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October 2017

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

D-Glucose, reaction products with nitric acid and sodium nitrite (1:1), sodium salts

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

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SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
STD/1616	Baker Hughes Australia Pty Ltd	D-Glucose, reaction products with nitric acid and sodium nitrite (1:1), sodium salts	ND*	≤ 300 tonnes per annum	Cooling water additive for industrial use

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified chemical cannot be classified 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.

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 its low hazard, its maximum annual importation volume, 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

- Based on the available hazard/toxicity data, no specific engineering controls, work practices or personal protective equipment are required for the safe use of the notified chemical itself. However, these should be selected on the basis of all ingredients in the formulation.

  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 containment, physical collection and subsequent safe disposal.

Regulatory Obligations

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

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

(1) Under Section 64(1) of the Act; if
- further information becomes available on the toxicity of the notified chemical;
- the notified chemical is imported in powder form;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from cooling water additive for industrial use, or is likely to change significantly;
- the amount of chemical being introduced has increased, or is likely to increase, significantly;
- the chemical has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

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

Safety Data Sheet
The 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(S)
Baker Hughes Australia Pty Ltd (ABN: 20 004 752 050)
Level 7 256 St George Tce PERTH WA 6000

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
No details are claimed exempt from publication.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: Flammability, Acute Dermal Toxicity, Repeated Dose Toxicity, in vitro Genotoxicity

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
US, Canada, EU

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Waterline™ CI (product containing the notified chemical at 52%)

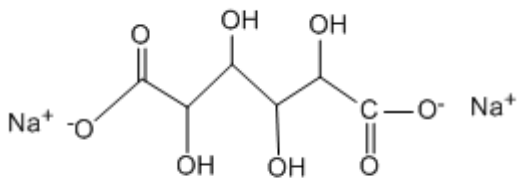
CAS NUMBER
1362053-75-5

CHEMICAL NAME
D-Glucose, reaction products with nitric acid and sodium nitrite (1:1), sodium salts

MOLECULAR FORMULA
Unspecified

STRUCTURAL FORMULA

Main component of UVCB



Di-sodium glucarate

In addition to the above component, in the analytical report the notified chemical is shown to contain other components as follows: sodium gluconate, disodium tartrate, disodium oxalate, sodium nitrite, sodium nitrate, sodium glycolate, disodium tartronate, mixed 2-, 3-, 4- and 5-keto-gluconate, sodium formate, sodium glucuronate, sodium maribersonate and sodium carbonate.

MOLECULAR WEIGHT
< 500 Da (components of UVCB)

ANALYTICAL DATA
Reference IC/MS, IR, UV, NMR and AAS spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
UVCB (variable composition)

IMPURITIES/RESIDUAL MONOMERS
None, as notified chemical is a UVCB

ADDITIVES/ADJUVANTS
None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: beige powder

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Suspected decomposition was observed between 96 °C and 145 °C
Boiling Point	> 80 °C	Decomposed at > 80 °C
Density	947 kg/m^3 at 20 °C	Measured
Vapour Pressure	0.75 kPa at 20 °C	Measured
Water Solubility	Miscible	Measured
Hydrolysis as a Function of pH	Not determined	Contains components which could be hydrolysed in the environmental pH range (4-9).
Partition Coefficient (n-octanol/water)	log P_{ow} < -2 at 20 °C	Measured
Adsorption/Desorption	log Koc = -1.02	Estimated for Analogue D-Gluconic Acid* (OECD SIDS, 2004)
Dissociation Constant	pKa = 3.7	Estimated for Analogue D-Gluconic Acid* (OECD SIDS, 2004)
Surface tension	67.7 mNm at 20 °C	Measured
Flash Point	> 100 °C at 102.5 kPa	Measured (product)
Flammability	Not determined	Imported in an aqueous solution
Autoignition Temperature	> 600 °C	Measured (product)
Explosive Properties	Considered negative	Measured (product)
Oxidising Properties	Not considered to be an oxidising liquid	Measured (product)

* D-Gluconic acid (CAS No. 526-95-4)

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 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 be imported at ≤ 52% concentration in water or at 30% concentration in a formulation.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	≤ 300	≤ 300	≤ 300	≤ 300	≤ 300

PORT OF ENTRY
Australia wide

IDENTITY OF RECIPIENTS
Baker Hughes Australia Pty Ltd

TRANSPORTATION AND PACKAGING
Waterline™ CI containing the notified chemical at 52% concentration will be imported into Australia in sealed 200 or 205 L drums with other (chemically compatible) products in either 6 or 12 m sealed shipping containers by sea. Upon arrival in Australia, the shipping containers will be transported by road transport to the reformulation sites.

Once reformulated, the formulated product will be transferred into either 1,000 L plastic Schütz containers or 1,350 L (or larger) stainless steel IBCs and transported via road transport directly to one of a number of potential customer locations. Upon arrival at a customer location the product may be decanted again into a larger storage tank.

USE
The notified chemical will be used as an additive at ≤ 30% in open recirculating cooling water systems in industrial facilities such as refineries and petrochemical plants.

OPERATION DESCRIPTION
Reformulation
Waterline™ CI containing the notified chemical at 52% concentration in water will be pumped from imported drums into the bottom of the mixing vessel, where it blends with other components. The pumping process consists of one sparge (a metal tube, two inches in diameter and approximately 1 meter long), two AS2117 compliant hoses and one pump. One end of each of the hoses is connected to the pump and the sparge is connected to the other end of the first hose. The other end of the second hose is connected to the bottom of the mixing vessel using a cam lock coupling, quick–connection. The transfer process occurs within a contained area with an impervious surface.

Once blended with the other components in the formulation, a sample of approximately 200 mL will be taken for quality control (QC) testing. Once the formulated product is deemed to meet QC specifications, the same sparge, pump and hoses are used to transfer the formulated product containing the notified chemical at ≤ 30% concentration to intermediate bulk containers (IBCs) in order to facilitate easier use by the customer.

End use
At the customers' sites, formulated products in IBCs containing the notified chemical at ≤ 30% concentration will be injected into the cooling water system via a chemical injection system which consists of a supply tank, piped to the suction of either an air driven or electric motor chemical injection pump. The discharge line of the pump is then hard-piped, using high pressure rated stainless steel piping, to a suitable injection point on the cooling water system. Chemical injection pump discharges are generally fitted with pressure sensing relief valves, to prevent over pressuring and rupture.

A typical injection rate from several ppm to several tens of ppm (< 0.01%) will depend on system-specific factors such as location, fluid chemistry and velocity, etc.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and storage workers	1	5-10
Reformulation plant workers	2-3	10-20
Oil field technicians	1	10-20

EXPOSURE DETAILS
Transport and storage workers are not expected to be exposed to the notified chemical (at ≤ 52 % concentration) except in the unlikely event of an accidental release due to container breach or spill.

Dermal and ocular exposure of reformulation plant workers to the notified chemical at up 52% concentration may occur during opening and closing of containers and coupling/decoupling of transfer hoses. At this stage of the process, inhalation exposure is not expected due to the relatively low vapour pressure (0.75 kPa). Personal protection equipment (PPE) is expected to be worn to minimise worker exposure.

Oil field technicians could potentially be exposed orally and dermally to the notified chemical at very low concentrations (< 0.01%) in the application process of formulated products, as workers at customer sites are only involved in the storage and movement of IBCs at their facility. The only potential for exposure for a field technician is either during a change-over or topping up of the base tank or when checking the injection rate of the formulated product. Exposure to the notified chemical through inhalation is not expected due to its low vapour pressure. PPE is expected to be worn to minimise worker exposure.

6.1.2. Public Exposure
The notified chemical will only be used at industrial facilities and public exposure is not expected.

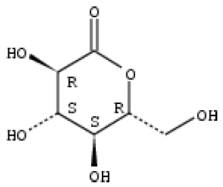
6.2. Human Health Effects Assessment

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.

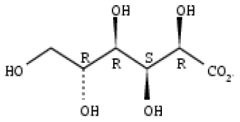
Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 > 5,000 mg/kg bw; low toxicity
Skin irritation (in vitro) Skin Irritation: Reconstructed Human Epidermis Test Method (52%)	not irritating
Eye irritation (in vitro) Bovine Corneal Opacity and Permeability Test Method for Identifying Ocular Corrosives and Severe Irritants (52%)	not irritating
Mouse, skin sensitisation – Local lymph node assay (52%)	no evidence of sensitisation
Mutagenicity – bacterial reverse mutation (52%)	not mutagenic

Identity of analogue chemicals
Use of information from the OECD SIDS report on Gluconic acid and derivatives (OECD, 2004) was considered adequate for hazard assessment of the notified chemical for the endpoints repeated dose toxicity and genotoxicity. Analogues used were:

Glucono-deltalactone (CAS No. 90-80-2)

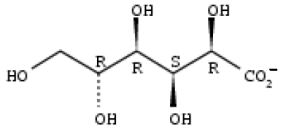


Sodium D-gluconate (CAS No. 527-07-1)



• Na

Calcium D-gluconate (299-28-5 and 18016-24-5)



• 1/2 Ca

Toxicokinetics, metabolism and distribution
Given the low molecular weight of the components of the notified chemical (< 500 Da), there is potential for absorption across biological membranes. However, dermal absorption may be limited by the hydrophilic nature of these components, as demonstrated by its high water solubility and low partition coefficient (log Pow < -2).

Acute toxicity
The notified chemical was found to have low acute oral toxicity in rats. No data on acute dermal and inhalation toxicity are available.

Based on the very low acute oral toxicity (LD50 > 5,000 mg/kg) and the very low partition coefficient (log Kow < -2), the acute dermal toxicity of the notified chemical is expected to be low.

Irritation
Based on *in vitro* studies, the notified chemical tested at 52% was not considered to meet the criteria for classification as a skin or eye irritant under the GHS.

Sensitisation
The notified chemical tested at 52% was not a skin sensitiser in a mouse local lymph node assay (LLNA) using BrdU-ELISA (Enzyme-Linked Immunosorbent Assay).

Repeated dose toxicity
No information on repeated dose toxicity of the notified chemical was available.

The NOAEL of the analogue sodium D-gluconate determined from a 28 day oral study in rats was 1,000 mg/kg bw/day for males and 2,000 mg/kg bw/day for females (OECD SIDS, 2004).

Mutagenicity/Genotoxicity
The notified chemical tested at 52% was not mutagenic in a bacterial reverse mutation assay.

The available in vitro and in vivo mutagenicity data on the analogue chemicals glucono-delta-lactone, sodium or calcium gluconate were all negative (OECD SIDS, 2004).

Health hazard classification
Based on the available information, the notified chemical cannot be classified 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
Based on the available in vitro data, the notified chemical at 52% concentration is not classified as irritating to the eyes and skin under the GHS. The available data are insufficient to consider the notified chemical for classification for these endpoints under the GHS.

6.3.1. Occupational Health and Safety
Worker exposure to the notified chemical is expected to be limited, based on the use scenarios. During reformulation, workers may be exposed to the notified chemical at 52% concentration during opening and closing of containers and coupling/decoupling of transfer hoses. During end-use, oil field technicians may be exposed to the notified chemical at very low concentrations (≤ 0.01%) when applying the formulated products. Appropriate PPE will be used to limit workers' exposure.

Therefore, under the occupational settings described, the risk to the health of workers from use of the notified chemical is not considered to be unreasonable.

6.3.2. Public Health
As the public is not expected to have exposure to the notified chemical, the risk to public health is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE
The notified chemical will be imported either as a component of a formulated product, or as a 52% solution in water for reformulation into a cooling water additive at reformulations sites in Australia. The reformulation process will occur within a contained area. Therefore, release of the notified chemical to the environment during reformulation, storage and transport is expected to be limited to accidental spills and leaks, which are expected to be absorbed on suitable materials and disposed of to landfill in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE
At the end-users sites, the formulated products containing the notified chemical will be injected into the cooling water systems in areas with secondary containment on an impervious floor. Release of the notified chemical to the environment due to accidental spills and leaks is expected to be absorbed on suitable materials, and disposed of to landfill in accordance with local government regulations. As a worst case scenario, 100% of annual import volume of the notified chemicals could be released to sewers through discharge of saturated cooling water.

RELEASE OF CHEMICAL FROM DISPOSAL
The empty import containers containing small amounts of residual notified chemical will be sent to a licensed company for safe disposal, and the empty end-used containers will be returned to the re-formulation facilities and re-used for the subsequent batch of formulated products.

7.1.2. Environmental Fate
Following its use, the majority of the notified chemical is expected to be released to sewers through discharge of saturated cooling water. A small amount of the notified chemical may also be released through condensation on the cooling water towers; however, based on its relatively low vapour pressure (0.75 kPa) and high water solubility, the notified chemical is unlikely to partition to the air compartment and is expected to remain as residue on cooling tower surfaces. For the details of the physical and chemical properties, please refer to Appendix A.

A ready biodegradation test conducted on the notified chemical indicates that the notified chemical is not readily biodegradable, but shows inherent biodegradability in aquatic environment (67% degradation over 28 days). For details of the biodegradation study, please refer to Appendix C. The notified chemical released to sewers is expected to be degraded quickly and effectively through biological wastewater treatment process before being released to surface water (OECD SIDS, 2004). The sodium ions released during the degradation can be removed by precipitation or adsorption to the sludge (OECD SIDS, 2004). Because of its water solubility and low log K_{ow} (< -2), the notified chemical is not expected to bioaccumulate. Any notified chemical being released to surface water is expected to eventually degrade through biotic and abiotic processes to form water and oxides of carbon and inorganic salts.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has been calculated to assume the worst case scenario, with 100% release of the notified chemical to a local sewage treatment plant (STP) over 260 working days per year, and no removal of the notified chemical by the local STP. A conservative flow rate of 40 ML/day of the smallest Australian STP in our database was used for the calculation as the worst case scenario.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	300,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	300,000	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	1153	kg/day
Individual Sewage Treatment Plant Average Daily Flow	40	ML/day
Removal within STP	0%	Mitigation
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	29	mg/L
PEC - Ocean:	2.9	mg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1,000 L/m^2/year (10 ML/ha/year). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1,500 kg/m^3). Using these assumptions, irrigation with a concentration of 29 mg/L may potentially result in a soil concentration of approximately 0.19 g/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of the notified chemical in the applied soil in 5 and 10 years may be approximately 0.96 g/kg and 1.9 g/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.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	LC50 (96h) > 1,448 mg/L	Not harmful to fish
Daphnia Toxicity	EC50 (48h) > 1,480 mg/L	Not harmful to aquatic invertebrates
Algal Toxicity	EC50 (72h) = 169 mg/L, NOEC = 68 mg/L	Not harmful to alga

Based on the above ecotoxicological endpoints for the notified chemical, it is not expected to be harmful to aquatic organisms. 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).

7.2.1. Predicted No-Effect Concentration

A predicted no-effect concentration (PNEC) for the aquatic compartment has not been calculated, since the notified chemical is not considered to be harmful to aquatic organisms.

7.3. Environmental Risk Assessment

The risk quotient (Q = PEC/PNEC) of the notified chemical has not been calculated as the PNEC was not calculated. Following its use, the majority of the notified chemical is expected to be released to sewers through discharge of saturated cooling water. The conservative PEC under the worst case scenario was estimated to be 29

mg/L which is lower than the no observed effect concentration (NOEC) = 68 mg/L of the most sensitive ecotoxicological endpoint alga, indicating that the release of the notified chemical during the cooling processes is not expected to lead to ecotoxicologically significant concentrations in the aquatic environment. The notified chemical is not expected to bioaccumulate based on its high water solubility and low log K_{ow}. Therefore, on the basic of its low hazard, its maximum annual importation volume and the assessed use pattern, the notified chemical is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point/Freezing Point Not determined (notified chemical)

Method	OECD TG 102 Melting Point/Melting Range. EC Council Regulation No 440/2008 A.1 Melting/Freezing Temperature.
Remarks	Photocell detection method was used. Suspected sample decomposition was observed during the test runs between 96 and 145 °C. The sample expanded and rose up the sample tube.
Test Facility	Chilworth Technology Limited (2015)

Boiling Point > 80 °C (notified chemical)

Method	OECD TG 103 Boiling Point. EC Council Regulation No 440/2008 A.2 Boiling Temperature.
Remarks	Differential Scanning Calorimetry method was used. A broad endotherm was observed at 80 °C which then went up to 110 °C. This was a characteristic of water being lost from the sample. This was followed by an exothermic event. The sample decomposed at > 80 °C.
Test Facility	Chilworth Technology Limited (2015)

Density 947 kg/m^3 at 20 °C (notified chemical)

Method	OECD TG 109 Density of Liquids and Solids. EC Council Regulation No 440/2008 A.3 Relative Density.
Remarks	Pycnometer method was used.
Test Facility	Chilworth Technology Limited (2015)

Vapour Pressure 0.75 kPa at 20.2 °C (notified chemical)

Method	OECD TG 104 Vapour Pressure. EC Council Regulation No 440/2008 A.4 Vapour Pressure.
Remarks	Static method was used.
Test Facility	Chilworth Technology Limited (2015)

Water Solubility > 1,000 g/L at 20 °C (notified chemical)

Method	OECD TG 105 Water Solubility. EC Council Regulation No 440/2008 A.6 Water Solubility.
Remarks	Flask Method was used. The test substance was miscible with water.
Test Facility	Chilworth Technology Limited (2015)

Partition Coefficient (n-octanol/water) log Pow = < -2 at 20 °C (notified chemical)

Method	OECD TG 117 Partition Coefficient (n-octanol/water). EC Council Regulation No 440/2008 A.8 Partition Coefficient.
Remarks	Flask Method was used.
Test Facility	Chilworth Technology Limited (2015)

Surface Tension 67.7 mN/m at 20 °C (notified chemical)

Method	EC Council Regulation No 440/2008 A.5 Surface Tension.
Remarks	Ring Method was used.
Test Facility	Chilworth Technology Limited (2015)

Flash Point > 100 °C at 102.5 kPa (product)

Method	EC Council Regulation No 440/2008 A.9 Flash Point.
Remarks	Pensky-Martens closed cup apparatus was used. No flash was observed. The test sample started boiling at around 90 ºC, producing grey vapours which extinguished the test flame.

The test was terminated at 100 ºC.
Test Facility Chilworth Technology Limited (2017a)

Autoignition Temperature product

Method EC Council Regulation No 440/2008 A.15 Auto-Ignition Temperature (Liquids and Gases).
Remarks A few orange sparks were observed about 1-2 seconds after injection of sample. As the sample contained a large proportion of water, it is suspected that boiling may quench any potential ignition and the sparks produced were from salt contact of the sample. A second injection was carried at 600°C at 100 µL to confirm a no ignition after being clear at first attempt.
Test Facility Chilworth Technology Limited (2017a)

Explosive Properties Considered negative (product)

Method EC Council Regulation No 440/2008 A.14 Explosive Properties.
Remarks The test substance was observed to exhibit no reaction at 40 J when the BAM Fallhammer apparatus was used. The test substance did not exhibit an explosion during any of the tests when Koenen tube was used.
Test Facility Chilworth Technology Limited (2017b)

Oxidizing Properties Not considered to be an oxidising liquid (product)

Method EC Council Regulation No 440/2008 A.21 Oxidizing Properties (Liquids).
Remarks The test substance was found to have a mean pressure rise time greater than that observed for the nitric acid reference sample.
Test Facility Chilworth Technology Limited (2017a)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical (51.2% in water)
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/Sprague-Dawlery
Vehicle	None
Remarks - Method	A limit test was used. No protocol deviations, except that the dosage of 5,000 mg/kg bw was higher than that described in the test guideline. Dosage was adjusted to take account of the concentration of the material tested.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	1 F	5,000	0/1
2	2 F	5,000	0/2

LD50	> 5,000 mg/kg bw
Signs of Toxicity	No signs of toxicity were noted for any of the three animals during the study.
Effects in Organs	No gross pathological findings were noted in any rat at necropsy.
Remarks - Results	All three animals gained body weight during the study.
CONCLUSION	The test substance is of low toxicity via the oral route.
TEST FACILITY	Nucro Technics (2015)

B.2. Irritation – skin (in vitro)

TEST SUBSTANCE	Notified chemical (52% in water)
METHOD	OECD TG 439 In vitro Skin Irritation: Reconstructed Human *Epidermis* Test Method (2015)
Vehicle	None
Remarks - Method	A minor deviation to the protocol was reported, but was not considered to affect the validity of the study. Phosphate buffered saline and 5% sodium dodecyl sulfate were used as negative control and positive control respectively. Test system of EpiDerm™ Tissue Models was used. Tissue viability meets the acceptance criterion for the negative control if the mean optical densities of the three samples are ≥ 1.0 and ≤ 2.5, slightly different to OECD TG 439 (for EpiDerm™, acceptability ranges for negative control OD values are ≥ 0.8 and ≤ 2.8). A statistical analysis was not performed.

RESULTS

Test material	*Relative mean Viability (%)*
Negative control	100.0
Test substance	78.2
Positive control	3.4

Remarks - Results	Optical density data were not provided. There was no explicit statement in the study report confirming the criteria for a valid test had been met. As the mean tissue viability was > 50%, the test substance was considered not to meet the criteria for classification as an irritant Category 2 under the GHS.
CONCLUSION	The test substance was non-irritating to the skin under the conditions of the test.
TEST FACILITY	Bioscience Laboratories Inc. (2016a)

B.3. Irritation – eye (in vitro)

TEST SUBSTANCE	Notified chemical (52% in water)
METHOD	OECD TG 437 Bovine Corneal Opacity and Permeability Test Method for Identifying Ocular Corrosives and Severe Irritants (2009)
Vehicle	None
Remarks - Method	No protocol deviations. Water for irrigation and ethanol were used as negative control and positive control respectively.

RESULTS

Test material	*Mean opacities of triplicate tissues*	*Mean permeabilities of triplicate tissues (OD_{490})*	*IVIS (SD)*
Vehicle control	0.985	-	-
*Test substance**	3.006	0.0322	2.3 (1.054)
*Positive control**	8.111	2.080	38.45 (7.470)

IVIS = in vitro irritancy score
*Corrected for background values
Standard deviation for mean opacities of triplicate tissues and mean permeabilities of triplicate tissues was not reported.

Remarks - Results	The IVIS for the positive control was in the acceptable range therefore the criteria for a valid test had been met. According to the TG, a test substance having IVIS score of ≤ 3 is classified as "No Category" under the GHS.
CONCLUSION	The notified chemical was not an eye irritant under the conditions of the test.
TEST FACILITY	Bioscience Laboratories Inc. (2016b)

B.4. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE	Notified chemical (52% in water)
METHOD	OECD TG 442B Skin Sensitisation: Local Lymph Node Assay: BrdU-ELISA
Species/Strain	Mouse/CBA/JN
Vehicle	Acetone:olive oil (4:1, v/v)
Preliminary study	Yes
Positive control	Hexylcinnamaldehyde
Remarks - Method	Doses for the main test were chosen on the basis of a pre-test, which indicated no systemic toxicity or excessive local skin irritation.

RESULTS

Concentration (% w/w)	*Number and sex of animals*	*Optical Density*	*Stimulation Index (Test/Control Ratio)*
Test Substance			
0 (vehicle control)	5 F	0.239	1.000 ± 0.068
25	5 F	0.318	1.332 ± 0.163
50	5 F	0.303	1.266 ± 0.181
100	5 F	0.274	1.147 ± 0.159
Positive Control			
25	5 F	0.524	2.191 ± 0249

Remarks - Results

No mortalities occurred in this study. No adverse clinical signs were observed. All five positive control females showed very slight erythema (barely perceptible) on both ears on day 3, but this was not perceptible on day 6.

No gross findings were noted on the lymph nodes of the animals. Over the 6-day period, the test substance at all three concentrations and the negative control resulted in no change in ear thickness while the positive control resulted in mean increase of 0.03 mm in ear thickness.

There were no significant differences in body weights or body weight gains in any of the groups compared to the negative control group during the treatment period.

The negative control and all three concentrations of the test substance were considered to have negative responses as the stimulation index (SI) was < 1.6. The SI for the positive control at 25% was > 1.6, confirming the validity of the test.

CONCLUSION

There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical.

TEST FACILITY

Nucro Technics (2016)

B.5. Genotoxicity – bacteria

TEST SUBSTANCE

Notified chemical (52% in water)

METHOD

OECD TG 471 Bacterial Reverse Mutation Test.
Plate incorporation procedure (test 1)/Pre incubation procedure (test 2)

Species/Strain: *S. typhimurium*: TA1535, TA1537, TA98, TA100
E. coli: WP2uvrA

Metabolic Activation System: Rat liver S9 corresponds to 9000 x g fraction of liver homogenate from male Sprague-Dawlery rats treated with Aroclor 1254.

Concentration Range in Main Test: a) With metabolic activation: 0, 0.31, 0.63, 1.3, 2.5, 5.0 µg/plate
b) Without metabolic activation: 0, 0.31, 0.63, 1.3, 2.5, 5.0 µg/plate

Vehicle: Water

Remarks - Method: Minor deviation did not affect the validity of the study.

RESULTS

Metabolic Activation	*Test Substance Concentration (µL/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent	> 5.0			
Test 1		> 5.0	> 5.0	negative
Test 2		> 5.0	> 5.0	negative

Present	> 5.0			
Test 1		> 5.0	> 5.0	negative
Test 2		> 5.0	> 5.0	negative

Remarks - Results

The colony counts per plate were within or below the concurrent negative control range for all tester strains and conditions for the main plate incorporation test.

The colony counts per plate were within or below the concurrent negative control range for all tester strains and conditions for the main pre incubation test with one exception, however, the slight increase in colony counts was not statistically significant (P > 0.01). The mean transformed colony counts for all conditions were also within the historical negative control range

The concurrent positive and negative controls produced satisfactory responses, thus confirming the activity of the S9-mix and the sensitivity of the bacterial strains.

CONCLUSION

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

TEST FACILITY

Nucro Technics (2017)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	The Waterline™ CI product containing approximately 52% of notified chemical (corrected for % solids)
METHOD	OECD TG 301 D Ready Biodegradability: Closed Bottle Test
Inoculum	Supernatant from settled secondary wastewater effluent
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Dissolved oxygen concentration measured by an oxygen electrode
Remarks - Method	No significant deviations from the test guidelines were reported. The test solution and the reference solution with COD concentration of 4 mg/L were prepared from concentrated stocks and inoculated mineral medium. The solutions were then dispensed into BOD bottles.

RESULTS

Test substance		*Potassium Hydrogen Phthalate*	
Day	*% Degradation*[*]	*Day*	*% Degradation*[*]
4	30.0	4	66.3
7	47.5	7	77.5
11	50.0	11	81.3
14	56.2	14	83.8
21	57.5	21	85.0
28	66.6	28	86.3

[*]Mean value of two replicates

Remarks - Results	All validity criteria for the test were satisfied. The percentage degradation of the reference compound, potassium hydrogen phthalate surpassed the threshold level of 60 % within 14 days indicating the suitability of the inoculums. The toxicity control exceeded 25% biodegradation after14 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 66.6%.
CONCLUSION	The test substance is not readily biodegradable, but shows inherent biodegradability.
TEST FACILITY	AquaTox Testing and Consulting Inc. (2015)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	The Waterline™ CI product containing approximately 52% of notified chemical (corrected for % solids)
METHOD	OECD TG 203 Fish, Acute Toxicity Test – Static
Species	*Oncorhynchus Mykiss*
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	Photometric method at 210 nm

Remarks – Method	No significant deviations from the test guidelines were reported. The test substance was weighted and directly added into the 20 L plastic pails with 15 L of dilution water. The solutions were hand mixed prior to introduction of test organisms.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control	Control	20	0	0	0	0	0
2000	1448	20	0	0	0	0	0

LC50	> 1,448 mg/L at 96 hours
NOEC (or LOEC)	Not determined
Remarks – Results	All validity criteria for the test were satisfied.

CONCLUSION	The test substance is not harmful to fish.
TEST FACILITY	AquaTox Testing and Consulting Inc. (2016)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	The Waterline™ CI product containing approximately 52% of notified chemical (corrected for % solids)
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test - Static
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	200 mg $CaCO_3$/L
Analytical Monitoring	Photometric method at 210 nm
Remarks - Method	No significant deviations from the test guidelines were reported. The test solution was prepared by weighting the test substance directly into 500 mL volumetric flasks and making this up using dilution water. The solutions were hand mixed prior to addition of the test organisms.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
Control	Control	20	0	0
2000	1480	20	0	0

EC50	> 1,480 mg/L at 48 hours
NOEC (or LOEC)	Not determined
Remarks - Results	All validity criteria for the test were satisfied.

CONCLUSION	The test substance is not harmful to aquatic invertebrates.
TEST FACILITY	AquaTox Testing and Consulting Inc. (2016)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE	The Waterline™ CI product containing approximately 52% of notified chemical (corrected for % solids)
METHOD	OECD TG 201 Alga, Growth Inhibition Test
Species	*Pseudokirchneriella Subcapitata*
Exposure Period	72 hours
Concentration Range	Nominal: 6.6, 14.8, 32.8, 72.9, 162, 360, 800 mg/L

	Actual: 5, 13, 30, 68, 147, 333 mg/L (time-weighted mean measured test concentrations)
Auxiliary Solvent	None
Water Hardness	Unknown
Analytical Monitoring	HPLC-UV detector
Remarks - Method	No significant deviations from the test guidelines were reported. The test solutions were prepared from a concentrated stock and laboratory dilution water.

RESULTS

Biomass		*Growth*	
EC50	*NOEC*	*EC50*	*NOEC*
mg/L at 72 h	*mg/L*	*mg/L at 72 h*	*mg/L*
169 (95% CL 150-189)	68	> 333	30

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

CONCLUSION The test substance is not harmful to alga.

TEST FACILITY AquaTox Testing and Consulting Inc. (2015)

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