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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Chemical in Blazebrake Fire Rated Foam

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
NICNAS

TABLE OF CONTENTS

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/1634	ITW Australia Pty Ltd	Chemical in Blazebrake Fire Rated Foam	No	≤ 3 tonnes per annum	Component of foam sealants for construction

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 of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia.

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.

There could be uncertainties regarding the potential long-term effects of the notified chemical, based on the characteristics of other brominated flame retardants (BFR). The notified chemical is not expected to be bioaccumulative, but is expected to be persistent in the environment, which could lead to secondary human exposure to the chemical or its degradants. The proposed pattern of use in Australia is not expected to lead to high build-up of indoor dust containing the notified chemical, therefore secondary exposure and consequent risk to the public are expected to be low.

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 low hazard of the notified chemical, the assumed low hazard of the notified chemical's degradants and the reported 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 controls to minimise occupational exposure during use of the product containing the notified chemical:
  - Use in a well ventilated area.

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during use of the product containing the notified chemical:
  - Avoid skin and eye contact
  - Clean up spills and waste material promptly
  - Avoid inhaling dust during sanding of applied surfaces

- 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 during use of the product containing the notified chemical:

- Protective clothing, including gloves
- Respiratory protection if dust is generated

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

- 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.

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.

Emergency procedures

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

Regulatory Obligations

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

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

(1) Under Section 64(1) of the Act; if
- The notified chemical is imported other than as a component of ready-to-use sealant at a concentration < 15%.
- The product containing the notified chemical is supplied for use by the public.
- If studies become available indicating levels of the notified chemical have been detected in any environmental compartment (including water, air, soil or biota) above any relevant Australian guideline values, including those from the Australian and New Zealand Environment and Conservation Council (ANZECC) or the National Environment Protection Council (NEPC).

or

(2) Under Section 64(2) of the Act; if
- The function or use of the chemical has changed from component of foam sealant for construction, 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 or its degradants 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 SDS of the product containing the notified chemical provided by the notifier was reviewed by NICNAS. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT
ITW Australia Pty Ltd (ABN: 63 004 235 063)
Level 3, 74 Doncaster Road
BALWYN NORTH VIC 3104

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: chemical name, other names, CAS number, molecular and structural formulae, molecular weight and impurities.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
EU REACH

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Blazebrake Fire Rated Foam (product containing the notified chemical)

MOLECULAR WEIGHT
500–1000 Da

ANALYTICAL DATA

METHOD	Appearance, physical state by visual inspection at ambient temperature (23 °C)
REMARKS	The test item was described as colourless, slight viscous liquid.
TEST FACILITY	Currenta (2017)
METHOD	Fourier Transform – Infrared Spectrometry (FTIR) The sample was prepared in form of a thin film on a KBr disk. A high resolution FTIR spectrum was scanned and evaluated.
REMARKS	The found structure elements were correlated with the test item.
TEST FACILITY	Currenta (2017)
METHOD	Nuclear Magnetic Resonance (NMR) Spectroscopy: 1H-NMR and 13C-NMR spectra The sample was weighed and dissolved in deuterated chloroform (CDCl3) for NMR technique. Finally, 1H-NMR and 13C-NMR spectra were recorded. The structure of the analyte was derived from the spectral characteristics of the signals.
REMARKS	The observed resonances were in agreement with the test item.
TEST FACILITY	Currenta (2017)
METHOD	Residue of evaporation The sample was weighed into a tared round bottom flask with standard ground joint. Under the conditions 250 °C, < 0.1hPa, the sample was slowly heated up in a Büchi-bulb tube distilling oven until constant weight was reached.
REMARKS	Residue of evaporation was 0.63 %
TEST FACILITY	Currenta (2017)

METHOD Contents and mass spectra by Capillary Gas Chromatography (GC) with FID and MS detection
REMARKS The composition of the notified chemical was determined.
TEST FACILITY Currenta (2017)

METHOD Water content by Karl Fischer technique
Karl Fischer solvent and Karl Fischer titrant are commercial reagents for determination of water content.
The originally weighted sample of the test item was dissolved in the Karl Fischer solvent or in an appropriate solvent mixture and titrated back with the Karl Fischer titrant. The end point detection was detected biampero-metrically using a Pt-indicator electrode.
REMARKS Water content was < 0.1 %
TEST FACILITY Currenta (2017)

3. COMPOSITION

DEGREE OF PURITY
Typically 95.5% (range 91–98%)

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Light yellow liquid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Pour point: -27 °C	Measured
Boiling Point	> 300 °C at 101.3 kPa	Measured
Density (of liquid)	1.541 kg/m^3 at 20 °C	Measured
Vapour Pressure	3.56 x 10^{-10} kPa at 25 °C	Calculated via EPISuite v4.11 MPBPWIN model
Water Solubility	< 1 mg/L at 20 °C	Measured
Hydrolysis as a Function of pH	$t_{1/2}$ = 30.29 h at pH 4 at 50°C $t_{1/2}$ = 44.08 h at pH 7 at 50°C $t_{1/2}$ = 77.52 h at pH 9 at 50°C	Measured
Partition Coefficient (n-octanol/water)	log P_{ow} = 10.2	Measured
Adsorption/Desorption	log K_{oc} = 7.3	Measured
Dissociation Constant	Not determined	Contains no dissociable functionalities.
Flash Point	207 °C at 1013 hPa	Measured
Auto-ignition Temperature	370 °C at 1013 hPa	Measured
Explosive Properties	Not expected to be explosive	Contains no functional groups that would imply explosive properties.
Oxidising Properties	Not expected to be oxidising	Contains no functional groups that would imply oxidative properties.
Dynamic Viscosity	2036 mPa.s at 20 °C	Measured
Corrosive properties	Not corrosive to metals (Negative corrosion result - uniform and localised - for steel and aluminium)	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 transport, storage and use.

Physical hazard classification
Based on the submitted physico-chemical data depicted in the above table, the notified chemical is not recommended for physical hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will not be manufactured in Australia. It will be imported into Australia as a component of a formulation.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	1.5	1.9	2.3	2.6	3.0

PORT OF ENTRY
Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
Recipient: Ramsetreid, 1 Ramset Drive, Chirnside Park, VIC 3116, Australia

TRANSPORTATION AND PACKAGING
The notified chemical will be transported as part of a product in 750 mL tinplate aerosol canisters.

USE
The notified chemical is used as a component of foam sealants for construction. It is imported and marketed at a concentration < 15% in polyurethane foam, packed in ready-to-use aerosol canisters. The polyurethane foam is dispensed through a tube or application gun into construction joints, which may be made of wood, metal, concrete, and or PVC. The foam expands after dispensing to fill the joints; after which it is cured with moisture from the environment. The notified chemical is incorporated in the polyurethane matrix. After the polyurethane has cured, it is hard, insoluble and inert.

OPERATION DESCRIPTION
The notified chemical will not be manufactured, repackaged and/or reformulated in Australia. At the building construction sites, which may include domestic, commercial or industrial settings, the foam containing the notified chemical at < 15% will be dispensed from 750 mL canisters via a tube or application gun, to fill gaps in joints. The foam expands considerably when dispensed, with one canister forming up to 40 L of foam. After the foam is dispensed, it cures (hardens) in contact with moisture from the environment, and forms a solid matrix. Trimming or sanding of the dispensed product may occur in order to form an even surface. Once the polyurethane matrix has been formed in the joint, it will be covered over e.g. with plaster, with wooden, plastic or metal plinths/strips, or with caulking/silicone sealant.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transportation and warehouse employees	Not known*	Not known
Professional building applicator	0.5	50

*Product containing the notified chemical is transported and stored in a closed aerosol container.

EXPOSURE DETAILS
Transportation and warehouse workers are not expected to have contact with the notified chemical, except in the case of accidental rupture of the product canisters.

At the construction sites, workers applying the polyurethane foam containing the notified chemical may have incidental dermal and ocular exposure. As the product will be dispensed as foam rather than spray, aerosols are not expected to be generated during the dispensing and application process. In addition, the notified chemical is not expected to vaporise as it has a low vapour pressure. Therefore inhalation exposure is not expected during

these processes. After application, the foam may be trimmed or sanded in order to produce a level surface. If this occurs, there may be additional dermal or inhalation exposure to the waste material. As the product containing the notified chemical is hazardous, it is expected that workplace controls (including PPE) for the other ingredients in the product will minimise exposure to the notified chemical.

Workers may have dermal contact with the cured polyurethane matrix containing the notified chemical, for example while applying coatings to the matrix. However the notified chemical is expected to be incorporated in the matrix and not available for exposure.

6.1.2. Public Exposure

Direct exposure
The notified chemical is marketed for use at construction and building sites and is intended to be used by workers only. It is possible that the public may have dermal exposure to the cured polyurethane matrix. However this is less likely as the matrix is expected to be covered by other layers, as part of the construction process. Therefore public exposure is expected to be very low with the proposed use of the notified chemical.

Indirect exposure
Dust ingestion is considered to be a major pathway of human exposure to brominated flame retardants (undisclosed references; NICNAS, 2012). The notified chemical can be released into the general environment from its industrial use and disposal, leaching and emissions from landfill and from end-of-life scenarios in buildings. The distribution of the notified chemical into the different environmental compartments (air, water, soil and sediment) is described in Section 7.

Although exposure via ingestion and/or inhalation of dust is not immediately relevant to the proposed use of the notified chemical in Australia, it may be relevant at some level of the life cycle of the chemical, for example in old buildings. In the USA, the notified chemical was detected in the respirable (< 4 μm) and inhalable fraction (> 4 μm) of air samples collected in public buildings containing polyurethane foams (undisclosed reference). The potential for exposure via ingestion could be greater for toddlers and young children, as a result of behavioural patterns during childhood (mouthing of objects or hands contaminated with dust). In Canada, the notified chemical was also detected in breast milk of nursing women. About a third of the samples tested contained the chemical, at very low concentrations (undisclosed reference). However, release into local environments such as inside houses is not expected to occur with the proposed use of the notified chemical in polyurethane foam in Australia. The public could be exposed to the notified chemical via incidental ingestion and/or inhalation of dust through the outdoor environment, which is expected to be lower.

Therefore the indirect exposure of the public to the notified chemical is expected to be of a low magnitude.

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.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 > 5000 mg/kg bw. Low toxicity
Rat, acute dermal toxicity	LD50 > 2000 mg/kg bw. Low toxicity
Rabbit, skin irritation	Slightly irritating
Rabbit, eye irritation	Slightly irritating
Guinea pig, skin sensitisation – non-adjuvant test.	Not sensitising
Rat, repeat dose oral toxicity – 28 days	NOAEL = 2210 / 2450 mg/kg bw/day for M/F
Mutagenicity – bacterial reverse mutation	Non mutagenic
Genotoxicity – *in vitro* mammalian gene mutation assay	Non genotoxic
Genotoxicity – *in vitro* mammalian chromosomal aberration test	Weakly genotoxic
Genotoxicity – *in vivo* micronucleus test	Negative

Toxicokinetics, metabolism and distribution
The notified chemical with radioactive labelling was poorly absorbed following oral administration in rats and mice (undisclosed reference). Most (> 90%) of a single dose administered to rats and mice was excreted unchanged in the faeces within 72 hours, and less than 1% excreted in the urine. About 1% of the oral dose was

detected in tissues within 72 hours. Similarly, repeated oral administration of the notified chemical to rats showed that most of the dose was recovered in the faeces; however increased levels of radioactivity were retained in tissues such as the liver and adrenals after repeated dosing.

When the notified chemical was made systemically available by intravenous (i.v.) administration to rats in the same study, the radioactivity was slowly eliminated in the faeces as a mixture of parent and metabolite(s). Up to 78% of the dose was recovered in the faeces within 72 hours. Biliary excretion was identified as a method of excretion. Approximately 20% of the radioactivity of the i.v. dose was detected in tissues within 24 hours, with the highest levels in liver, muscle, skin and fat.

Based on a study in *ex-vivo* human skin models, the notified chemical is expected to have poor percutaneous absorption, with only 0.04% of the dose detected in the receptor fluid. Significant amounts were found in the viable epidermis (9.5%) and dermis (0.5%). The results were considered to be the result of high lipophilicity (undisclosed reference).

Acute toxicity
The notified chemical has low acute oral and dermal toxicity based on the results from two rat studies. Information on acute inhalation toxicity is not available.

Irritation and sensitisation
The notified chemical was slightly irritating to skin and eyes in studies on rabbits. The notified chemical showed no sensitising properties in a delayed contact hypersensitivity test (Buehler) in guinea pigs.

Repeated dose toxicity
In a 28-day subchronic oral toxicity study similar to OECD TG 407, groups of CD rats (n = 10/sex/dose) were given the notified chemical in the diet at concentrations of 200, 2000 or 20000 ppm for four weeks. At mid dose, one male rat died during the study. No other mortality was observed. The notified chemical did not have similar effects to those of the positive control used in the study, diethylhexyl phthalate (DEHP). There was no clear evidence of toxicity at concentrations up to the highest dose of 2210 mg/kg bw/day and 2450 mg/kg bw/day in males and females respectively. These concentrations are therefore considered to be the NOAELs. A lower NOAEL (2000 ppm) was cited in other international assessments, based on the body weight and clinical chemistry changes in females at the highest dose (undisclosed reference).

Mutagenicity/Genotoxicity
Results were negative in a bacterial gene mutation assay using *Salmonella typhimurium* strains. Weakly positive results were observed in an *in vitro* chromosomal aberration test. Negative results were reported in an *in vitro* mammalian cell gene mutation test; however the results were incomplete because of the poor solubility of the test substance at the concentrations tested. Negative results were reported in an *in vivo* micronucleus test with intraperitoneal and dermal doses up to 2000 mg/kg bw. In the absence of toxicity in the bone marrow and as no clinical signs indicated systemic exposure, it is not clear whether the notified chemical actually reached the bone marrow. Therefore, potential for genotoxicity cannot be excluded.

Other endpoints
Information regarding carcinogenicity or toxicity to reproduction/development is not available.

Metabolites
An expected metabolite of the notified chemical elicited maternal thyrotoxic and hepatotoxic effects in pregnant rats given 500 mg/kg bw orally, and histopathological effects in foetal testes but did not reduce testosterone production up to 500 mg/kg bw (undisclosed reference).

Health hazard classification
Based on the available information, the notified chemical is not recommended for classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

6.3. Human Health Risk Characterisation
The notified chemical is a brominated flame retardant, part of the brominated phthalates group. The available toxicological information indicates that the notified chemical is not acutely toxic, is slightly irritating to the skin and eyes and is not sensitising to the skin. Adverse effects were not seen in a 28-day feeding study. Animal data suggest that the notified chemical is poorly absorbed via the oral and dermal routes. Some *in vitro* testing on the

notified chemical has indicated potential for endocrine disruption (undisclosed reference). However the significance of the studies is unclear.

6.3.1. Occupational Health and Safety

Before it is cured into a matrix, incidental dermal and ocular exposure to the product containing the notified chemical at a concentration < 15% may occur, during application and any trimming/sanding processes. In the latter, inhalation exposure may also occur. Dermal contact may also occur with the cured polyurethane matrix containing the notified chemical, for example while applying coatings to the matrix. The notified chemical is expected to be incorporated in the matrix and not directly available for exposure.

Should dermal or ocular contact occur, the workplace controls for the foam as stated in the SDS are considered adequate to minimise exposure. These include personal protective equipment (PPE), precautions for safe handling and recommendations specific to some of the other hazardous ingredients contained in the foam.

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

This risk assessment does not cover the exposure of workers to the notified chemical during end-of-life cycle activities, such as removal and disposal of material from building renovation or demolition.

6.3.2. Public Health

The notified chemical is intended for industrial and professional use, and public use is not expected. The general public may have dermal exposure to the cured polyurethane matrix containing the notified chemical, however this is less likely because the matrix is expected to be covered by other layers, as part of the construction process. Overall, direct public exposure to the notified chemical in its proposed use is expected to be very low.

Indirect exposure of the public to the notified chemical may occur through the outdoor environment. A very small amount of the notified chemical contained in dusts is expected to end up in soil from long-term degradation of construction materials from buildings, and may lead to public exposure through inhalation or ingestion. Because of the proposed pattern of use, significant exposure to dust in the interior of dwellings is not expected. Based on outdoor human exposure estimates of up to 4.8 ng/kg bw/day for another brominated flame retardant, hexabromocyclododecane (NICNAS, 2012), which is used widely in various articles, exposure to this chemical in outdoor dust is expected to be very low.

Based on the available hazard data indicating no concerns, and on the likely very low public exposure from the proposed use pattern, the notified chemical is not considered to pose an unreasonable risk to public health.

7. ENVIRONMENTAL IMPLICATIONS

The notified chemical is a member of a class of chemicals known as brominated flame retardants (BFRs). This class of chemicals has come under increased international attention because of the potential of these chemicals to cause adverse effects to the environment and human health. The notified chemical is a replacement BFR for PBDE. The polybrominated diphenyl ether (PBDE) class of chemicals are of particular concern because they are persistent in the environment and have high potential for bioaccumulation and chronic toxicity and as such, some PBDEs have been classified as Persistent Organic Pollutants (POPs).

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical will be imported as a component of end-use foam sealants for construction. Accidental spills of the products containing the notified chemical during import, transport or storage will only occur if the packaging is breached. Spillages are expected to be adsorbed onto suitable materials and collected for disposal, in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE

At construction sites, the foam containing the notified chemical will be dispensed from 750 mL canisters via a tube or application gun, to fill gaps in joints. The foam expands considerably when dispensed and after it is dispensed, it cures in contact with moisture from the environment to form a solid matrix, containing the notified

chemical. Once the polyurethane matrix has been formed in the joint, it will be covered over (e.g. with plaster, wooden, plastic or metal plinths/strips, or with caulking/silicone sealant).

RELEASE OF CHEMICAL FROM DISPOSAL
The notified chemical is expected to share the fate of the construction material to which it has been applied, to be disposed of to landfill at the end of its useful life. During disposal any release of the notified chemical is expected to be in the form of dust from the solid matrix, containing the notified chemical. Empty containers containing the notified chemical are expected to be disposed of in accordance with local government regulations.

7.1.2. Environmental Fate
Environmental fate studies conducted on the notified chemical show that it is not readily biodegradable and neither inherently biodegradable. According to the current knowledge, the potential for bioaccumulation of the notified chemical is low. For the details of the environmental fate studies refer to Appendix C.

Most of the notified chemical will share the fate of the construction material to which it has been applied, to be disposed of to landfill at the end of its useful life. In landfill, the notified chemical will be present as cured solids and will be neither bioavailable nor mobile. Low water solubility (< 1 mg/L), high partition coefficient (log P_{ow} = 10.2) and high adsorption coefficient (log K_{oc} = 7.3) indicate the notified chemical will be immobile in soil. The notified chemical is expected to undergo slow degradation by biotic and abiotic processes and has the potential to degrade to other BFRs. Eventually it is expected to form water and oxides of carbon and simpler compounds of bromine.

7.1.3. Predicted Environmental Concentration (PEC)
The predicted environmental concentration (PEC) has not been calculated as release of the notified chemical to the aquatic environment will be limited based on its reported use pattern.

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. The endpoints are presented as nominal concentrations.

Endpoint	*Result*	*Assessment Conclusion*
Acute fish toxicity	96 h EC50 > 1,000 mg/L	Not harmful to fish up to its water solubility limit
Acute daphnia toxicity	48 h EC50 > 10 mg WAF*/L	Not harmful to aquatic invertebrates up to its water solubility limit
Chronic daphnia toxicity	21 d EL50 > 1mg/L	Does not affect the reproduction of aquatic invertebrates up to its water solubility limit.
Acute algal toxicity	72 h EC50 > 100 mg/L	Not harmful to alga up to its water solubility limit
Inhibition of bacterial respiration	3 h EC50 > 1,000 mg/L	Not inhibitory to microorganisms at STPs

*WAF: Water Accommodated Fraction

Based on the above ecotoxicological endpoints for the notified chemical, it is not expected to be harmful to aquatic life and does not affect the reproduction of aquatic invertebrates up to the limit of its water solubility. Therefore, the notified chemical is not formally classified under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) for acute and chronic toxicities (United Nations, 2009). None of the potential degradants of the notified chemical are known to have an adverse impact upon the environment, but investigations may be ongoing.

7.2.1. Predicted No-Effect Concentration
The predicted no-effects concentration (PNEC) has not been calculated as the notified chemical is not expected to be harmful to aquatic organisms up to its water solubility limit.

7.3. Environmental Risk Assessment
The notified chemical does not display the characteristics of a Persistent Organic Pollutant (POP), as is it not bioaccumulative. None of its degradants are known to have an adverse impact upon the environment, but investigations are ongoing. A Risk Quotient (PEC/PNEC) has not been calculated as the notified chemical is not

expected to be harmful up to its water solubility limit, and release to the aquatic environment will be limited, based on its reported use pattern. Therefore, based on the low hazard of the notified chemical, the current understanding of its degradants and the use as a component of foam sealants for construction, the notified chemical is not considered to pose an unreasonable risk to the environment.

8. OVERSEAS INVESTIGATIONS

The group of chemicals to which the notified chemical belongs, the brominated phthalates, has been the subject of work in Canada and the US. A member of the group is currently listed on the EU CoRAP (Community Rolling Action Plan) for evaluation, due to suspected concerns on potential endocrine disruption, suspected PBT/vPvB characteristics, wide dispersive use and environmental exposure.

The data provided on the notified chemical for this assessment do not indicate human health or environmental concerns.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point/Freezing Point -27 °C

Method DIN ISO 3016 Determination of pour point
Remarks Study summary only was provided
Test Facility Bayer (2012)

Boiling Point > 300 °C at 101.3 kPa

Method EC Council Regulation No 440/2008 A.2 Boiling Temperature
Remarks Differential Scanning Calorimetry was used. Study summary only was provided.
Test Facility Bayer (2012)

Density 1.541 kg/m^3 at 20 °C

Method EC Council Regulation No 440/2008 A.3 Relative Density
Remarks U-tube method. Study summary only was provided
Test Facility Bayer (2012)

Water Solubility < 1 mg/L at 20 °C

Method OECD TG 105 Water Solubility
EC Council Regulation No 440/2008 A.6 Water Solubility
Remarks Column Elution Method
Test Facility Consilab (2017)

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

pH	*T (°C)*	*$t_{½}$ <hours>*
4	50	30.39
7	50	44.08
9	50	77.52

Remarks The corresponding acid of the notified chemical is detected as a hydrolysis product.
Test Facility Currenta (2013a)

Partition Coefficient (n-octanol/water) log P_{ow} = 10.2

Method OECD TG 117 Partition Coefficient (n-octanol/water).
EC Council Regulation No 440/2008 A.8 Partition Coefficient.
Remarks HPLC Method, the result was extrapolated.
Test Facility Currenta (2013b)

Adsorption/Desorption log K_{oc} = 7.3

Method OECD TG 121 Adsorption Coefficient Using HPLC Method
Remarks The result was extrapolated.
Test Facility Currenta (2013c)

Flash Point 207 °C at 101.3 kPa

Method EC Council Regulation No 440/2008 A.9 Flash Point
DIN EN ISO 2719
Remarks Closed cup method. Study summary only was provided.

Test Facility	Bayer Technology Services GmbH Process & Plant Safety (PPS)

Auto-ignition Temperature 370 °C at 1013 hPa

Method	EC Council Regulation No 440/2008 A.15 Auto-Ignition Temperature (Liquids and Gases) DIN 51794
Remarks	Study summary only provided.
Test Facility	Bayer (2012)

Viscosity 2036 mP.s at 20 °C

Method	OECD TG 114 Viscosity of Liquids
Remarks	Dynamic viscosity at 20 °C. Study summary only was provided.
Test Facility	Bayer (2012)

Corrosive Properties Not corrosive to metals

Method	UN Manual of Tests and Criteria, Rev. 6 (2015) - Test C.1
Remarks	Highest weight losses over 7 days: 0.42 % wt (Steel specimen) 0.09 % wt (Aluminium specimen) The weight losses (indicating uniform corrosion) for both metals were well below the threshold of 13.5% weight loss over 7 days. Localised corrosion did not occur.
Test Facility	Consilab (2017)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 401 Acute Oral Toxicity (1981)
- Species/Strain: Rat/Charles River
- Vehicle: Maize oil (corn oil)
- Remarks - Method: Limit test (single dose)

RESULTS

Group	*Number and Sex of Animals*	*Dose (mg/kg bw)*	*Mortality*
1	5F, 5M	5000	0/10

- LD50: > 5000 mg/kg bw
- Signs of Toxicity: No signs of toxicity were reported.
- Effects in Organs: No test-item related effects were reported. A single incidence of dark areas on the thymus, and fluid distension in the uterus of another animal were considered incidental effects.
- Remarks - Results: No animal died during the study.

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

TEST FACILITY: Life Science Research (LSR) (1987a)

B.2. Acute toxicity – dermal

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 402 Acute Dermal Toxicity (1981)
- Species/Strain: Rabbit/New Zealand White
- Vehicle: N/A
- Type of dressing: Occlusive
- Remarks - Method: Limit test (single dose)

RESULTS

Group	*Number and Sex of Animals*	*Dose (mg/kg bw)*	*Mortality*
1	5 F, 5 M	2 ml/kg bw	0/10

- LD50: > 2000 mg/kg bw
- Signs of Toxicity - Local: No signs of dermal reaction were observed.
- Signs of Toxicity - Systemic: No significant signs of systemic toxicity were observed.
- Effects in Organs: Necropsy did not reveal any abnormality considered to be related to treatment.
- Remarks - Results: No animal died during the study.

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

TEST FACILITY: LSR (1987b)

B.3. Irritation – skin

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 404 (1981) Acute Dermal Irritation/Corrosion
- Species/Strain: Rabbit/New Zealand White
- Number of Animals: 3 females, 3 males

Vehicle	N/A
Observation Period	72 hours post-exposure
Type of Dressing	Semi-occlusive
Remarks - Method	GLP study A single dose of 0.5 mL of the test chemical was applied to the clipped skin of six rabbits under semi-occlusive conditions for 4 hours. Reactions were recorded 1, 24, 48 and 72 hours following exposure.

RESULTS

Lesion	*Mean Score**						*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3	4	5	6			
Erythema/Eschar	0	0.25	0	0	1	0.25	1	< 48 hours	0
Oedema	0	0	0	0	0	0	0	N/A	0

* Calculated on the basis of the scores at 1, 24, 48, and 72 hours for EACH animals

Remarks - Results	Two animals showed slight erythema (score: 1) 1 hour post-exposure, reversible within 24 hours. A third rabbit also had slight erythema (score: 1) 1 hour post-exposure, still visible within 24 hours but reversible within 48 hours. No other effects were seen.

CONCLUSION The notified chemical is slightly irritating to the skin.

TEST FACILITY LSR (1987c)

B.4. Irritation – eye

TEST SUBSTANCE Notified chemical

METHOD OECD TG 405 (1981) Acute Eye Irritation/Corrosion

Species/Strain	Rabbit/New Zealand White
Number of Animals	2 females, 4 males
Observation Period	72 hours post-exposure
Remarks - Method	N/A

RESULTS

Lesion	*Mean Score**						*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3	4	5	6			
Conjunctiva: redness	1	0.25	0.25	0.25	0.25	0.25	2	< 24 hours	0
Conjunctiva: chemosis	0	0	0	0	0	0	0	N/A	0
Conjunctiva: discharge	1	0.25	0.25	0	0.25	0	2	< 24 hours	0
Corneal opacity	0	0	0	0	0	0	0	N/A	0
Iridial inflammation	0	0	0	0	0	0	0	N/A	0

* Calculated on the basis of the scores at 1, 24, 48, and 72 hours for EACH animals

Remarks - Results	All animals showed some redness of the treated eye, and four rabbits also had discharge, 1 hour following exposure. These effects had resolved within 24 hours. All reactions were graded 1, except for one rabbit showing redness and discharge scores of 2. Two rabbits had a response to pain rated 1 'Practically no initial pain', the other rabbits had no observable response to pain.

CONCLUSION The notified chemical is slightly irritating to the eye.

TEST FACILITY LSR (1987d)

B.5. Skin sensitisation – Modified Buehler test method

TEST SUBSTANCE Notified chemical

METHOD OECD TG 406 Skin Sensitisation – Modified Buehler test method
Species/Strain Guinea pig/Dunkin-Hartley
PRELIMINARY STUDY Maximum Non-irritating Concentration: 100 %
Intradermal: N/A
Topical: The test substance was applied under occlusive dressing at a concentration of 10, 30, 50 and 100 % on the skin of 4 guinea pigs (sex not provided) for 6 hours.
The undiluted test material (100 %) was chosen for induction and challenge.
MAIN STUDY
Number of Animals Test Group: 10 M, 10 F Control Group: 5 M, 5 F
Vehicle Paraffin oil
Positive control Dinitrochlorobenzene 0.1 % (w/v)
INDUCTION PHASE Induction Concentration: 100 %
Intradermal: N/A
Topical: Each animal was exposed to undiluted test substance under occlusive patch for 6 hours, on days 1, 8 and 15 of the main study. Control group was not treated during induction but received the same treatment as treated animals for challenge phase.
Signs of Irritation No irritation was seen.
CHALLENGE PHASE
1st challenge Topical: On day 29 of the main study, the test and control animals were exposed to undiluted test substance under occlusive patch for 6 hours. On the day following exposure, each animal was examined for erythema and swelling of the treated area.
2nd challenge Topical: N/A
Remarks - Method N/A

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*			
		1st challenge		*2nd challenge*	
		24 h	*48 h*	*24 h*	*48 h*
Test Group	100 %	0/20	0/20	N/A	N/A
Control Group	100 %	0/10	0/10	N/A	N/A

Remarks - Results After challenge, a very faint erythema was observed in one animal of the control group at the 48 hour examination. No dermal reactions were observed in treated guinea pigs.
The animals challenged with the positive control dinitrochlorobenzene showed faint confluent erythema (grade 1) in 8/9 surviving animals, confirming the validity of the test system.

CONCLUSION There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.

TEST FACILITY LSR (1987e)

B.6. Repeat dose toxicity (oral)

TEST SUBSTANCE Notified chemical

METHOD Similar to OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in

	Rodents (1981)
Species/Strain	Rat/CD (Sprague-Dawley)
Route of Administration	Oral – diet
Exposure Information	Total exposure days: 28 days Dose regimen: *ad libitum* except overnight Post-exposure observation period: none (no satellite group)
Vehicle	N/A
Remarks - Method	No satellite group was used for recovery period of 14 days post-exposure. Urinalysis was carried out on the controls and high dose animals. The study used a positive control group of rats (n = 5/sex), treated with di-2-ethylhexyl phthalate (DEHP) at a concentration of 15000 ppm in the diet.

RESULTS

Group	*Number and Sex of Animals*	*Dose/Concentration*		*Mortality*
		ppm	*mg/kg bw/day (males/females)*	
control	10F, 10M	0	0	0
low dose	10F, 10M	200	21 / 23	0
mid dose	10F, 10M	2000	213 / 233	1/10 (M)
high dose	10F, 10M	20000	2210 / 2450	0
positive control	5F, 5M	15000	1370 / 1650	
control recovery	-	-	-	-
high dose recovery	-	-	-	-

Mortality and Time to Death

One male rat, from the mid dose group, died before the end of the study (during routine blood sampling).

Clinical Observations

No clinical signs of toxicity were observed in treated rats.
Food consumption was slightly lower in female rats compared with controls during the first two weeks.
High-dosed female rats had slightly lower body weight gain compared with controls.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Clinical chemistry: Two changes were observed. Plasma phosphorus concentrations were significantly lower in low-dosed and mid-dosed female rats and high-dosed male and female rats, compared with control. A 'marginally low alanine-transferase' activity was observed in high-dosed female rats, significantly different from controls.
Haematology: Mean values of prothrombin time were significantly shorter in treated groups compared with control rats, but not at the individual level.
Urinalysis: Urinary composition was unaffected by treatment.

Effects in Organs

The treatment did not affect absolute or relative organ weights during the study.
A number of lesions were observed that were not considered to be treatment-related by the study authors:

- Cortical scar of the kidney and craniopharyngeal cyst of the pituitary gland in one high-dosed male
- Interstitial inflammation of the prostate in one high-dosed male
- Stomach *lamina propria* inflammation in one high-dosed male
- Phthisis bulbi of the eye in one low-dosed male rat and one mid-dosed female
- Physiological dilatation of the uterus in two low-dosed females
- Pigmented macrophages of popliteal lymph nodes in one mid-dosed male

Minor macroscopic changes were noted in the appearance of some tissues, including lungs, cervical lymph nodes, pancreas, but none of these changes was statistically significant compared with controls.

Remarks – Results

The oral dietary administration of the test substance caused some minor changes in treated rats. However none of these effects was considered adverse. Effects on the liver and testes were seen in the positive control group. A No Observed Adverse Effect Level was not assigned by the study author.

CONCLUSION

The chemical produced no evidence of toxicity up to the highest dose tested.

TEST FACILITY LSR (1988)

B.7. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical

METHOD OECD TG 471 Bacterial Reverse Mutation Test (1983)
Plate incorporation procedure

Species/Strain	*Salmonella typhimurium*: TA1538, TA1535, TA1537, TA98, TA100
Metabolic Activation System	Rat liver microsome preparation (S-9 mix) treated with Aroclor 1254
Concentration Range in Main Test	a) With metabolic activation: 50–5000 µg/plate b) Without metabolic activation: 50–5000 µg/plate
Vehicle	Dimethyl sulfoxide (DMSO)
Remarks - Method	A preliminary cytotoxicity test was conducted (2.5–5000 µg/plate) to determine the minimum level causing a visible thinning of the bacterial lawn. This level is used as top concentration in the main test. In the main test, five concentrations of the test material (50–5000 µg/plate) were used in triplicates for each strain. Tests were conducted twice for each strain.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:* *Cytotoxicity in Preliminary Test*	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 5000	Not observed	> 5000	Negative
Test 2		Not observed	> 5000	Negative
Present				
Test 1	> 5000	Not observed	> 5000	Negative
Test 2		Not observed	> 5000	Negative

Remarks - Results There was no increase in the number of revertant colonies in any of the strains tested with the notified chemical, with or without metabolic activation. The positive controls showed the expected increases in revertant colonies, confirming the validity of the test system.

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

TEST FACILITY LSR (1987f)

B.8. Genotoxicity – *in vitro* (gene mutation assay)

TEST SUBSTANCE Notified chemical

METHOD OECD TG 476 *In vitro* Mammalian Cell Gene Mutation Test (1997)

Species/Strain	Chinese hamster
Cell Type/Cell Line	V79 cells
Metabolic Activation System	Mammalian liver microsome preparation (S9 mix) treated with phenobarbital/β-naphthoflavone
Vehicle	Acetone 0.5 %
Remarks - Method	The test substance at 0.05 mg/mL and 500 mg/mL in acetone was found to be homogeneous and stable at room temperature for at least 24 h. A preliminary toxicity test was conducted to determine the concentrations used for the main experiment.

In the main study, six concentrations of the test item were used (3–486 µg/mL). Two independent experiments were conducted, each using duplicate cultures. In experiment I, cells were exposed to the test item for 4 hours, with and without metabolic activation. In experiment II, cells were exposed to the test item for 4 hours with or 24 hours without metabolic activation.

The concentrations that could be tested were limited by phase separation seen at 54 µg/mL and above. Cultures at the highest concentration of 486 µg/mL were not evaluated, to avoid use of too many insoluble concentrations.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Experiment I	3, 9, 18, 54 [PS], 162 [PS], 486* [PS]	4 h	7 days post-treatment
Experiment II	3, 9, 18, 54 [PS], 162 [PS], 486* [PS]	24 h	7 days post-treatment
Present			
Experiment I	3, 9, 18, 54 [PS], 162 [PS], 486* [PS]	4 h	7 days post-treatment
Experiment II	3, 9, 18, 54 [PS], 162 [PS], 486* [PS]	4 h	7 days post-treatment

[PS] Phase separation
*Cultures at this concentration were removed from the analysis because of phase separation

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation/Phase separation*	*Genotoxic Effect*
Absent				
Experiment I	> 5800	> 486	≥ 54	Not observed
Experiment II	> 5800	> 486	≥ 54	Not observed
Present				
Experiment I	> 5800	> 486	≥ 54	Not observed
Experiment I	> 5800	> 486	≥ 54	Not observed

Remarks - Results

Preliminary test
No toxicity occurred up to the maximum concentration tested in the preliminary test, with or without metabolic activation. Phase separation was observed at the end of the test for all concentrations tested, indicating the poor solubility of the test item.
Concentrations chosen for the main study included a range of soluble and insoluble concentrations.

Main study
In experiments I and II, no reproducible increase in mutant colony numbers was observed up to the highest concentration analysed (162 µg/mL), with or without metabolic activation. Slight marginal increases (induction factor between 1.5–1.7 compared with the solvent control) were observed in some of the studies. They were not considered to meet the criteria for a positive response because they were less than the threefold increase threshold, were not dose dependant and/or were not seen in both cultures of the main study.

Test conditions may have been affected by the phase separation occurring at concentrations ≥ 54 µg/mL.

CONCLUSION

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

TEST FACILITY

Harlan CCR, 2013

B.9. Genotoxicity – *in vitro* (chromosome aberration assay)

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 473 *In vitro* Mammalian Chromosomal Aberration Test (1983)
Species/Strain	Human
Cell Type/Cell Line	Lymphocytes
Metabolic Activation System	Rat liver microsome preparation (S9 mix)
Vehicle	Dimethyl sulfoxide (DMSO)
Physical Form	Liquid
Remarks - Method	A preliminary test was conducted to assess the toxicity of the test item in order to choose concentrations for the main study. In the main study, cell cultures were exposed to the test item up to 1000 µg/mL, with or without metabolic activation. Initial exposure period was 2 hours in a shaking bath followed by 22 hours continuous exposure in static conditions. Cell division was stopped, using colcemid. Mitotic indexes were measured by examining 1000 cells per culture. Chromosome aberrations were measured by examining 100 metaphases per culture. Positive controls (Cyclophosphamide at 0.6 µg/mL and Chlorambucil at 0.1µg/mL) were used in the main test.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Preliminary test	0, 1.6, 8, 40, 200, 1000	24 h	24 h
Main test	0, 40, 200, 1000	24 h	24 h
Present			
Preliminary test	0, 1.6, 8, 40, 200, 1000	2 h	24 h
Main test	0, 40, 200, 1000	2 h	24 h

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Cytogenetic test	≥ 1000	> 1000	None observed	Weakly positive at 1000 µg/mL
Present				
Cytogenetic test	≥ 1000	> 1000	None observed	Weakly positive at 1000 µg/mL

Remarks - Results

Preliminary test

Mean mitotic activity was only slightly decreased at the highest concentration of the test item (7.3 compared with 8.5 in the control group). Therefore, 1000 µg/mL was chosen as the highest concentration for the main cytogenetic test.

Cytogenetic test

There was a slight increase in the number of cells with aberrations at all concentrations tested compared with the control group. While the mean incidence of aberrant cells (including gaps) was 1.3% in the control group (range 1–3%), it was 2.8% (range 2–4), 2% (range 0–3) and 4.2% (range 3–5) with increasing concentrations of the test item. The study authors considered that the increased incidence of 4.2% overall (4.3% and 4% with and without metabolic activation respectively) at the highest concentration of 1000 µg/mL had a biological and statistical significance. The incidence of aberrant cells without gaps was also statistically significant at this concentration. Statistical significance was calculated on the pooled values of aberrations with and without gaps. The positive controls produced the expected high increases in cells with aberrations, confirming the validity of the test system.

CONCLUSION The notified chemical was weakly clastogenic to human lymphocytes treated *in vitro* under the conditions of the test.

TEST FACILITY LSR (1987g)

B.10. Genotoxicity – *in vivo* (micronucleus test)

TEST SUBSTANCE Notified chemical

METHOD OECD TG 474 Mammalian Erythrocyte Micronucleus Test (1984)
Species/Strain Mice/CD-1
Route of Administration Dermal – non-occluded
Intraperitoneal
Vehicle Corn oil
Remarks - Method Preliminary test
Groups of mice (n = 2/sex/dose) were administered single intraperitoneal doses of the test item at 250, 500, 1000 or 2000 mg/kg bw and killed 72 hours post-treatment for examination.

Main test – Intraperitoneal route
Groups of mice (n = 5/sex/dose) were administered single intraperitoneal doses of the test item at 0, 80, 400 or 2000 mg/kg bw and killed 24 hours after treatment. In the control group and the high dose group, additional animals (n = 10/sex/dose) were used, and 5 animals of each group and sex were killed for examination 48 and 72 hours post-exposure.
A positive control (Chlorambucil) was orally administered to mice at 30 mg/kg bw.

Main test – Dermal route
Groups of mice (n = 10/sex/dose) were exposed to a daily dose of either corn oil or 2000 mg/kg bw of the test item on shaved skin, for 5 consecutive days. Examination was conducted 18 and 48 hours post the final treatment.

Intraperitoneal route	*Number and Sex of Animals*	*Dose (mg/kg bw)*	*Sacrifice Time (hours)*
I (vehicle control)	15M, 15F	0	24, 48, 72
II (low dose)	5M, 5F	80	24
III (mid dose)	5M, 5F	400	24
IV (high dose)	15M, 15F	2000	24, 48, 72
V (positive control)	5M, 5F	30	24

Dermal route	*Number and Sex of Animals*	*Dose (mg/kg bw)*	*Sacrifice Time (hours)*
I (vehicle control)	10 M, 10 F	0	18, 48
II (dosed group)	10 M, 10 F	2000	18, 48

RESULTS
Doses Producing Toxicity No mortality occurred before the scheduled terminations. No toxicity was observed during the study at any of the doses tested, as measured by the ratio of polychromatic and mature erythrocytes. Significant weight loss was not seen after dosing
Genotoxic Effects There was no statistically significant increase of micronuclei in the erythrocytes of treated mice compared with controls.
Remarks - Results In the preliminary test, slight piloerection was observed in all 4 animals at 1000 mg/kg bw and moderate piloerection in 2 male mice at 500 mg/kg bw. No clinical signs were noted in the main study.

CONCLUSION The notified chemical was not clastogenic under the conditions of this *in vivo* micronucleus test.

TEST FACILITY	LSR (1987h)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301B Ready Biodegradability: CO_2 Evolution Test
Inoculum	Activated sludge from a domestic sewage treatment plant (STP)
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	CO_2, Dissolved Organic Carbon (DOC) and Chemical Oxygen Demand (COD)
Remarks - Method	No major deviations from the test guidelines were reported. The test substance was added directly to the test vessels. A toxicity control was run.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
6	2	6	66
21	2	21	88
28	3	28	91

Remarks - Results	All validity criteria for the test were satisfied. The toxicity control exceeded 25% biodegradation after 14 days showing that toxicity was not a factor inhibiting the biodegradability of the test substance. The degree of degradation of the test substance after 28 days was 3%. DOC measurements indicated that the test substance was not soluble at the tested levels of 10 and 20 mg/L. COD represented only 69% of the Theoretical Oxygen Demand (ThOD), indicating the test substance was not completely oxidised under the COD test conditions.
CONCLUSION	The test substance is not readily biodegradable.
TEST FACILITY	LSR (1989a)

C.1.2. Bioaccumulation

TEST SUBSTANCE	Notified chemical
METHOD	Similar to OECD TG 305 Bioconcentration: Dietary Exposure
Species	Fathead Minnows (*Pimephales Promelas*)
Exposure Period	Exposure: 56 days Depuration: 22 days
Auxiliary Solvent	None
Feed	0.2g/day (about 6% of fish body wt) or equivalent to 150–180 µg notified chemical/fish/day
Analytical Monitoring	Gas Chromatography-Electron-Capture Negative Ion Mass Spectrometry (GC/ECNI-MS)
Remarks - Method	Fish was sampled on days 14, 28, 56 and 78 for analysis of the test substance
RESULTS	
Bio-magnification Factor	Approximately 0.17–0.20, lipid corrected, estimated from graphical representation of the concentration of notified chemical in the lipid portion of the fish.

Remarks - Results	Dietary exposure of the notified chemical induced repairable DNA damage in the hepatic tissue of fathead minnows. The notified chemical were detected in tissues at approximately 1% of daily dosage along with brominated metabolites. The exact metabolic pathways and mechanism of actions that result in the observed adverse effects to genetic integrity is largely unknown in the present study.
CONCLUSION	The notified chemical is not considered to be bioaccumulative.
REFERENCE	undisclosed reference

C.1.3. Inherent biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 302C Inherent Biodegradability: Modified MITI Test (II)
Inoculum	40% activated sludge from each of two domestic STPs, and 20% activated sludge from an industrial STP
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Biochemical Oxygen Demand (BOD) by OxiTop System
Remarks – Method	No major deviations from the test guidelines were reported. The test substance was added directly to the test vessels. A toxicity control was not run as results from the microbial activity inhibition test indicate the chosen test substance concentration in this test was not inhibitory to microorganisms.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
1	1	1	26
14	7	14	63
28	7	28	61

Remarks – Results	All validity criteria for the test were satisfied. The degree of degradation of the test substance after 28 days was 7%.
CONCLUSION	The test substance is not inherently biodegradable
TEST FACILITY	Currenta (2012a)

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	Rainbow trout - *Salmo gairdneri*
Exposure Period	96 hours
Auxiliary Solvent	Ethanol
Water Hardness	198–208 mg $CaCO_3$/L
Analytical Monitoring	HPLC-UV spectrometry
Remarks – Method	No major deviations from the test guidelines were reported. The test concentrations were prepared individually by adding ethanol (2 mL) to the appropriate weights of test material, and then adding these mixtures directly to the dilution water (20 L).

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*
Nominal	*Actual*		*96 h*
Control	0	10	0
62.5	3.14	10	0
125	5.73	10	0
250	31.34	10	0
500	15.62	10	0
1,000	15.66	10	0

LC50	>1,000 mg/L nominal concentration at 96 hours
Remarks – Results	All validity criteria for the test were satisfied. The dissolved oxygen concentration in the test solution during the test was ≥ 69%. Undissolved test material was observed at all test concentrations. Analytical results showed that the material was poorly soluble in water and not homogeneously dispersed in the test medium. Thus, the results were presented as nominal concentration.
CONCLUSION	The test substance is not harmful to fish up to its water solubility limit.
TEST FACILITY	LSR (1989b)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 202 *Daphnia sp.* Acute Immobilisation Test and Reproduction Test - Static EC Council Regulation No 440/2008 C.2 Acute Toxicity for Daphnia - Static
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	Not determined
Analytical Monitoring	None
Remarks - Method	No major deviations from the test guidelines were reported. The test concentrations were prepared individually by adding the appropriate weights of test material to dilution water (1 L) and treating in ultrasonic bath for 60 minutes, then stirring for 24 hours. Undissolved particles of the test item were removed by filtration (0.45 ± 0.2 µm) and the dissolved part or water accommodated fractions (WAFs) are used for testing.

RESULTS

Concentration mg WAF/L		*Number of D. magna*	*Number Immobilised*
Nominal	*Actual*		*48 h*
Control	Not determined	10	0
0.1	Not determined	10	0
0.4	Not determined	10	0
1	Not determined	10	0
10	Not determined	10	0

LC50	> 10 mg WAF/L (nominal concentration) at 48 hours
Remarks - Results	All validity criteria for the test were satisfied. The dissolved oxygen concentration in the test solution during the test was ≥ 8 mg/L at 21°C (≥ 90%, USGS, 2011).
CONCLUSION	The test substance is not harmful to aquatic invertebrates up to its water

solubility limit.

TEST FACILITY Currenta (2012b)

C.2.3. Chronic toxicity to aquatic invertebrates

TEST SUBSTANCE Notified chemical

METHOD OECD TG 211 *Daphnia magna* Reproduction Test
EC Council Regulation No 440/2008 C.20 *Daphnia magna* Reproduction Test

Species	*Daphnia magna*
Exposure Period	21 days
Auxiliary Solvent	None
Water Hardness	259–295 mg $CaCO_3$/L
Analytical Monitoring	HPLC-UV/VIS
Remarks - Method	A limit test was run with no major deviations from the test guidelines. The test item was directly added to the test medium.

RESULTS

Test Concentration (mg/L)		Survival (% of control)	Total no. offspring released by survived *Daphnia*
Nominal	Actual		
Control	Control	100	80
1	<LOQ*	90	84

**LOQ: Limit of quantitation of 0.0334 mg/L*

21 day EL50	> 1 mg/L (nominal concentration)
21 day NOEL	≥ 1 mg/L (nominal concentration)
Remarks - Results	All the validity criteria for the test were satisfied. During the test, dissolved oxygen concentration in the test water was ≥ 8.0 mg/L at 19°C (≥ 86% saturation; USGS 2011).

CONCLUSION The test substance does not affect the reproduction of aquatic invertebrates up to its water solubility limit.

TEST FACILITY Currenta (2012c)

C.2.4. Algal growth inhibition test

TEST SUBSTANCE Notified chemical

METHOD OECD TG 201 Alga, Growth Inhibition Test
EC Council Regulation No 440/2008 C.3 Algal Inhibition Test

Species	*Desmodesmus subspicatus* (formerly *Scene-desmus subspicatus*)
Exposure Period	72 hours
Concentration Range	Nominal: 100 mg/L Actual: < LOQ of 0.0334 mg/L
Auxiliary Solvent	None
Water Hardness	22.5 mg $CaCO_3$/L
Analytical Monitoring	HPLC-UV/VIS
Remarks - Method	A limit test was run with no major deviations from the test guidelines. The test item was directly added to the test medium. The test water was sampled for HPLC analysis of test substance at 0 and 72 hours.

RESULTS

Biomass		*Growth*	
EC50 (mg/L at 72 h)	*NOEC (mg/L)*	*EC50 (mg/L at 72 h)*	*NOEC (mg/L)*
> 100	≥ 100	> 100	≥ 100

Remarks - Results	All the validity criteria for the test were satisfied. The mean cell density in the control increased by 111 times.
CONCLUSION	The test substance is not harmful to alga up to its water solubility limit.
TEST FACILITY	Currenta (2012d)

C.2.5. Inhibition of microbial activity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test EC Council Regulation No 440/2008 C.11 Biodegradation: Activated Sludge Respiration Inhibition Test
Inoculum	Activated sludge
Exposure Period	3 hours
Concentration Range	Nominal: 10, 100, and 1,000 mg/L
Remarks – Method	No major deviations from the test guidelines were reported. The test item was directly added to the test medium.
RESULTS	
IC50	> 1,000 mg/L (nominal concentration)
Remarks – Results	All the validity criteria for the test were satisfied
CONCLUSION	The test substance is not inhibitory to microbial organisms at STPs
TEST FACILITY	Currenta (2012e)

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