

File No: STD/1434

March 2013

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

PUBLIC REPORT

1*H*-Imidazolium, 3-ethyl-1-methyl-, ethyl sulfate (1:1)

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health and Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of Sustainability, Environment, Water, Population and Communities.

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:

Street Address:	Level 7, 260 Elizabeth Street, SURRY HILLS NSW 2010, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

**Director
NICNAS**

TABLE OF CONTENTS

SUMMARY	3
CONCLUSIONS AND REGULATORY OBLIGATIONS	3
ASSESSMENT DETAILS	5
1. APPLICANT AND NOTIFICATION DETAILS	5
2. IDENTITY OF CHEMICAL.....	5
3. COMPOSITION.....	5
4. PHYSICAL AND CHEMICAL PROPERTIES	6
5. INTRODUCTION AND USE INFORMATION	6
6. HUMAN HEALTH IMPLICATIONS	7
6.1. Exposure Assessment.....	7
6.1.1. Occupational Exposure.....	7
6.1.2. Public Exposure.....	7
6.2. Human Health Effects Assessment	8
6.3. Human Health Risk Characterisation	9
6.3.1. Occupational Health and Safety	9
6.3.2. Public Health	9
7. ENVIRONMENTAL IMPLICATIONS.....	9
7.1. Environmental Exposure & Fate Assessment	9
7.1.1. Environmental Exposure	9
7.1.2. Environmental Fate	10
7.1.3. Predicted Environmental Concentration (PEC).....	10
7.2. Environmental Effects Assessment.....	10
7.2.1. Predicted No-Effect Concentration	11
7.3. Environmental Risk Assessment	11
<u>APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES</u>	<u>12</u>
<u>APPENDIX B: TOXICOLOGICAL INVESTIGATIONS</u>	<u>14</u>
B.1. Acute toxicity – oral.....	14
B.2. Acute toxicity – dermal	14
B.3. Irritation – skin.....	15
B.4. Irritation – eye	15
B.5. Skin sensitisation – mouse local lymph node assay (LLNA)	16
B.6. Repeat dose toxicity – 28 day oral	16
B.7. Repeat dose toxicity – 90 day oral (detailed summary only provided)	17
B.8. Genotoxicity – bacteria	18
B.9. Genotoxicity – in vitro	18
B.10. Genotoxicity – in vivo.....	19
B.11. Developmental toxicity	20
<u>APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS</u>	<u>21</u>
C.1. Environmental Fate	21
C.1.1. Ready biodegradability.....	21
C.1.2. Inherent biodegradability.....	21
C.2. Ecotoxicological Investigations	22
C.2.1. Acute toxicity to fish	22
C.2.2. Chronic toxicity to fish.....	22
C.2.3. Acute toxicity to aquatic invertebrates	23
C.2.4. Chronic toxicity to aquatic invertebrates	23
C.2.5. Algal growth inhibition test.....	24
C.2.6. Inhibition of microbial activity.....	24
BIBLIOGRAPHY	26

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/1434	BASF Australia Pty Ltd	1H-Imidazolium, 3-ethyl-1-methyl-, ethyl sulfate (1:1)	No	≤50 tonne/s per annum	Component of polyurethane articles

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available information, the notified chemical is not recommended for classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

Human health risk assessment

Under the conditions of the occupational settings described, the notified 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

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 as introduced:
 - Use closed system processes and/or local exhaust ventilation during polyurethane manufacture and where mists or aerosols are expected to be generated.
- 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 as introduced:
 - Coveralls
 - Goggles
 - Impervious gloves

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(2) of the Act; if
 - the function or use of the chemical has changed from a component of polyurethane articles, or is likely to change significantly;
 - the amount of chemical being introduced has increased from 50 tonnes per annum, or is likely to increase, significantly;
 - the chemical has begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

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

No additional secondary notification conditions are stipulated.

(Material) Safety Data Sheet

The (M)SDS of the notified chemical provided by the notifier was reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

BASF Australia Pty Ltd (ABN: 62 008 437 867)
Level 12, 28 Freshwater Place
SOUTHBANK VIC 3006

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: Other names, analytical data, degree of purity, polymer constituents, residual monomers, impurities, additives/adjuvants, use details, import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows: adsorption/desorption, dissociation constant and acute inhalation toxicity.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

Canada (2011)
EU (2006)
Korea (2012)
USA (2010)

2. IDENTITY OF CHEMICAL

CHEMICAL NAME

1*H*-Imidazolium, 3-ethyl-1-methyl-, ethyl sulfate (1:1)

MARKETING NAME(S)

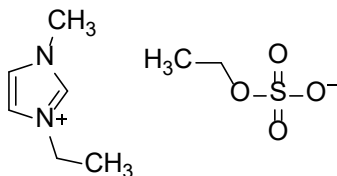
Basionics LQ 01

CAS NUMBER

342573-75-5

MOLECULAR FORMULA

C₈ H₁₆ O₄ N₂ S

STRUCTURAL FORMULA**MOLECULAR WEIGHT**

236.29 Da

ANALYTICAL DATA

Reference NMR, IR, UV and HPLC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY >90%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: A clear, viscous, light yellow liquid.

Property	Value	Data Source/Justification
Melting Point	<-30 °C	(M)SDS
Boiling Point	>325 °C at 101.3 kPa	Measured. Some decomposition observed >145 °C.
Density	1.2391 kg/m ³	Measured
Vapour Pressure	<1 × 10 ⁻⁷ kPa	Measured
Water Solubility	Miscible at 20 °C	Measured
Hydrolysis as a Function of pH	t _{1/2} > 1 year at 25 °C	Measured
Partition Coefficient (n-octanol/water)	log Pow = -2.6 to -3.1 at 23 °C	Measured
Adsorption/Desorption	Not determined	The notified chemical is expected to be mobile in soils and sediments based on its water solubility.
Dissociation Constant	Not determined	Expected to be ionised in environmental pH (4-9) as the notified chemical is a salt.
Flash Point	176 °C	Measured
Flammability (contact with water)	Not flammable	Measured
Autoignition Temperature	405 °C	Measured
Explosive Properties	Not explosive	Not expected to be an explosophore, on the basis of structure and DSC results.
Oxidising Properties	Not oxidising	Measured

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 to Australia by sea.

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

Year	1	2	3	4	5
Tonnes	10-20	10-20	10-50	10-50	10-50

PORT OF ENTRY

Melbourne, Sydney, Brisbane, Perth, Adelaide and Hobart

IDENTITY OF MANUFACTURER/RECIPIENTS

BASF Australia Pty Ltd

TRANSPORTATION AND PACKAGING

Imported in small packages (<1 L), 10 L, 50 L, 100 L, 200 L and 1000 L intermediate bulk containers. Within Australia it will be transported by road.

USE

Component in the manufacture of industrial polyurethane articles (examples include conveyor scrapers, skirt rubbers and belt splicing) for use in underground coal mines.

OPERATION DESCRIPTION*Reformulation*

At the reformulation site, the notified chemical will be decanted into an enclosed mixing tank (up to 10,000 L) and blended with other liquid additives. Blending of additives can include high speed dispersion. The formulated product (20-30% concentration of the notified chemical) will be decanted into pails (1 kg, 4 kg, or 20 kg), for use in the manufacture of industrial polyurethane articles.

Manufacture of articles

At the polyurethane manufacturing site, the formulated product or the notified chemical itself will be added to polyurethane pre-polymers by machine or drill prior to manufacture of the industrial articles. The concentration of the notified chemical in end-use articles will be 4-6%.

End-use

Articles containing the notified chemical will be used as part of equipment in underground coal mines.

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>
Transport and Storage (3-10 people)	6-8	12-15
Blender (1-5 people)	6-8	125-225
QA Analysis (1-2 people)	6-8	125-225
End-users (>10,000 people)	10-30 min	200

EXPOSURE DETAILS

Workers involved with transport and storage may come into dermal and ocular contact with the notified chemical in the event of an accident.

Blending workers at the reformulation site or the polyurethane manufacturing site may experience dermal and ocular exposure to the notified chemical during transfer from import containers to tanks, charging of the mixer or during filling of pails. QA workers may experience dermal and ocular exposure to the notified chemical during sampling and analysis of the notified chemical as imported and during blending processes. The potential for exposure will be greatest where these processes are not carried out in automated and closed systems.

Inhalation exposure to the notified polymer is not expected to be significant due to its low vapour pressure ($<1 \times 10^{-7}$ kPa). However, volatility may be higher during polyurethane manufacture, where high temperatures are generated. Ventilation controls to minimise inhalation exposure to the notified chemical are expected to be diverse depending on the articles to be manufactured and the equipment used at the reformulation and polyurethane manufacturing sites. Engineering controls may include closed system processes, vacuum extraction and fan forced ventilation.

Once moulded into polyurethane components, the notified chemical will be incorporated in a polymer matrix (although not chemically bound) and is not expected to be bioavailable.

6.1.2. Public Exposure

The notified chemical as imported is intended for use in industrial settings and will not be sold to the public. Articles containing the notified chemical will not be sold to the public; therefore, it is not expected that the public will come into contact with them. Furthermore, within articles the notified chemical will be incorporated into the polyurethane matrix and is not expected to be bioavailable.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified chemical 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
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	non-irritating
Mouse, skin sensitisation – Local lymph node assay	no evidence of sensitisation
Rat, repeat dose (oral gavage) toxicity – 28 days.	NOAEL 1,000 mg/kg/bw day
Rat, repeat dose (oral gavage) toxicity – 90 days.	NOAEL 1,000 mg/kg/bw day
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro (chromosome aberration)	non genotoxic
Genotoxicity – in vivo (mouse micronucleus)	non genotoxic
Rat, developmental toxicity	NOAEL 1,000 mg/kg/bw day

Toxicokinetics, metabolism and distribution.

No data were available to assess toxicokinetics, metabolism and distribution of the notified chemical. Dermal absorption is expected to be low as the notified chemical is an aprotic molten salt.

Acute toxicity.

The acute oral LD50 and acute dermal LD50 were >2,000 mg/kg bw in rats for the notified chemical; it was considered to be of low toxicity. Acute inhalation studies were not submitted on the notified chemical; however, exposure via this route is not expected, given the low vapour pressure of the notified chemical.

Irritation and sensitisation.

In skin irritation and eye irritation studies in rabbits, the notified chemical was non-irritating to the skin and only slightly irritating to the eyes. It was not a skin sensitiser in a local lymph node assay (LLNA).

Repeated Dose Toxicity.

In separate 28-day and 90-day repeat dose gavage studies in rats the NOAEL for repeated dose effects was established at 1,000 mg/kg bw/day. (For the 90-day study, a detailed summary only was available.)

Mutagenicity/Genotoxicity.

The notified chemical was non mutagenic in a bacterial reverse mutation test. There was no evidence of clastogenicity in an *in vitro* mammalian chromosome aberration test in cultured human lymphocytes or in an *in vivo* mouse micronucleus test in bone marrow cells of NMRI mice. Based on these studies, the notified chemical is not expected to be genotoxic.

Toxicity for reproduction.

During a developmental toxicity study in rats, no adverse outcomes were noted in dams, fetuses or gestational parameters. A statistically significant increase in one variety of foetal skeletal variation was seen at the high dose, however the incidence was within the historical controls for this variation. A NOAEL of 1,000 mg/kg bw/day was determined.

Health hazard classification

Based on the available information, the notified chemical is not recommended for classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

Based on the toxicity data provided the notified chemical is of low toxicity via the dermal and oral routes and is not considered a skin sensitiser. Workers with potential for exposure to the notified chemical include transportation and warehouse workers, those involved in blending and QA tasks. The potential for exposure is greatest during blending of the notified chemical into formulated products and during polyurethane manufacture.

Potential dermal and ocular exposure would be minimised by use of personal protective equipment (PPE) such as protective coveralls, goggles and impervious gloves when handling products containing the notified chemical. Exposure to mists or aerosols is not expected; however, if generated, would be controlled by use of local exhaust ventilation or similar engineering controls.

Once incorporated within the polyurethane matrix as articles, the notified polymer is not expected to be bioavailable.

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

6.3.2. Public Health

The notified chemical as imported and articles containing the notified chemical will not be sold to the public. The public is not expected to come into contact with the manufactured articles. Furthermore, the notified chemical will be incorporated within the polyurethane matrix and is not expected to be bioavailable. Therefore the risk to the health of the public is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical will not be manufactured in Australia. Therefore no release to the environment is expected from this activity. Releases to the environment may occur following accidental spills during import, transport or storage. Any notified chemical that is spilled is expected to be adsorbed onto a suitable material and collected for disposal in accordance with local regulations.

The notified chemical may enter wastewater streams during reformulation. Up to 0.01% of the notified chemical is estimated to be released as a result of rinsing empty import containers via drum recyclers and up to 0.01% is expected to be released to wastewater due to equipment cleaning activities. Therefore, up to 10 kg of the notified chemical per year is estimated to be released in aqueous waste streams due to reformulation activities. Wastewaters are expected to be disposed of to sewer via waste water treatment plants (WWTP).

RELEASE OF CHEMICAL FROM USE

The majority of the notified chemical is expected to be incorporated and fixed in industrial polyurethane articles and is not expected to be released to the environment during use.

RELEASE OF CHEMICAL FROM DISPOSAL

The majority of the notified chemical is expected to share the fate of the polyurethane articles which are expected to be disposed of to landfill at the end of their useful life.

7.1.2. Environmental Fate

The notified chemical will be incorporated into polyurethane articles where it is expected to remain within the polymer matrix. Therefore, the notified chemical is not expected to be bioavailable in this form. The majority of the notified chemical is expected to be disposed of to landfill at the end of its useful life. In landfill, the notified chemical is expected to eventually degrade to form water and oxides of carbon, nitrogen and sulphur. The notified chemical is not readily biodegradable; however, it is considered to have potential for inherent, primary biodegradability. Therefore, the notified chemical is not expected to persist in the environment. For the details of the environmental fate studies please refer to Appendix C.

Any notified chemical that is released to the environment during activities associated with reformulation is not expected to persist in the environment based on its potential for inherent, primary biodegradability. Free notified chemical disposed of to landfill is expected to be mobile based on its high water solubility and expected low adsorption/desorption partition coefficient. Any notified chemical that is released to sewer is not expected to be removed by sewage treatment plant (STP) processes based on its water solubility and is expected to remain in the aqueous phase. However, any notified chemical that enters surface waters through sewers and landfill leachate is not expected to bioaccumulate based on its low n-octanol/water partition coefficient and high water solubility. The notified chemical is expected to eventually disperse and degrade to form water and oxides of carbon, nitrogen and sulphur.

7.1.3. Predicted Environmental Concentration (PEC)

The notified chemical is not expected to be released to the aquatic environment after incorporation into polyurethane articles. However, a small amount of notified chemical may be released to the environment during reformulation via cleaning of reformulation equipment and empty import containers. An estimate provided by the notifier indicates that up to 0.02% of the total import volume of the notified chemical may be released to sewer at one site in Sydney where the sewage treatment plant (STP) flow rate is approximately 456 ML/day. As a conservative estimate, release from these activities may occur up to once per week, or 50 days per year.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	50,000	kg/year
Proportion expected to be released to sewer	0.02%	
Annual quantity of chemical released to sewer	10	kg/year
Days per year where release occurs	50	days/year
Daily chemical release:	0.2	kg/day
Individual Sewage Treatment Plant Average Daily Flow:	456	ML/day
Removal within STP	0%	
Dilution Factor - River	1	
Dilution Factor - Ocean	10	
PEC - River:	0.44	µg/L
PEC - Ocean:	0.04	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1,000 L/m²/year (10 ML/ha/year). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1,500 kg/m³). Using these assumptions, irrigation with a concentration of 0.439 µg/L may potentially result in a soil concentration of approximately 2.92 µg/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 14.6 µg/kg and 29.2 µg/kg, respectively.

7.2. Environmental Effects Assessment

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

<i>Endpoint</i>	<i>Result</i>	<i>Assessment Conclusion</i>
<u>Acute Toxicity</u>		
Fish Toxicity (96 h)	EC ₅₀ > 100 mg/L	Not harmful
Daphnia Toxicity (48 h)	EC ₅₀ > 100 mg/L	Not harmful
Algal Toxicity (72 h)	E _r C ₅₀ > 100 mg/L	Not harmful

Inhibition of Bacterial Respiration (30 min)	EC50 \geq 100 mg/L	May have the potential to be inhibitory to microbial activity at concentrations \geq 100 mg/L
--	----------------------	---

Chronic Toxicity

Fish Toxicity (34 d)	NOEC > 10 mg/L	Not harmful
Daphnia Toxicity (21 d)	NOEC > 39.1 mg/L	Not harmful
Algal Toxicity (72 h)	NOEC = 100 mg/L	Not Harmful

The notified chemical has been found to not be harmful to fish, daphnia or algae on an acute or chronic basis. Based on the expected low hazard to aquatic organisms on an acute basis, the notified chemical is not formally classified under the Globally Harmonised System of Classification and Labelling of Chemicals for acute or long term hazard (GHS; United Nations, 2009).

7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) was calculated using the limit of the lowest available toxicity endpoint. The chronic toxicity to fish was used as this is the lowest available endpoint. An assessment factor of 10 was used as acute and chronic toxicity studies were available for three trophic levels.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
NOEC (Fish; 34 d)	>10	mg/L
Assessment Factor	10	
PNEC:	>1,000	µg/L

7.3. Environmental Risk Assessment

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	0.44	>1,000	<0.01
Q - Ocean	0.044	>1,000	<0.01

The risk quotient (Q = PEC/PNEC) for aquatic exposure is calculated to be less than 1 based on the above calculated PEC and PNEC values. The majority of the notified chemical will remain fixed in polyurethane articles and is not expected to be exposed to the aquatic environment or to be bioavailable. Since there is expected to be very limited exposure to aquatic organisms, and based on the value of Q being less than 1, the notified chemical is not expected to pose an unreasonable risk to the environment based on its assessed use pattern.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Boiling Point No boiling observed up to 325 °C at 101.3 kPa

Method OECD TG 103 Boiling Point.
 Remarks The differential scanning calorimetry (DSC) method was used.
 Evidence of decomposition was observed at 145 °C.
 Test Facility NOTOX (2004a)

Density 1.2403 kg/m³ at 20 °C

Method OECD TG 109 Density of Liquids and Solids.
 Remarks Oscillating densitometer method
 Test Facility BASF (2010)

Vapour Pressure <1 × 10⁻⁷ kPa at 20 °C

Method OECD TG 104 Vapour Pressure.
 Remarks Effusion method
 Test Facility BASF (2010)

Water Solubility Miscible at 20 °C

Method BASF SE Standard Operating Procedure (STD/001) from Competence Center Analytics
 Remarks The OECD TG 105 flask method was not used as a saturated solution could not be achieved. An in-house method was used to investigate complete miscibility. The test substance was mixed with water at ratios of 1:9, 1:1 and 9:1. The mixtures were shaken by hand and allowed to settle overnight. Clear homogenous solutions were observed with no changes overnight.
 Test Facility BASF (2010)

Hydrolysis as a Function of pH $t_{1/2} > 1$ year at pH 4, 7 and 9

Method OECD TG 111 Hydrolysis as a Function of pH.

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

Remarks No hydrolysis was observed under the test conditions.
 Test Facility BASF (2010)

Partition Coefficient (n-octanol/water) log Pow = -2.6 to -3.1 at 23 °C

Method OECD TG 107 Partition Coefficient (n-octanol/water).
 Remarks Flask Method. The log Pow was determined to be -2.6 for detection of 1-ethyl-3-methylimidazolium via HPLC. Log Pow was determined to be -3.1 for detection of ethyl sulphate via ion chromatography. The notified chemical is also completely miscible in water.
 Test Facility BASF (2010)

Surface Tension 72 mN/m at 20 °C

Method EC Council Regulation No 440/2008 A.5 Surface Tension.
 Remarks Concentration: 1 g/L
 Test Facility BASF (2006a)

Adsorption/Desorption Not determined

Method	OECD TG 121 Estimation of the Adsorption Coefficient (K _{oc}) on Soil and on Sewage Sludge using High Performance Liquid Chromatography (HPLC).
Remarks	The HPLC method was deemed unsuitable for the determination of log K _{oc} for the notified chemical.
Test Facility	BASF (2010)

Flash Point 176.0 °C

Method	EC Council Regulation No 440/2008 A.9 Flash Point.
Remarks	Closed cup
Test Facility	BASF (2006b)

Flammability None

Method	EC Council Regulation No 440/2008 A.12 Flammability (Contact with Water).
Remarks	Not considered as highly flammable
Test Facility	BASF (2011a)

Autoignition Temperature 405 °C

Method	EC Council Regulation No 440/2008 A.15 Auto-Ignition Temperature (Liquids and Gases).
Remarks	
Test Facility	BASF (2011a)

Explosive Properties Not applicable

Method	EC Council Regulation No 440/2008 A.14 Explosive Properties.
Remarks	Test was not performed as the exothermic decomposition energy determined by DSC is <0.5 kJ/g.
Test Facility	BASF (2011a)

Oxidizing Properties

Method	EC Council Regulation No 440/2008 A.21 Oxidizing Properties (Liquids).
Remarks	Overpressure of 20.7 bar reached. The test substance was not considered an oxidising liquid.
Test Facility	BASF (2011a)

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

TEST SUBSTANCE	Notified Chemical
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method Limit Test.
Species/Strain	Rat/Wistar
Vehicle	None
Remarks - Method	No significant protocol variations

RESULTS

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

LD50	>2,000 mg/kg bw
Signs of Toxicity	None
Effects in Organs	None
Remarks - Results	On day 1, hunched posture was noted in all females and piloerection was noted in one female.

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

TEST FACILITY	NOTOX (2004b)
---------------	---------------

B.2. Acute toxicity – dermal

TEST SUBSTANCE	Notified Chemical
METHOD	OECD TG 402 Acute Dermal Toxicity. EC Council Regulation No 440/2008 B.3 Acute Toxicity (Dermal).
Species/Strain	Rat/Wistar Strain, CrI:WI
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 F, 5 M	2,000	0

LD50	>2,000 mg/kg bw
Signs of Toxicity - Local	Scales were seen in the treated skin area of one male and two females between days 3 and 9
Signs of Toxicity - Systemic	Flat and/or hunched posture, chromodacryorrhoea, lethargy and/or ptosis were shown by most animals on days 1 and/or 2.
Effects in Organs	A reduced size of the testes and epididymis seen in one animal was considered not to be related to the test substance.
Remarks - Results	

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

TEST FACILITY	NOTOX (2005a)
---------------	---------------

B.3. Irritation – skin

TEST SUBSTANCE	Notified Chemical
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion. EC Directive 2004/73/EC B.4 Acute Toxicity (Skin Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 males
Vehicle	None
Observation Period	72 h
Type of Dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations. One animal was treated initially, and two animals were treated 14 days later. The observation period for the two animals treated later was 72 h.
RESULTS	
Remarks - Results	No irritation, corrosion, staining or systemic toxicity was observed in the animals during the test period. No mortality occurred during the test period. The table of individual skin irritation scores was not provided.
CONCLUSION	The notified chemical is non-irritating to the skin.
TEST FACILITY	NOTOX (2004c)

B.4. Irritation – eye

TEST SUBSTANCE	Notified Chemical
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion. EC Directive 2004/73/EC B.5 Acute Toxicity (Eye Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 males
Observation Period	72 h
Remarks - Method	No protocol deviations were reported. One animal was treated initially, and a further two animals five days later. Observations were terminated after 72 h.

RESULTS

<i>Lesion</i>	<i>Mean Score* Animal No.</i>			<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
	1	2	3			
<i>Conjunctiva: redness</i>	0.33	1	0.33	2	48 h	0
<i>Conjunctiva: chemosis</i>	0	0	0.33	2	24 h	0
<i>Conjunctiva: discharge</i>	0.33	0.33	0.33	1	24 h	0
<i>Corneal opacity</i>	0	0	0	0	-	0
<i>Iridial inflammation</i>	0	0	0	1	1 h	0

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

Remarks - Results	No evidence of corrosion, staining or systemic toxicity was observed during the test period. No mortality occurred during the test period.
CONCLUSION	The notified chemical is slightly irritating to the eye.
TEST FACILITY	NOTOX (2004d)

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

TEST SUBSTANCE	Notified Chemical
METHOD	OECD TG 429 Skin Sensitisation: Local Lymph Node Assay EC Directive 2004/73/EC B.42 Skin Sensitisation (Local Lymph Node Assay)
Species/Strain	Mouse/CBA
Vehicle	DMF
Remarks - Method	Doses were chosen on the basis of a preliminary irritation study. Results of vehicle control animals from another study were used for this study. Treatment was with same vehicle using the same procedures and within the same timeframe. The reliability of the methodology was verified by a study on the positive control alpha-hexyl cinnamic aldehyde, performed within six months of the study on the notified chemical.
RESULTS	The stimulation index for all concentrations tested was <3.

<i>Concentration (% w/w)</i>	<i>Proliferative response (DPM/lymph node)</i>	<i>Stimulation Index (Test/Control Ratio)</i>
<i>Test Substance</i>		
0 (vehicle control)	-	-
25	411 ± 188	1.1 ± 0.5
50	385 ± 105	1.0 ± 0.3
100	243 ± 137	0.7 ± 0.6

Remarks - Results

CONCLUSION	There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical.
TEST FACILITY	NOTOX (2004e)

B.6. Repeat dose toxicity – 28 day oral

TEST SUBSTANCE	Notified Chemical
METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents. EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral).
Species/Strain	Rat (Wistar Crl)
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 7 days per week
Vehicle	Water
Remarks - Method	The study integrity was not adversely affected by slight deviations to the protocol.

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw/day</i>	<i>Mortality</i>
control	5 (males), 5 (females)	0 (vehicle)	0
low dose	5 (males), 5 (females)	50	0
mid dose	5 (males), 5 (females)	150	0
high dose	5 (males), 5 (females)	1,090	0

Remarks – Results

No mortality occurred during the study.

Statistically significant increases were seen at the high dose in alanine aminotransferase and cholesterol levels (males), albumen (females) and potassium (males and females) but were not considered adverse by the study authors as they were not associated with other changes, Organ weights and organ to body weight ratios in treatment animals were considered similar to controls.

Necropsy did not reveal any changes that were considered toxicologically relevant by the study authors. Findings considered incidental included enlarged and/or discoloured mandibular lymph nodes in 3/5 males, associated with plasmacytic hyperplasia, fracture of the tip of the tail (1 animal) and isolated instances of fluid in the uterus.

CONCLUSION

The No Observed Adverse Effect Level (NOAEL) was established as 1000 mg/kg bw/day, based on no signs of toxicity observed up to the limits of the study.

TEST FACILITY NOTOX (2005b)

B.7. Repeat dose toxicity – 90 day oral (detailed summary only provided)

TEST SUBSTANCE	Notified Chemical
METHOD	OECD TG 408 Repeated Dose 90-Day Oral Toxicity Study in Rodents. EC Directive 440/2008/EC B Sub-Chronic Oral Toxicity Test: 90-Day Repeated Oral Dose Study using Rodent Species.
Species/Strain	Rat (Wistar Crl)
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 90 days Dose regimen: 5/7 days per week
Vehicle	Water
Remarks - Method	There were no deviations from the study protocol

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw/day</i>	<i>Mortality</i>
control	10 (male), 10 (female)	0 (Vehicle)	0
low dose	10 (male), 10 (female)	100	0
mid dose	10 (male), 10 (female)	500	0
high dose	10 (male), 10 (female)	1,000	0

Mortality and Time to Death

No mortality occurred during the study period.

Clinical Observations

No treatment-related, adverse findings were observed. Slight and moderate salivation was observed in the high dose group from day 20 onwards. Slight and moderate salivation was observed in the mid dose group in males from day 53 and females from day 31. Reductions in motor activity in mid and high dose males were within historical controls and considered incidental.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Crystals with unknown origin were found in the urine sediment of females rates of the low dose group. They were not found dose-dependently and were not accompanied by any other finding among the urine or blood parameters and were considered incidental.

Effects in Organs

A statistically significant increase in relative liver weights in high dose males was considered to be adaptive. Other changes in absolute organ weights in females were considered incidental as they were not dose related and not associated with histopathological changes. No treatment-related, adverse findings were observed.

Remarks – Results

CONCLUSION

The No Observed Adverse Effect Level (NOAEL) was established as 1,000 mg/kg bw/day in this study, based on no signs of toxicity observed up to the limits of the study.

TEST FACILITY BASF (2011b)

B.8. Genotoxicity – bacteria

TEST SUBSTANCE Notified Chemical

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
Species/Strain *S. typhimurium*: TA1535, TA1537, TA98, TA100
E. coli: WP2uvrA
Metabolic Activation System S9-mix from Aroclor- induced rat liver
Concentration Range in Main Test a) With metabolic activation: 100-5,000 µg/plate
b) Without metabolic activation: 100-5,000 µg/plate
Vehicle Water
Remarks - Method There were no deviations from the study protocol.

RESULTS

<i>Metabolic Activation</i>	<i>Test Substance Concentration (µg/plate) 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	>5,000		None	Negative
Test 2		>5,000	None	Negative
<i>Present</i>				
Test 1	>5,000		None	Negative
Test 2		>5000	None	Negative

Remarks - Results

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

TEST FACILITY NOTOX (2004f)

B.9. Genotoxicity – in vitro

TEST SUBSTANCE Notified Chemical

METHOD OECD TG 473 In vitro Mammalian Chromosome Aberration Test.
EC Directive 2000/32/EC B.10 Mutagenicity - In vitro Mammalian Chromosome Aberration Test.
Species/Strain Human
Cell Type/Cell Line Cultured peripheral lymphocytes
Metabolic Activation System Microsomal enzymes (S9-mix) from Aroclor-1254 induced rat liver
Vehicle RPMI 1640 medium
Remarks - Method There were no deviations from the protocol.

<i>Metabolic Activation</i>	<i>Test Substance Concentration (µg/mL)</i>	<i>Exposure Period</i>	<i>Harvest Time</i>
<i>Absent</i>			
Test 1	333*, 1,000*, 1,500, 2,363*	3	24
Test 2	333*, 1,000*, 1,500, 2,363*	24	24
Test 2	333, 500*, 1,000*, 1,500*, 2,000, 2,363	48	48

<i>Present</i>			
Test 1	333*, 1,000*, 1,500, 2,363*	3	24
Test 2	333*, 1,000*, 2,363*	3	48

*Cultures selected for metaphase analysis.

RESULTS

<i>Metabolic Activation</i>	<i>Test Substance Concentration (µg/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	>2,363	>2,363	None	Negative
Test 2 (24 h)	>2,363	>2,363	None	Negative
Test 2 (48 h)	>1,000	>1,000	None	Negative
<i>Present</i>				
Test 1	>2,363	>2,363	None	Negative
Test 2		>2,363	None	Negative

Remarks - Results

Both in the presence and absence of S9-mix, the notified chemical did not induce a statistically significant or biologically relevant increase in the number of cells with chromosome aberrations. No increase in the number of polyploid cells or endoreduplicated cells was seen. Positive controls performed as expected, verifying the validity of the test system.

CONCLUSION

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

TEST FACILITY

NOTOX (2005c)

B.10. Genotoxicity – in vivo

TEST SUBSTANCE

Notified Chemical

METHOD

OECD TG 474 Mammalian Erythrocyte Micronucleus Test.
EC Directive 2008/440/EC B.12 Mutagenicity – In Vivo Mammalian Erythrocyte Micronucleus Test.

Species/Strain

Mouse (CrI:NMRI)

Route of Administration

Oral – gavage

Vehicle

Water

Remarks - Method

The vehicle control and the high dose were tested at both 24h and 48h sacrifice time.

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Sacrifice Time hours</i>
I (vehicle control)	5 (male)	-	24
I (vehicle control)	5 (male)	-	48
II (low dose)	5 (male)	500	24
III (mid dose)	5 (male)	1,000	24
IV (high dose)	5 (male)	2,000	24
IV (high dose)	5 (male)	2,000	48
V (positive control, CP)	5 (male)	20	24
VI (positive control, VN)	5 (male)	0.15	24

CP=cyclophosphamide.

VN=vincristine

RESULTS

Doses Producing Toxicity

None observed

Genotoxic Effects

None observed

Remarks - Results

The PCE/NCE ratio was within historical controls for the laboratory. It is not clear whether the chemical reached the bone marrow. Although no

clinical signs were seen after treatment, there was a slight reduction in the PCE/NCE ratio in the high dose 24 h group, compared with the low and medium dose groups, which could be an indication of bone marrow toxicity.

CONCLUSION The notified chemical was not clastogenic to NMRI mice in vivo under the conditions of the test.

TEST FACILITY BASF (2011c)

B.11. Developmental toxicity

TEST SUBSTANCE Notified Chemical

METHOD OECD TG 414 Prenatal Developmental Toxicity Study.
EC Directive 2008/440/EC B. Methods for the determination of toxicity and other health effects: Prenatal Developmental Toxicity Study.

Species/Strain Rats (Wistar Crl)
Route of Administration Oral – gavage
Exposure Information Exposure days: days GD 6 to GD 19.
Post-exposure observation period: Not recorded

Vehicle Water
Remarks - Method The study was carried out in 3 cohorts. Each dose group was represented in each cohort.

RESULTS

<i>Group</i>	<i>Number of Animals</i>	<i>Dose mg/kg bw/day</i>	<i>Mortality</i>
Control	25	0 (Vehicle)	0
Low dose	25	100	0
Mid dose	25	300	0
High dose	25	1,000	0

Remarks - Results

No test substance related adverse effects on dams, gestational parameters or fetuses were observed during the study. A statistically significant increase in one variety of fetal skeletal variation (incomplete ossification of interparietal; unchanged cartilage) was seen at the high dose, however the incidence was within the historical controls for this variation. There were no substance-related or spontaneous mortalities in any of the groups.

CONCLUSION

The No Observed Adverse Effect Level (NOAEL) was established as 1,000 mg/kg bw/day in this study, based on no adverse maternal or foetal findings of toxicological relevance observed under the conditions of the test.

TEST FACILITY BASF (2011d)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 B Ready Biodegradability: CO ₂ Evolution Test.
Inoculum	Activated sludge
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Titration with Ba(OH) ₂
Remarks - Method	The test was conducted according to good laboratory practice (GLP) and test guidelines with no significant deviations.

RESULTS

<i>Test substance</i>		<i>Sodium acetate</i>	
<i>Day</i>	<i>% Degradation</i>	<i>Day</i>	<i>% Degradation</i>
7	1	7	56
28	4	28	83

Remarks - Results All relevant test validity criteria were met. A toxicity control test indicated that the notified chemical is not inhibitory to microbial activity.

CONCLUSION The notified chemical is not readily biodegradable.

TEST FACILITY NOTOX (2004g)

C.1.2. Inherent biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 302 B Inherent Biodegradability: Zahn-Wellens EMPA Test.
Inoculum	Activated Sludge
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Chemical oxygen demand (COD) monitoring
Remarks – Method	The test was conducted according to good laboratory practice (GLP) and test guidelines with no significant deviations. The test was conducted in the dark.

RESULTS

<i>Test substance</i>		<i>Ethylene Glycol</i>	
<i>Day</i>	<i>% Degradation</i>	<i>Day</i>	<i>% Degradation</i>
28	30.9	14	100

Remarks – Results All relevant test validity criteria were met. A toxicity control test indicated that the notified chemical is not inhibitory to microbial activity.

CONCLUSION The notified chemical has the potential to be considered to have inherent, primary biodegradability.

TEST FACILITY Guangdong Detection Center of Microbiology (2011a)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test - Static
Species	Zebra fish (<i>Brachydanio rerio</i>)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	119 mg CaCO ₃ /L
Analytical Monitoring	UHPLC-MS/MS
Remarks – Method	The test was conducted according to good laboratory practice (GLP) and test guidelines with no significant deviations.

RESULTS

Concentration mg/L Nominal	Number of Fish	Mortality				
		1 h	24 h	48 h	72 h	96 h
0	10	0	0	0	0	0
100	10	0	0	0	0	0

LC50	>100 mg/L at 96 hours.
NOEC	100 mg/L at 96 hours.
Remarks – Results	All relevant test validity criteria were met. The values for LC50 and NOEC were adjusted based on the purity of the substance tested.

CONCLUSION	The notified chemical is not harmful to fish.
------------	---

TEST FACILITY	Guangdong Detection Center of Microbiology (2011b)
---------------	--

C.2.2. Chronic toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 210 Fish, Early-Life Stage Toxicity Test – Flow-through
Species	Fathead minnow (<i>Pimephales promelas</i>)
Exposure Period	34 days
Auxiliary Solvent	None
Water Hardness	100 mg CaCO ₃ /L
Analytical Monitoring	Total organic carbon (TOC) analysis, HPLC
Remarks - Method	The test was conducted according to good laboratory practice (GLP) and test guidelines with no significant deviations.

RESULTS

Concentration mg/L Nominal	Actual	Number of Embryos	% Hatched	% Overall survival	Mean length (cm)	Mean weight (mg)
0	0	100	98	96	2.9	233
0.1	0.105	100	98	96	2.9	233
0.32	0.318	100	97	96	2.9	223
1.0	1.068	100	98	98	2.9	234
3.2	3.326	100	98	97	2.8	226
10	10.59	100	98	98	2.9	246

LOEC	>10 mg/L at 34 days.
NOEC	>10 mg/L at 34 days.
Remarks - Results	All relevant test validity criteria were met. No behavioural or physical abnormalities were observed over the range of concentrations tested.

CONCLUSION The notified chemical is not harmful to fish with long lasting effects.

TEST FACILITY BASF (2011e)

C.2.3. 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 None
 Water Hardness 250 mg CaCO₃/L
 Analytical Monitoring Not reported
 Remarks - Method The test was conducted according to good laboratory practice (GLP) and test guidelines with no significant deviations.

RESULTS

Concentration mg/L Nominal	Number of <i>D. magna</i>	Number Immobilised	
		24 h	48 h
0	20	0	0
100	20	0	1

EC50 >100 mg/L at 48 hours

NOEC 100 mg/L at 48 hours

Remarks - Results All relevant test validity criteria were met. A range-finding test determined there was no immobilisation of daphnids up to 100 mg/L of test substance.

CONCLUSION The notified chemical is not harmful to aquatic invertebrates.

TEST FACILITY NOTOX (2004h)

C.2.4. Chronic toxicity to aquatic invertebrates

TEST SUBSTANCE Notified chemical

METHOD OECD TG 211 *Daphnia magna* Reproduction Test – Semi-static
 Species *Daphnia magna*
 Exposure Period 21 days
 Auxiliary Solvent None
 Water Hardness 210-240mg/L
 Analytical Monitoring Not reported
 Remarks - Method The test was conducted according to good laboratory practice (GLP) and test guidelines with no significant deviations. The test solution was renewed every 48 hours.

Nominal Loading rate (mg/L)	Mean Percent Survival	Test Day 21	
		Mean Number of Offspring Released per female ± SD	Mean Total Body Length in mm ± SD
Blank Control	100%	113 ± 8	2.87 ± 0.07
15.3	100%	112 ± 12	2.84 ± 0.08
24.4	100%	112 ± 10	2.82 ± 0.06
39.1	100%	115 ± 13	2.83 ± 0.11
62.5	100%	100 ± 14	2.68 ± 0.15*
100	50%	32 ± 16*	2.50 ± 0.22*

*The test result is significantly statistically different ($P \leq 0.05$)

EC50 (reproduction)	87.1 mg/L at 21 days
LOEC	100 mg/L for reproduction at 21 days 100 mg/L for mortality at 21 days 62.5 mg/L for mean body length at 21 days
NOEC	62.5 mg/L for reproduction at 21 days 62.5 mg/L for mortality at 21 days 39.1 mg/L for mean body length at 21 days
Remarks - Results	All relevant test validity criteria were met.
CONCLUSION	The notified chemical is not harmful to aquatic invertebrates with long lasting effects.
TEST FACILITY	Guangdong Detection Center of Microbiology (2011c)

C.2.5. Algal growth inhibition test

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 201 Alga, Growth Inhibition Test.
Species	<i>Selenastrum capricornutum</i>
Exposure Period	72 hours
Concentration Range	Actual: 0.1, 1, 10, 100 mg/L
Auxiliary Solvent	None
Water Hardness	24 mg CaCO ₃ /L
Analytical Monitoring	HPLC
Remarks - Method	The test was conducted according to good laboratory practice (GLP) and test guidelines with no significant deviations.

RESULTS

<i>Biomass</i>		<i>Growth</i>	
<i>E_bC₅₀</i> mg/L at 72 h	<i>NOE_bC</i> mg/L at 72 h	<i>E_rC₅₀</i> mg/L at 72 h	<i>NOE_rC</i> mg/L at 72 h
>100	<100	>100	100

Remarks - Results	All relevant test validity criteria were met. It is noted that a reduction in cell density is observed at 100 mg/L test substance concentration, therefore the no-observed effect concentration is between 10 and 100 mg/L. NOE _b C is greater than 10 mg/L.
CONCLUSION	The notified chemical is not harmful to algae.
TEST FACILITY	NOTOX (2005d)

C.2.6. Inhibition of microbial activity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test.
Inoculum	Activated sludge
Exposure Period	30 minutes
Concentration Range	Nominal: 100 mg/L
Remarks – Method	The test was conducted according to good laboratory practice (GLP) and test guidelines with no significant deviations.

RESULTS

EC50

 ≥ 100 mg/L

Remarks – Results

All relevant test validity criteria were met. There was an 11% inhibition in respiration rate of the sludge at 100 mg/L in the 30 minute timeframe.

CONCLUSION

The notified chemical may have the potential to be inhibitory to microbial activity at concentrations ≥ 100 mg/L.

TEST FACILITY

NOTOX (2005e)

BIBLIOGRAPHY

- BASF (2006a) Physico-chemical properties of "EMIM EtSO₄" for the notification according to the German Chemicals Act (Study No. 06L00040, February, 2006). Ludwigshafen, Germany, BASF SE (Unpublished report submitted by the notifier).
- BASF (2006b) Evaluation of physical and chemical properties according to Directive 92/69/EC: Annex A.9-A.17 and A.21. (Project No. 06/0395, March, 2006). Ludwigshafen, Germany, BASF SE. (Unpublished report submitted by the notifier).
- BASF (2010) Physico-chemical properties of "1-ethyl-3-methylimidazolium ethylsulfat" (Study No. 10L00255, July, 2010). Ludwigshafen, Germany, BASF SE (Unpublished report submitted by the notifier).
- BASF (2011a) Evaluation of physical and chemical properties according to Regulation (EC) No 440/2008. (Project No. 10/1349, February, 2011). Ludwigshafen, Germany, BASF SE. (Unpublished report submitted by the notifier).
- BASF (2011b) 1-Ethyl-3-methylimidazolium ethylsulphate: Repeated-dose 90-day oral toxicity study in Wistar rats, Administration by gavage. (Project No. 50C0104/06S003, June, 2011). Ludwigshafen, Germany, BASF SE. (Unpublished report submitted by the notifier).
- BASF (2011c) 1-Ethyl-3-methylimidazolium ethylsulphate: Micronucleus Test in Bone Marrow Cells of the Mouse. (Project No. 26M0104/06M005, October, 2011). Ludwigshafen, Germany, BASF SE. (Unpublished report submitted by the notifier).
- BASF (2011d) 1-Ethyl-3-methylimidazolium ethylsulphate: Prenatal Developmental Toxicity Study in Wistar Rats, Oral Administration (Gavage). (Project No. 30R0104/06R010, November, 2011). Ludwigshafen, Germany, BASF SE. (Unpublished report submitted by the notifier).
- BASF (2011e) 1-Ethyl-3-methylimidazolium ethylsulphate: Early-Life-Stage Toxicity Test on Fathead Minnow (*Pimephales promelas*) in a flow through system (Study No. 50F0104/06E004, September, 2011). Ludwigshafen, Germany, BASF SE (Unpublished report submitted by the notifier).
- Guangdong Detection Center of Microbiology (2011a) Inherent Biodegradability: Zahn-Wellens/EMPA Test of Basonics™ LQ 01 (Study No. 2011ESG0111, September, 2011). Guangzhou, China, Guangdong Detection Center of Microbiology (Unpublished report submitted by the notifier).
- Guangdong Detection Center of Microbiology (2011b) Fish, Acute Toxicity to Basonics™ LQ 01 (Study No. 2011ESG0083, September, 2011). Guangzhou, China, Guangdong Detection Center of Microbiology (Unpublished report submitted by the notifier).
- Guangdong Detection Center of Microbiology (2011c) *Daphnia magna*, Reproduction Test with Basonics™ LQ 01 (Study No. 2011ESG0084, December, 2011). Guangzhou, China, Guangdong Detection Center of Microbiology (Unpublished report submitted by the notifier).
- NOHSC (2004) Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.
- NOTOX (2004a) Determination of the boiling temperature of 1-Ethyl-3-methylimidazolium ethylsulfate by differential scanning calorimetry (Project No. 420244, November, 2004). 's-Hertogenbosch, The Netherlands, NOTOX B.V. (Unpublished report submitted by the notifier).
- NOTOX (2004b) Assessment of acute oral toxicity with 1-Ethyl-3-methylimidazolium ethylsulfate in the rat (Acute Toxic Class Method) (Project No. 417217, November, 2004). 's-Hertogenbosch, The Netherlands, NOTOX B.V. (Unpublished report submitted by the notifier).
- NOTOX (2004c) Primary Skin Irritation/Corrosion Study with 1-Ethyl-3-methylimidazolium ethylsulfate in the Rabbit (4-Hour Semi-occlusive application) (Project No. 417228, November, 2004). 's-Hertogenbosch, The Netherlands, NOTOX B.V. (Unpublished report submitted by the notifier).
- NOTOX (2004d) Acute Eye Irritation/Corrosion Study with 1-Ethyl-3-methylimidazolium ethylsulfate in the Rabbit (Project No. 417239, November, 2004). 's-Hertogenbosch, The Netherlands, NOTOX B.V. (Unpublished report submitted by the notifier).
- NOTOX (2004e) Assessment of Contact Hypersensitivity to 1-Ethyl-3-methylimidazolium ethylsulfate in the Mouse (Local Lymph Node Assay) (Project No. 417241, December, 2004). 's-Hertogenbosch, The Netherlands, NOTOX B.V. (Unpublished report submitted by the notifier).

- NOTOX (2004f) Evaluation of the Mutagenic Activity of 1-Ethyl-3-methylimidazolium ethylsulfate in the *Salmonella Typhimurium* Reverse Mutation Assay and the *Escherichia Coli* Reverse Mutation Assay (with Independent Repeat). (Project No. 417252, October, 2004). 's-Hertogenbosch, The Netherlands, NOTOX B.V. (Unpublished report submitted by the notifier).
- NOTOX (2004g) Determination of 'Ready' Biodegradability; Carbon Dioxide (CO₂) Evolution Test (Modified Sturm Test) of 1-ethyl-3-methyl imidazolium ethylsulfate (EMIM ES) (Study No. 417263, September, 2004). 's-Hertogenbosch, The Netherlands, NOTOX B.V. (Unpublished report submitted by the notifier).
- NOTOX (2004h) Acute Toxicity Study in *Daphnia magna* with 1-ethyl-3-methyl imidazolium ethylsulfate (EMIM ES) (Static) (Study No. 417274, November, 2004). 's-Hertogenbosch, The Netherlands, NOTOX B.V. (Unpublished report submitted by the notifier).
- NOTOX (2005a) Assessment of acute dermal toxicity with 1-Ethyl-3-methylimidazolium ethylsulfate in the rat (Project No. 431246, April, 2005). 's-Hertogenbosch, The Netherlands, NOTOX B.V. (Unpublished report submitted by the notifier).
- NOTOX (2005b) Repeated Dose 28-day oral toxicity study with 1-Ethyl-3-methylimidazolium ethylsulfate by Daily Gavage in the Rat. (Project No. 431257, July, 2005). 's-Hertogenbosch, The Netherlands, NOTOX B.V. (Unpublished report submitted by the notifier).
- NOTOX (2005c) Evaluation of the Ability of 1-Ethyl-3-methylimidazolium ethylsulfate to Induce Chromosome Aberrations in Cultured Peripheral Human Lymphocytes (with Repeat Experiment). (Project No. 417279, April, 2005). 's-Hertogenbosch, The Netherlands, NOTOX B.V. (Unpublished report submitted by the notifier).
- NOTOX (2005d) Fresh Water Algal Growth Inhibition Test with 1-ethyl-3-methyl imidazolium ethylsulfate (EMIM ES) (Study No. 431292, April, 2005). 's-Hertogenbosch, The Netherlands, NOTOX B.V. (Unpublished report submitted by the notifier).
- NOTOX (2005e) Activated Sludge Respiration Inhibition Test with 1-ethyl-3-methyl imidazolium ethylsulfate (EMIM ES) (Contact Time: 30 Minutes) (Study No. 431303, March, 2005). 's-Hertogenbosch, The Netherlands, NOTOX B.V. (Unpublished report submitted by the notifier).
- NTC (National Transport Commission) 2007 Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG code), 7th Edition, Commonwealth of Australia
- United Nations (2009) Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 3rd revised edition. United Nations Economic Commission for Europe (UN/ECE), <http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html>.