

File No: STD/1615

June 2017

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME
(NICNAS)**

PUBLIC REPORT

1-Butanamine, N-butyl-N-[(triethoxysilyl)methyl]-

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:

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**Director
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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/1615	Wacker Chemie AG	1-Butanamine, <i>N</i> -butyl- <i>N</i> -[(triethoxysilyl)methyl]-	Yes	≤ 12 tonnes per annum	Component of coatings

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

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

<i>Hazard classification</i>	<i>Hazard statement</i>
Flammable liquids (Category 4)	H227 - Combustible liquid
Skin sensitisation (Category 1B)	H 317 – May cause an allergic skin reaction

Human health risk assessment

Provided that the recommended controls are being adhered to, under the conditions of the occupational settings described, the notified chemical is not considered to pose an unreasonable risk to the health of workers.

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

Environmental risk assessment

On the basis of 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:
 - Flammable liquids (Category 4): H227 – Combustible liquid
 - Skin sensitisation (Category 1): H317 – May cause an allergic skin reaction

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.

Health Surveillance

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

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following isolation and engineering controls to minimise occupational exposure to the notified chemical:
 - Enclosed and automated system during reformulation, where possible
 - Sufficient ventilation
- 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:
 - Avoid contact with skin
 - Avoid inhalation of aerosols
- 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:
 - Protective clothing
 - Impervious gloves
 - Respiratory protection during spray application

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

- Spray applications should be carried out in accordance with the Safe Work Australia Code of Practice for *Spray Painting and Powder Coating* (SWA, 2015) or relevant State or Territory Code of Practice.
- A copy of the SDS should be easily accessible to employees.
- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Globally Harmonised System 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.

Public Health

- The following measures should be taken by formulators to minimise public exposure to the notified chemical:
 - Provide safe use instructions for the use of coating products containing the notified chemical.

Disposal

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

Storage

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

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by containment, physical 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
 - further information becomes available on the repeated dose, reproductive or developmental effects of the notified chemical;or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the chemical has changed from a component of coatings, or is likely to change significantly;
 - the amount of chemical being introduced has increased, or is likely to increase, significantly;
 - the chemical has begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

Safety Data Sheet

The SDSs 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 SDSs remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Wacker Chemie AG (ABN: 11 607 113 062)
1/35 Dunlop Road
MULGRAVE VIC 3170

NOTIFICATION CATEGORY

Standard: Chemical other than polymer (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

No details are claimed exempt from publication.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed for adsorption/desorption, dissociation constant, flammability, oxidising properties, explosive properties and acute inhalation toxicity.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

Canada (2016) and New Zealand (2016)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Silan DBA-TEO
Silres BS 710 (contains $\leq 10\%$ notified chemical)

CAS NUMBER

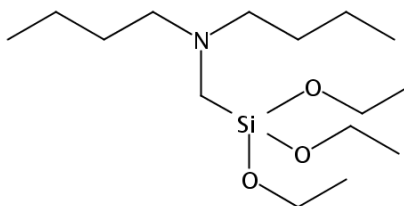
35501-23-6

CHEMICAL NAME

1-Butanamine, *N*-butyl-*N*-[(triethoxysilyl)methyl]-

MOLECULAR FORMULA

$C_{15}H_{35}NO_3Si$

STRUCTURAL FORMULA**MOLECULAR WEIGHT**

305.53 Da

ANALYTICAL DATA

Reference NMR spectra were provided.

3. COMPOSITION

DEGREE OF PURITY

> 98.7%

IMPURITIES

<i>Chemical Name</i>	1-Butanamine, <i>N</i> -butyl-		
<i>CAS No.</i>	111-92-2	<i>Weight %</i>	0.5
<i>Hazardous Properties</i>	H226 (Flammable liquid and vapour) H332 (Harmful if inhaled) H312 (Harmful in contact with skin) H302 (Harmful if swallowed)		
<i>Chemical Name</i>	Ethanol		
<i>CAS No.</i>	64-17-5	<i>Weight %</i>	0.3
<i>Hazardous Properties</i>	H225 (Highly flammable liquid and vapour) H319 (Causes serious eye irritation)		
<i>Chemical Name</i>	Bis(<i>N,N</i> -dibutylaminomethyl)-tetraethoxy disiloxane		
<i>CAS No.</i>	Unassigned	<i>Weight %</i>	0.5
<i>Hazardous Properties</i>	Unclear		

ADDITIVES/ADJUVANTS

None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: liquid

Property	Value	Data Source/Justification
Freezing Point	-132.5 °C	Measured
Boiling Point	248.2 °C at 101.3 kPa 135 °C at 101.3 kPa (decomposes with humidity)	Measured with dynamic method Measured with capillary tube method /photocell detection
Density	893 kg/m ³ at 20 °C	Measured
Vapour Pressure	7 × 10 ⁻² kPa at 100 °C 1 kPa at 130 °C 5.2 kPa at 160 °C 15.3 kPa at 190 °C 6.5 × 10 ⁻⁴ kPa at 20 °C 1.58 × 10 ⁻³ kPa at 30 °C 4.64 × 10 ⁻³ kPa at 40 °C	Measured with dynamic method Measured with effusion method
Water Solubility	Not determined	Hydrolyses rapidly in contact with water
Hydrolysis as a Function of pH	< 2 min at pH 4, 7 and 9	Measured
Partition Coefficient (<i>n</i> -octanol/water)	Not determined	Hydrolyses rapidly in contact with water
Adsorption/Desorption	Not determined	Hydrolyses rapidly in contact with water
Dissociation Constant	Not determined	Hydrolyses rapidly in contact with water
Flash Point	74.5 °C at 101.3 kPa	Measured
Flammability	Combustible liquid	Classified under GHS based on the measured flash point
Autoignition Temperature	175 °C	Measured
Viscosity	2.91 mm ² /s	Measured
Explosive Properties	Not determined	Contains no structural functionality that imply explosive properties
Oxidising Properties	Not determined	Contains no structural functionality that imply oxidising properties

DISCUSSION OF PROPERTIES

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

Reactivity

The notified chemical reacts rapidly with water (including ambient humidity) to form large polymer structures and release highly flammable ethanol.

Physical hazard classification

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

<i>Hazard classification</i>	<i>Hazard statement</i>
Flammable liquids (Category 4)	H227 - Combustible liquid

5. INTRODUCTION AND USE INFORMATION**MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS**

The notified chemical will not be manufactured in Australia. It will be imported as a component of coating formulations (at $\leq 10\%$ concentration).

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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	3	4	6	8	12

PORT OF ENTRY

Melbourne

TRANSPORTATION AND PACKAGING

The coating formulations containing the notified chemical at $\leq 10\%$ concentration will be imported and distributed in 180 L steel drums or 5 – 25 L steel pails. The formulations may be reformulated and the resulting products may be repacked.

USE

The notified chemical will be used as a component of anti-graffiti coatings for mineral building materials such as concrete, brick, limestone, plaster, as well as wood and metal. The finished coatings will contain the notified chemical at $\leq 6\%$ concentration and will be applied by brush, roller and spray.

OPERATION DESCRIPTION*Reformulation*

The imported formulation containing the notified chemical at $\leq 10\%$ concentration will be transferred to the coating mixing tank by gravity feed or low pressure pumps where it will be blended with other ingredients in the mixing tank, with local exhaust ventilation being expected. Following blending, the finished coatings will be filled into containers through gravity feed or low pressure pumps. At the end of the reformulation process the equipment will be flushed with solvent for cleaning. Quality control staff may test samples of the finished products.

End-use

The finished coatings may be manually decanted and then applied by brush, roller or airless spray. The majority of the finished coatings will be for commercial use with a small fraction will be used by do-it-yourself (DIY) users.

6. HUMAN HEALTH IMPLICATIONS**6.1. Exposure Assessment****6.1.1. Occupational Exposure****CATEGORY OF WORKERS**

<i>Category of Worker</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Transportation and storage	< 0.1	240

<i>Category of Worker</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Reformulation	7	240
Application	7	240

EXPOSURE DETAILS

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

Reformulation processes

Dermal, ocular and inhalation exposure to the notified chemical at $\leq 10\%$ concentration may occur when weighing, mixing and connecting or disconnecting transfer hoses, and during cleaning and maintenance of equipment. Exposure should be minimised through the use of enclosed and automated systems, local exhaust ventilation and personal protective equipment (PPE: goggles, impervious gloves, protective clothing and respirators as stated in the SDS provided by the notifier).

Coating application

Dermal, ocular and inhalation exposure to the notified chemical at $\leq 6\%$ concentration may occur during rolling, brushing and spraying of the finished coatings. Exposure should be minimised through the use of semi-automatic processes (applicator-operated spray guns), good general ventilation, and PPE (including goggles, impervious gloves, protective clothing and respirators as stated in the SDS provided by the notifier).

Once the coating is dried and cured, the notified chemical will be bound into an inert solid matrix and will not be available for further exposure.

6.1.2. Public Exposure

Coatings containing the notified chemical at up to 6% concentration may be applied by DIY users using brush, roller or airless spray. Similar to application workers, dermal, ocular and inhalation exposure to the notified chemical at $\leq 6\%$ concentration may occur; however it is expected to be in low frequency. It is not known whether protective equipment would be used by DIY users during coating applications. DIY users are expected to avoid coating splashes, and wash any spills from the skin.

Once the coating is dried and cured, the notified chemical will be bound into an inert solid matrix and will not be available for further exposure.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified chemical or a structurally similar chemical (Analogue 1, Morpholine, 4-[(triethoxysilyl)methyl]-, CAS No. 21743-27-1) are summarised in the following table. For full details of the studies, refer to Appendix B.

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Rat, acute oral toxicity	LD50 > 2,000 mg/kg bw; low toxicity
Rat, acute dermal toxicity	LD50 > 2,000 mg/kg bw; low toxicity*
Skin irritation (<i>in vitro</i>)	non-irritating
Rabbit, eye irritation	non-irritating
Mouse, skin sensitisation – Local lymph node assay (LLNA)	evidence of sensitisation (EC3 = 67.7%)
Rat, repeat dose oral toxicity combined with reproductive and developmental toxicity – ≤ 54 days (dose range finding)	Maternal toxicity effects observed at 1,000 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – <i>in vitro</i> chromosome aberration test	non genotoxic

* Data for Analogue 1

Toxicokinetics

The notified chemical hydrolyses rapidly in contact with water to form large polymer structures and release ethanol. When in contact with biological membranes, there is low potential for the resulting polymer to be absorbed through the membranes. However, released ethanol may rapidly be absorbed and metabolised.

Acute toxicity

The notified chemical was found to be of low toxicity via the oral route in a study conducted in rats.

Analogue 1 was found to be of low toxicity via the dermal route in a study conducted in rats. Analogue 1 contains the triethylsilyl functionality of the notified chemical; however, the morpholine group is not similar to the dibutylamino functional group in the notified chemical. There is an uncertainty as to whether the toxicity of the analogue chemical is similar to the notified chemical.

Irritation

In an *in vitro* skin irritation study conducted using the reconstructed human epidermis model (EpiSkin™), the notified chemical was determined to be non-irritating to the skin. The notified chemical was also found to be non-irritating in an eye irritation study in rabbits.

Sensitisation

The notified chemical was a skin sensitizer in mice (LLNA: stimulation indices were 1.7, 1.9 and 5.0 at 25%, 50% and 100%, respectively). The EC₃ value was calculated to be 67.7%.

Repeated dose toxicity

In a range finding study for repeated dose oral (gavage) toxicity study combined with reproduction/developmental toxicity screening test, the notified chemical was administered to rats at 100, 300 and 1,000 mg/kg bw/day.

No mortality was noted during the treatment period of the study. At dose level of 1,000 mg/kg bw/day, adverse effects observed included clinical signs of piloerection and hunched back observed during the lactation period in single female, lower body weight associated with lower food consumption, lower number of corpora lutea, lower implantation sites, lower number of live pups, higher still births and higher percent post implantation loss. There were also markedly lower pup mean weight, total litter weight, male litter weight and females litter weight in this dose group.

Only range finding study was provided. Based on the maternal toxicity observed in the study, a high dose level below 1,000 mg/kg bw/day was recommended for the main study including further dose reductions at the low and mid dose levels. However, at the time of this assessment, main study on repeated dose toxicity and reproduction/developmental toxicity has not been submitted.

Mutagenicity/Genotoxicity

The notified chemical tested negative in a bacterial reverse mutation assay and in an *in vitro* chromosomal aberration study in Chinese hamster V79 cells.

Health hazard classification

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

<i>Hazard classification</i>	<i>Hazard statement</i>
Skin Sensitisation (Category 1)	H 317 – May cause an allergic skin reaction

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

Based on the available toxicological data, the notified chemical is expected to exhibit a low acute toxicity profile, presenting only as a skin sensitizer. Adverse effects after repeated exposure remain uncertain with possible toxicity signs at high dose level.

During reformulation and applications, exposure of workers to the notified chemical is expected to be low given the use of engineering controls (such as enclosed and automated system, sufficient ventilation and spray booth) and PPE (including protective clothing, impervious gloves, safety glasses and respiratory protection). Once the coating is dried and cured, the notified chemical will be bound within an inert solid matrix and will not be bioavailable.

Under the conditions of the occupational settings and assessed use patterns, the risk to workers from use of the notified chemical is not considered to be unreasonable.

6.3.2. Public Health

The potential for dermal, ocular and inhalation exposure of DIY users to the notified chemical at up to 6% is expected when coatings are applied by brush, roller or spray. The frequency and extent of exposure of DIY users is expected to be less than that of professional users. The potential of risk to the DIY users is expected to be minimised by following safe use instructions of the coating products. Once the coating is dried and cured, the notified chemical will be bound within an inert solid matrix and will not be bioavailable.

Therefore, given the relatively low final use concentrations and low use frequency, the risk to the public from use of the notified chemical is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical will be imported into Australia and reformulated into final products locally. During reformulation, the notified chemical will be blended with other ingredients in a sealed mixing tank. Therefore, significant release of the notified chemical from this process is not expected. Equipment used in reformulation will be cleaned with solvent and no release of the notified chemical to water system is expected from equipment cleaning. Drums containing notified chemical residues are expected to be disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

The notified chemical will be used as a component of coatings for building material such as concrete, brick, limestone, plaster, wood and metal. The coating products containing the notified polymer are expected to be used by both professionals and DIY users. All users are expected to apply coatings with brushes, rollers and airless spray.

Significant release of the notified chemical is not expected when the coating products are applied to substrates by brush or rollers. Overspray may occur at the construction sites during spray applications. However, the notified chemical rapidly reacts with water and is expected to form a three-dimensional polymeric structure and be cured into the matrix of the coating. This reaction is irreversible and is expected to consume the majority of the notified chemical from the overspray. Therefore, no significant environmental release is expected from the use of products containing the notified chemical.

RELEASE OF CHEMICAL FROM DISPOSAL

The majority of the notified chemical is expected to be disposed of to landfill along with the substrates at the end of their useful life. In landfill, the notified chemical is expected to remain associated with the substrates to which it has been applied.

Empty containers containing residues of the notified chemical will be completely emptied and thoroughly cleaned with solvent before being sent to an approved recycling facility. Product residues (formulations containing less than 10% of the notified substance) will be left to cure and then be disposed of with the usual solid waste streams, typically to landfill.

7.1.2. Environmental Fate

The notified chemical is not readily biodegradable (41% in 28 days) but is likely to be inherently biodegradable as a plateau of the biodegradation curve was not reached after 28 days in the biodegradability study. For the details of the environmental fate studies please refer to Appendix C.

The majority of the notified chemical is expected to share the fate of substrates to which it applied, to be disposed of to landfill or subject for metal remediation at the end of their useful life. In landfill, the notified chemical bound to coated articles is not expected to be bioavailable nor bioaccumulative. The notified chemical is not expected to bioaccumulate either even in its free form due to the rapid hydrolysis in water.

Aquatic exposure to the notified chemical is not expected when it is used as proposed in coating products. If the coating products are washed to water, for example following spills or cleaning of residues from application equipment, the notified chemical will degrade rapidly because of its hydrolytic instability (hydrolysis half lives < 2 minutes at pH 4, 7 and 9 at 25 °C).

The notified chemical is expected to eventually degrade via biotic or abiotic process to form water, oxides of carbon, nitrogen and silicon.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) is not calculated because significant aquatic exposure of the notified chemical is not expected when it is used as proposed in coating products.

7.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on the notified chemical and Analogue 1 are summarised in the table below. Details of these studies can be found in Appendix C.

Analogue 1 contains the triethylsilyl functionality of the notified chemical; however, the morpholine group is not similar to the dibutylamino functional group in the notified chemical. Therefore, it is highly uncertain as to whether the ecotoxicity effects of the analogue chemical is similar to the notified chemical.

<i>Endpoint</i>	<i>Result</i>	<i>Assessment Conclusion</i>
Fish Toxicity (analogue)	96 h LC50 > 97.5 mg/L	Not harmful to fish
Daphnia Toxicity (notified chemical)	48 h EC50 > 4.0 mg/L	Not toxic to aquatic invertebrates up to the water solubility
Algal Toxicity (notified chemical)	72 h EC50 > 4.0 mg/L	Not toxic to algae up to the water solubility

The results above were based on nominal concentration without identifying the test substance or its hydrolysis products. Ecotoxicity data in the table demonstrate that the hydrolysis products of the notified chemical had no toxic effects to aquatic organisms given the notified chemical readily hydrolyses in water.

Noting that the above toxic effects do not apply to the notified chemical itself, the notified chemical has not been formally classified for acute and chronic toxicities under the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS; United Nations, 2009).

7.2.1. Predicted No-Effect Concentration

The Predicted No-Effects Concentration (PNEC) is not calculated because significant aquatic exposure to the notified chemical is not expected. Moreover, the notified chemical readily hydrolyses in water.

7.3. Environmental Risk Assessment

It is neither necessary nor meaningful to estimate the PEC/PNEC ratio as the notified chemical is not expected to enter aquatic environments and will hydrolyse rapidly in water if it did.

On the basis of the hydrolytic instability of the notified chemical and the assessed use pattern, the notified chemical is not considered to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES**Freezing Point** -132.5 °C

Method EC Council Regulation No 440/2008 A.1 Melting/Freezing Temperature.
 Remarks Differential scanning calorimetry method
 Test Facility Wacker (2014)

Boiling Point 248.2 °C at 101.3 kPa

Method OECD TG 103 Boiling Point.
 EC Council Regulation No 440/2008 A.2 Boiling Temperature.
 Remarks Dynamic method
 Test Facility Wacker (2014)

Boiling Point 135 °C at 101.3 kPa (decomposes with humidity)

Method OECD TG 103 Boiling Point.
 EC Council Regulation No 440/2008 A.2 Boiling Temperature.
 Remarks Capillary tube method/photocell detection
 Test Facility Wacker (2014)

Density 893 kg/m³ at 20 °C

Method OECD TG 109 Density of Liquids and Solids.
 EC Council Regulation No 440/2008 A.3 Relative Density.
 Remarks Apparatus: PAAR DMA 4500
 Test Facility Wacker (2014)

Vapour Pressure 7 × 10⁻² kPa at 100 °C
1 kPa at 130 °C
5.2 kPa at 160 °C
15.3 kPa at 190 °C

Method OECD TG 104 Vapour Pressure.
 EC Council Regulation No 440/2008 A.4 Vapour Pressure.
 Remarks Dynamic method. The vapour pressure was extrapolated from the boiling temperature/vapour pressure relationship which could not provide reliable extrapolation of the vapour pressure to lower temperatures (below 50 °C).
 Test Facility Wacker (2014)

Vapour Pressure 6.5 × 10⁻⁴ kPa at 20 °C
1.58 × 10⁻³ kPa at 30 °C
4.64 × 10⁻³ kPa at 40 °C

Method OECD TG 104 Vapour Pressure.
 EC Council Regulation No 440/2008 A.4 Vapour Pressure.
 Remarks Effusion method was selected for valid data points in the range between 20 and 50 °C.
 Test Facility Wacker (2014)

Hydrolysis as a Function of pH

Method OECD TG 111 Hydrolysis as a Function of pH.
 EC Council Regulation No 440/2008 C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH.

<i>pH</i>	<i>T</i> (°C)	<i>t</i> _{1/2} (Minutes)
4	25	< 2
7	25	< 2
9	25	< 2

Remarks Because hydrolysis was finished after the first ^1H NMR measurement (about 2 minutes after mixing the test sample) no exact half-life time or reaction rate could be calculated.

Test Facility Wacker (2014)

Flash Point 74.5 °C at 101.3 kPa

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

Remarks Closed cup method

Test Facility Wacker (2014)

Autoignition Temperature 175 °C

Method EC Council Regulation No 440/2008 A.15 Auto-Ignition Temperature (Liquids and Gases).

Remarks The test resulting value was rounded to the next integral number.

Test Facility Wacker (2014)

Viscosity 2.91 mm²/s at 20 °C

Method DIN 51562

Remarks Determined by Ubbelohde viscosimeter

Test Facility Wacker (2014)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS**B.1. Acute toxicity – oral**

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/Wistar CrI: WI(Han)
Vehicle	Cotton seed oil
Remarks - Method	No significant protocol deviations

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
1	3F	2,000	0/3
2	3F	2,000	0/3

LD50	> 2,000 mg/kg bw
Signs of Toxicity	There were no test substance-related signs of toxicity.
Effects in Organs	No macroscopic findings were noted at necropsy.
Remarks - Results	The body weight gain of the animals was within the range commonly recorded for this strain and age.

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

TEST FACILITY BSL (2014a)

B.2. Acute toxicity – dermal

TEST SUBSTANCE	Analogue 1 (morpholine, 4-[(triethoxysilyl)methyl]-, CAS No. 21743-27-1)
METHOD	OECD TG 402 Acute Dermal Toxicity – Limit Test.
Species/Strain	Rat/HsdRccHan: WIST
Vehicle	None
Type of dressing	Occlusive
Remarks - Method	No significant protocol deviations

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
1	5 per sex	2,000	0/10

LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	There were no clinical signs of local toxicity.
Signs of Toxicity - Systemic	There were no clinical signs of local toxicity.
Effects in Organs	No abnormalities were noted at necropsy.
Remarks - Results	The body weight gain of the animals was within the range commonly recorded for this strain and age.

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

TEST FACILITY BSL (2007)

B.3. Irritation – skin (*in vitro*)

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 439 In vitro Skin Irritation: Reconstructed Human <i>Epidermis</i> Test Method EPISKIN-SM™ Reconstructed 3D Human Epidermis Model
Vehicle	None
Remarks - Method	The test substance (10 µL) was applied to the tissues in triplicate. Following exposure period of 15 minutes (at room temperature), the tissues were rinsed, treated with MTT [3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazolium bromide] and then incubated at 37 °C for 3 hours. In a preliminary test the test substance was shown not to directly reduce MTT. Positive and negative controls were run in parallel with the test substance: <ul style="list-style-type: none"> - Negative control (NC): phosphate buffered saline - Positive control (PC): 5% sodium dodecyl sulphate in distilled water

RESULTS

<i>Test material</i>	<i>Mean OD₅₅₀ of triplicate tissues</i>	<i>Relative mean Viability (%)</i>	<i>SD of relative mean viability</i>
<i>Negative control</i>	0.892	100	5.8
<i>Test substance</i>	1.099	123.1	3.4
<i>Positive control</i>	0.048	5.4	0.6

OD = optical density; SD = standard deviation

Remarks - Results	The test substance showed no irritation effects (the mean relative tissue viability was > 50%). The positive and negative controls gave satisfactory results, confirming the validities of the test systems.
CONCLUSION	The notified chemical was non-irritating to the skin under the conditions of the test.
TEST FACILITY	BSL (2014b)

B.4. Irritation – eye

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	3F
Observation Period	72 hours
Remarks - Method	No significant protocol deviations

RESULTS

Remarks - Results	There were no mortality or clinical signs of systemic toxicity or signs of irritation. Irritation scores were zero at all observation periods.
CONCLUSION	The notified chemical is non-irritating to the eye.
TEST FACILITY	BSL (2015a)

B.5. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 429 Skin Sensitisation: Local Lymph Node Assay
Species/Strain	Mouse/ CBA/Ca
Vehicle	Acetone/olive oil (4:1)
Preliminary study	Yes
Positive control	Not conducted in parallel with the test substance, but had been conducted previously in the test laboratory using p-phenylenediamine.
Remarks - Method	No significant protocol deviations

RESULTS

Concentration (% w/w)	Number and sex of animals	Proliferative response (DPM/lymph node)	Stimulation Index (Test/Control Ratio)
<i>Test Substance</i>			
0 (vehicle control)	5F	665 ± 161	-
25%	5F	1115 ± 142	1.7
50%	5F	1295 ± 327	1.9
100%	5F	3304 ± 727	5.0

EC3
Remarks - Results

67.7%

In the preliminary study, there were no signs of systemic toxicity or erythema formation noted (the latter was indicated by $\leq 20\%$ increase in mean ear thickness).

In the main study, there were no mortality or signs of systemic toxicity observed in the test or control animals. Sticky fur, hair loss and bald skin were noted for the animals treated at 100% concentration.

The auricular lymph nodes of the animals in control and 25% and 50% concentration groups were considered normal in size while the nodes of the animals in 100% concentration groups were considered enlarged. No macroscopic abnormalities of the surrounding area were noted for any animals.

The test substance elicited a $SI \geq 3$ and is therefore considered a skin sensitiser.

All treated animals showed expected body weight gain.

CONCLUSION

There was evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical.

TEST FACILITY

BSL (2015b)

B.6. Dose Range Finding for Repeated dose toxicity combined with reproduction/developmental toxicity screening

TEST SUBSTANCE	Notified chemical
METHOD	Dose range finding study for OECD TG 422 Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test.
Species/Strain	Rat/Wistar, Crl:WI(Han)
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: - minimum 28 days for male animals: 14 days of pre-mating,

	maximum 14 days of mating, post-mating until minimum 28 days completed
	- up to 54 days for female animals: 14 days prior to mating, maximum 14 days of mating, gestation period, up to post-natal day 3
Vehicle	Dose regimen: 7 days per week
Remarks - Method	Post-exposure observation period: None
	Corn oil
	Dose range finding study for repeated dose toxicity study combined with reproduction/developmental toxicity screening test.

RESULTS

Group	Number and Sex of Animals	Dose mg/kg bw/day	Mortality
control	3 per sex	0	0/6
low dose	3 per sex	100	0/6
mid dose	3 per sex	300	0/6
high dose	3 per sex	1,000	0/6

Mortality and Time to Death

There were no unscheduled deaths.

Clinical Observations

In the high dose group, nasal discharge (1/3 males), moving the bedding (3/3 males, 3/3 females), slight salivation (3/3 males, 3/3 females), moderate salivation (3/3 males, 2/3 females), alopecia (1/3 females), slight piloerection (3/3 females), moderate piloerection (1/3 females) and hunched posture (1/3 females) were noted. In the mid dose group, nasal discharge (1/3 males), moving the bedding (1/3 males, 2/3 females) and alopecia (1/3 females) were noted. In the low dose group, nasal discharge (1/3 males) was noted. There were no clinical signs in the control group and in female animals of the low dose group.

Piloerection and hunched back noted during the lactation period in a single female of the high dose group was considered by the study authors to be adverse as the clinical signs would be associated with the probable complication during the parturition considering longer gestation period for this animal compared to the others. The clinical signs in the mid and low dose groups were not considered by the study authors to be adverse as they were noted on a single occasion (nasal discharge, alopecia) or were considered to be local signs (moving the bedding, salivation).

In the high dose group, female animals showed significantly lower body weight during the late gestation and lactation period, accompanying with lower food intake. These effects were considered by the study authors to be adverse.

Effects in Organs

There were no macroscopic findings at necropsy. There were no adverse effects on the organ weights of the treated animals compared to the control.

Reproductive performance and clinical examinations in F1 pups

In the high dose group, there were lower number of corpora lutea, lower implantation sites, lower number of live pups, higher still births and higher percent post implantation loss. There were also significantly lower pup mean weight, total litter weight and male/female litter weight on post natal day (PND) 0 and PND 4 compared to the control, indicating effects on growth of pups from PND 0 to PND 4. These effects were considered by the study authors to be adverse.

In the high dose group, the precoital interval and gestation duration were slightly longer, which was considered by the study authors to be test substance-related but not adverse.

There were no effects on copulation index, fertility index and delivery index. The viability index in the high dose group was affected by the mortality of a pup and not considered by the study authors to be treatment-related. Higher mean pup mortality in the high dose group was not considered by the study authors to be treatment-related as it was only due to the mortality of 1 pup out of 9 pups.

Remarks – Results

Effects on litter data were considered by the study authors to be secondary to the maternal toxicity.

CONCLUSION

Based on the maternal toxicity observed in the study, a high dose level below 1,000 mg/kg bw/day was recommended for the main study including further dose reductions at the low and mid dose levels. The main study is desirable for establishing a No Observed Adverse Effect Level (NOAEL) for the notified chemical.

TEST FACILITY BSL (2016)

B.7. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical

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, TA102
Metabolic Activation System S9 mix from β -naphthoflavone/phenobarbital induced rat liver
Concentration Range in Main Test a) With metabolic activation: 0.00316-5 μ L/plate
b) Without metabolic activation: 0.00316-5 μ L/plate
Vehicle Dimethyl sulfoxide
Remarks - Method A dose range-finding study was carried out at 0.00316-5 μ L/plate. The dose selection for the main tests was based on toxicity observed in the range-finding study.

Positive controls:
With metabolic activation: 2-aminoanthracene
Without metabolic activation: sodium azide (TA1535, TA100); 4-nitro-o-phenylene-diamine (TA1537, TA98); methyl methanesulfonate (TA102)

RESULTS

Metabolic Activation	Test Substance Concentration (μ L/plate) Resulting in:			
	Cytotoxicity in Preliminary Test	Cytotoxicity in Main Test	Precipitation	Genotoxic Effect
<i>Absent</i>				
Test 1	> 5	> 5	> 5	negative
Test 2		\geq 5	> 5	negative
<i>Present</i>				
Test 1	> 5	> 5	> 5	negative
Test 2		> 5	> 5	negative

Remarks - Results No significant increases in the frequency of revertant colonies were observed for any of the bacterial strains, with any dose of the test substance, either with or without metabolic activation.

The positive and negative controls gave a satisfactory response confirming the validity of the test system.

CONCLUSION

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

TEST FACILITY BSL (2014c)

B.8. Genotoxicity – in vitro

TEST SUBSTANCE Notified chemical

METHOD OECD TG 473 *In vitro* Mammalian Chromosome Aberration Test.

Species/Strain	Chinese hamster
Cell Type/Cell Line	V79
Metabolic Activation System	S9 mix from β -naphthoflavone/phenobarbital induced rat liver
Vehicle	Tetrahydrofuran
Remarks - Method	A dose range-finding study was carried out at 7.8 – 2000 $\mu\text{g/mL}$. The dose selection for the main experiments was based on toxicity observed in the range-finding study and solubility test.
	Vehicle and positive controls (ethyl methanesulfonate and cyclophosphamide) were run concurrently with the notified chemical.

<i>Metabolic Activation</i>	<i>Test Substance Concentration ($\mu\text{g/mL}$)</i>	<i>Exposure Period</i>	<i>Harvest Time</i>
<i>Absent</i>			
Test 1	2, 5, 10, 25, 50*, 100*, 250*	4 h	21 h
Test 2	10, 25, 50*, 100*, 250*, 500	21 h	21 h
<i>Present</i>			
Test 1	5, 10, 20, 50, 100*, 200*, 500*, 1000	4 h	21 h

*Cultures selected for metaphase analysis.

RESULTS

<i>Metabolic Activation</i>	<i>Test Substance Concentration ($\mu\text{g/mL}$) Resulting in:</i>			
	<i>Cytotoxicity in Preliminary Test</i>	<i>Cytotoxicity in Main Test</i>	<i>Precipitation</i>	<i>Genotoxic Effect</i>
<i>Absent</i>				
Test 1	≥ 500	> 250	≥ 250	negative
Test 2		≥ 250	≥ 250	negative
<i>Present</i>				
Test 1	> 2000	> 1000	≥ 500	negative

Remarks - Results In the main tests, no statistically significant increases in the frequency of cells with structural or numerical chromosome aberrations were noted in the presence or absence of metabolic activation.

The results of the positive controls confirmed the validity of the test system.

CONCLUSION The notified chemical was not clastogenic to Chinese hamster V79 cells treated *in vitro* under the conditions of the test.

TEST FACILITY Eurofins (2016)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 F Ready Biodegradability: Manometric Respirometry Test.
Inoculum	Activated sludge
Exposure Period	28 days
Auxiliary Solvent	No
Analytical Monitoring	Electro-chemical analysis of CO ₂ produced during biodegradation
Remarks - Method	The test was conducted according to test guideline without significant deviation from the protocol.

RESULTS

<i>Test substance</i>		<i>Sodium benzoate</i>	
<i>Day</i>	<i>% Degradation</i>	<i>Day</i>	<i>% Degradation</i>
7	24	7	74
14	32	14	82
21	37	21	85
28	41	28	87

Remarks - Results

All validity criteria for the test are satisfied.

The test substance is not considered to be readily biodegradable because the biodegradation did not pass the 10-day window for ready biodegradability.

The mean biodegradation of the test substance was 41% and a plateau of the biodegradation curve was not reached after 28 days. The results can be considered as an evidence for inherent biodegradation.

Biodegradation in the toxicity control was greater than the threshold of > 25% within 14 days (57%) and therefore, the test substance had no inhibitory effects on microorganism activity at the tested concentration.

CONCLUSION

The notified chemical is not considered to be readily biodegradable.

TEST FACILITY

Harlan (2014)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Analogue chemical (morpholine, 4-[(triethoxysilyl)methyl]-, CAS No. 21743-27-1)
METHOD	OECD TG 203 Fish, Acute Toxicity Test - Static
Species	Rainbow trout (<i>Oncorhynchus mykiss</i>)
Exposure Period	96 hours
Auxiliary Solvent	No
Water Hardness	250 mg CaCO ₃ /L
Analytical Monitoring	Total organic carbon
Remarks – Method	Fish were exposed to hydrolysis products, as the test substance hydrolyses spontaneously in water to form siloxanes, and was introduced into the test medium 24 hours before the fish. The analytic method is nonspecific. A limit test only was conducted, at a nominal 110 mg/L (mean measured

concentration 95.7 mg/L). The analysis of the test substance in the test solution was performed by determination of the total organic carbon.

RESULTS

Concentration mg/L		Number of Fish	Mortality			
Nominal	Actual		24 h	48 h	72 h	96 h
Control	-	7	0	0	0	0
110	95.7	7	0	0	0	0

LC50 > 95.7mg/L at 96 hours.

NOEC ≥ 95.7 mg/L at 96 hours.

Remarks – Results No mortalities occurred. One fish in the test vessel showed symptoms of intoxication (apathy) after 96 hours.

CONCLUSION Hydrolysis products of the analogue are not considered to be harmful to fish

TEST FACILITY IBACON (2005)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified chemical

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

Species *Daphnia magna*

Exposure Period 48 hours

Auxiliary Solvent Tetrahydrofuran

Water Hardness 250 mg CaCO₃/L

Analytical Monitoring No

Remarks - Method The test substance hydrolysed rapidly in the test solutions. A measurement of total organic carbon was not reasonable due to the low test item concentrations and the use of the solvent tetrahydrofuran. Therefore, the analysis of the test concentration in the test solutions was not conducted.

RESULTS

Concentration mg/L		Number of <i>D. magna</i>	Number Immobilised	
Nominal	Actual		24 h	48 h
Control	-	20	0	0
Solvent control	-	20	0	0
0.25		20	0	0
0.5		20	0	0
1.0	Not determined	20	0	0
2.0		20	0	0
4.0		20	0	0

EC50 > 4.0 mg/L at 48 hours

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

Based on visual inspection of the test media, the solubility limit to achieve stable solutions of the test substance or its hydrolysis product was considered to be below 4.0 mg/L. No acute toxic effects was observed up to this maximum technically feasible concentration, 4.0 mg/L, of the test substance or its hydrolysis products in test water under the test conditions.

CONCLUSION Hydrolysis products of the notified chemical are not expected to be toxic to aquatic invertebrates up to the maximum technically feasible concentration

TEST FACILITY Harlan (2015a)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified chemical

METHOD OECD TG 201 Alga, Growth Inhibition Test.

Species *Pseudokirchneriella subcapitata*

Exposure Period 72 hours

Concentration Range Nominal: Control, solvent control, 0.13, 0.25, 0.5, 1.0, 2.0 and 4.0 mg/L

Actual: Not determined

Auxiliary Solvent Tetrahydrofuran

Water Hardness 15 mg CaCO₃/L

Analytical Monitoring No

Remarks - Method The test substance hydrolysed rapidly in the test solutions. A measurement of total organic carbon was not reasonable due to the low test item concentrations and the use of the solvent tetrahydrofuran. Therefore, the analysis of the test concentration in the test solutions was not conducted.

RESULTS

<i>Growth</i>	
<i>EC50</i> mg/L at 72 h	<i>NOEC</i> mg/L at 72 h
> 4.0	> 4.0

Remarks - Results

The validity criteria for the test are satisfied.

Based on visual inspection of the test media, the solubility limit to achieve stable solutions of the test substance or its hydrolysis product was considered to be below 4.0 mg/L. No acute toxic effects was observed up to this maximum technically feasible concentration, 4.0 mg/L, of the test substance or its hydrolysis products in test water under the test conditions.

CONCLUSION

Hydrolysis products of the notified chemical are not expected to be toxic to aquatic invertebrates up to the maximum technically feasible concentration

TEST FACILITY

Harlan (2015b)

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