effect

# **CONCLUSION**

The No Observed (Adverse) Effect Level (NO(A)EL) was established as 225 mg/kg bw/day in this study based on the absence of systemic effects at the highest dose tested.

TEST FACILITY Henkel (1994)

# **B.7.** Genotoxicity – bacteria

TEST SUBSTANCE Analogue A (83%)

**METHOD** OECD TG 471 Bacterial Reverse Mutation Test.

EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test

using Bacteria.

Plate incorporation procedure/Pre incubation procedure S. typhimurium: TA1535, TA1537, TA98 and TA100

Metabolic Activation System S9-mix from Aroclor 1254 or phenobarbital/β-naphthoflavone induced rat

Concentration Range in

Species/Strain

a) With metabolic activation: 1-5000 µg/plate Main Test b) Without metabolic activation: 1-5000 µg/plate

Vehicle Water

Remarks - Method There were no deviations from the study protocol. However, in test 2,

> phenobarbital/β-naphthoflavone co-induced rat liver S9 fraction was used instead of Aroclor induced S9 which was run out and the supplier had

changed the method of enzyme induction. This deviation from the study protocol did not adversely affect the evaluation of the study outcome.

The four *S. Typhimurium* strains were treated with the test substance by the Ames test plate incorporation (Test 1) as well as the preincubation method (Test 2).

# RESULTS

Metabolic	Test Substance Concentration (µg/plate) Resulting in:					
Activation	Cytotoxicity in	Cytotoxicity in	Precipitation	Genotoxic Effect		
	Preliminary Test	Main Test				
Absent						
Test 1		> 5000 (TA98,	None	Negative		
		TA100)				
		$\geq$ 1000 (TA1535)				
		$\geq$ 500 (TA1537)				
Test 2		> 5000 (TA98,	None	Negative		
		TA100)				
		> 100 (TA1535)				
		> 500 (TA1537)				
Present						
Test 1		> 5000 (TA98,	None	Negative		
		TA100)				
		$\geq$ 5000 (TA1535)				
		≥ 1600 (TA1537)				
Test 2		> 5000 (TA98,	None	Negative		
		TA100)				
		> 1000 (TA1535)				
		> 500 (TA1537)				
Remarks - Results	aminoa with ea	or bacterial strains we nthracene in DMSO). ch strain and the mean ptable range.	Solvent controls (wa	ter) were also tested		
CONCLUSION	Analog	Analogue A was not mutagenic to bacteria under the conditions of the test.				
TEST FACILITY	Hüls (1	Hüls (1996)				

# APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

# **C.1.** Environmental Fate

### C.1.1. Ready biodegradability

TEST SUBSTANCE Product containing the notified chemical (90%)

METHOD OECD TG 301 B Ready Biodegradability: CO<sub>2</sub> Evolution Test

Inoculum Activated sludge

Exposure Period 28 days Auxiliary Solvent None reported

Analytical Monitoring TOC-5000A Total Carbon Analyser

laboratory practice (GLP). No significant deviations from the test

guidelines were reported.

### **RESULTS**

Test	Test substance		nce (Sodium benzoate)
Day	% Degradation	Day	% Degradation
4	38.2	3	51.3
11	73.7	7	88.7
14	72.9	14	90.2
28	80.6	28	94.9

Remarks - Results

All validity criteria for the test were satisfied. The reference compound, sodium benzoate, reached the 60% pass level by day 11 indicating the suitability of the inoculum. The toxicity control exceeded 25% biodegradation within 14 days showing that toxicity was not a factor inhibiting the biodegradability of the test substance. The degree of degradation of the test substance after the cultivation period was 80.6% and it reached the pass level within the 10-day window. Therefore, the test substance is classified as readily biodegradable according to the OECD (301 B) guideline.

CONCLUSION The test substance is readily biodegradable

TEST FACILITY Hydrotox (2004)

# C.2. Ecotoxicological Investigations

### C.2.1. Acute toxicity to fish

TEST SUBSTANCE Product containing notified chemical (94.4%)

METHOD EEC specification 92/69/EEC and OECD TG 203: Fish, Acute Toxicity

Test – Flow-through Test

Species Brachydanio rerio

Exposure Period 96 hours
Auxiliary Solvent Not reported
Water Hardness Not reported
Analytical Monitoring MBAS-analysis

Remarks – Method The test was conducted according to the guidelines above and good

laboratory practice (GLP) principles. No significant deviations from the

test guidelines were reported.

RESULTS

Nominal Concentration	Number of Fish	Accumulative mortality (%)			
(mg/L)	-	24 h	48 h	72 h	96 h
Control	10	0	0	0	0
2.1	10	0	0	0	0
3.5	10	0	0	0	0
6.0	10	0	0	0	0
10.0	10	100	100	100	100
17.0	10	100	100	100	100

LC50

7.7 (6.0 - 10.0) mg/L at 96 hours

**NOEC** 

6.0 mg/L at 96 hours.

Remarks - Results

All validity criteria for the test were satisfied. For the analytical determinations, samples were taken repeatedly from the intake line of the test tank during the test period and were analysed. Due to the conditions of the flow-through experiment, any stability test on the test substance was not conducted. Most of the mean measured concentrations for each day did not deviate by more than 20% from the nominal concentrations. Therefore, the endpoints were calculated based on the nominal concentrations. The concentrations are based on the active substance. The 96-hour LC50 value was calculated graphically.

CONCLUSION The test substance is toxic to fish

TEST FACILITY Hüls (1999a)

# C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Product containing notified chemical (94.4%)

METHOD EEC specification 92/69/EEC (C.2.) OECD TG 202 Daphnia sp. Acute

Immobilisation Test – Static Test

Species Daphnia magna STRAUS

Exposure Period 48 hours
Auxiliary Solvent Not reported
Water Hardness Not reported

Analytical Monitoring MBAS-analysis approached to German Standard DIN-Norm 38409 H 23

laboratory practice (GLP) principles. No significant deviations from the

test guidelines were reported.

### RESULTS

Nominal Concentration	Number of D. magna	Cumulative % Immobilised	
(mg/L)		24 h	48 h
Control	20	5	5
0.4	20	0	0
0.7	20	5	30
1.2	20	5	0
2.0	20	0	0
3.5	20	0	5
6.0	20	0	0
10	20	40	100

EC50 NOEC 7.7 mg/L at 48 hours 6 mg/L at 48 hours

Remarks - Results

All validity criteria for the test were satisfied. The actual concentrations of the test substance in the treatment solutions were measured periodically at 0 and 48 hours within the 48 hours test period. The measured test concentrations after 0 and 48 hours showed that treatment concentrations during the 48 hours test period were well above 80% compared to the

nominal concentrations. Therefore, The test endpoints were calculated based on nominal concentrations. The concentrations are based on the active substance. The 48-hour EC $_{50}$  value was calculated directly from the test concentrations with 0 % and 100% inhibition by geometric mean.

CONCLUSION The test substance is toxic to aquatic invertebrates

TEST FACILITY Hüls (1999b)

# C.2.3. Algal growth inhibition test

TEST SUBSTANCE Product containing notified chemical (94.4%)

METHOD OECD TG 201 Alga, Growth Inhibition Test.

Species Pseudokirchneriella subcapitata

Exposure Period 96 hours

Concentration Range Nominal: 1, 2, 4, 8, 16, and 32 mg/L

Auxiliary Solvent Not reported Water Hardness Not reported

Analytical Monitoring MBAS-analysis approached to German Standard DIN-Norm 38409 H 23

Remarks - Method The test was conducted according to the guidelines above and good

laboratory practice (GLP) principles. No significant deviations from the

test guidelines were reported.

### RESULTS

Bioma	ss (72 h)	Growth	ı (72 h)
$E_{y}C50$	$NOE_yC$	$E_rC50$	$NOE_rC$
(mg/L)	(mg/L)	(mg/L)	(mg/L)
Not reported	Not reported	14	2

Remarks - Results

All validity criteria for the test were satisfied. The actual concentrations of the test substance in the treatment solutions were measured periodically at 0 and 72 hours within the 72-h test period. The measured test concentrations after 0 and 72 hours showed that treatment concentrations during the 72-h test period were well above 80% compared to the nominal concentrations. Therefore, The test endpoints were calculated based on nominal concentrations. The concentrations are based on the active substance. Probit analysis was used to calculate the endpoints.

CONCLUSION The test substance is toxic to algae

TEST FACILITY Hüls (1999c)

# C.2.4. Inhibition of bacterial growth

TEST SUBSTANCE Product containing notified chemical (94.4%)

METHOD German Standard DIN 38412 Part 8: Bacteriotoxicity in the

Pseudomonas cell multiplication inhibition test

Test organism Pseudomonas putida Migula

Exposure Period 16 hours

Concentration Range Nominal: 1250, 2500, 3750, 5000, 7500, 10,000 mg/L

Remarks - Method The test was conducted according to the guidelines above and good

laboratory practice (GLP) principles. No significant deviations from the

test guidelines were reported.

RESULTS

EC10 > 10,000 mg/L

EC50 > 10,000 mg/L

Remarks – Results All validity criteria for the test were satisfied. The EC50 was out of the

tested concentration range (> 10,000 mg/L).

CONCLUSION The test substance is not inhibitory to bacterial growth

TEST FACILITY Hüls (1999d)

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