File No: STD/1589

May 2017

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Nitric acid, ammonium calcium salt (1:?:?)

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/1589	Yara Australia Pty Ltd	Nitric acid, ammonium calcium salt (1:?:?)	Yes	< 20,000 tonnes per annum	An emulsifying agent in offshore oil and gas, and mining applications

CONCLUSIONS AND REGULATORY OBLIGATIONS

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

Hazard classification	*Hazard statement*
Acute Toxicity (Category 4)	H302 - Harmful if swallowed.
Serious eye damage/eye irritation (Category 1)	H318 - Causes serious eye damage

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

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

Environmental risk assessment
On the basis of the low toxicity to aquatic organisms and low potential for exposure to the aquatic environment, the notified chemical is not considered to pose an unreasonable risk to the environment.

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- The notified chemical should be classified as follows:
  - H302 - Harmful if swallowed.
  - H318 - Causes serious eye damage

The above should be used for products/mixtures containing the notified chemical, if applicable, based on the concentration of the notified chemical present and the intended use/exposure scenario.

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical:
  - Avoid direct skin and eye contact

- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical:
  - Gloves
  - Face shield, chemical glasses or goggles
  - Protective clothing.

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

- A copy of the (M)SDS should be easily accessible to employees.

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Globally Harmonised System 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 and/or accidental release of the notified chemical should be handled by physical containment, collection and subsequent safe disposal.

Regulatory Obligations

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

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

(1) Under Section 64(2) of the Act; if
  - the function or use of the chemical has changed from an emulsifying agent in offshore oil and gas, and mining applications, 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.

No additional secondary notification conditions are stipulated.

Safety Data Sheet
The SDS of 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)
Yara Australia Pty Ltd (ABN: 77 076 301 221)
Level 1, 6 Holt Street,
MCMAHONS POINT NSW 2060

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: analytical data, degree of purity, manufacture/import volume, and site of manufacture.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: Melting point/Boiling point, Vapour pressure, Hydrolysis as a Function of pH, Partition coefficient, Absorption/Desorption, Dissociation constant and Flash point.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
European Union: REACH (2010)
Turkey (2011)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Petrocare
DipCal
NitCal
CN-TQ

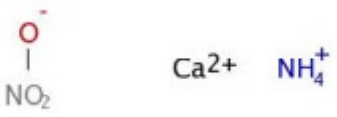
CAS NUMBER
15245-12-2

CHEMICAL NAME
Nitric acid, ammonium calcium salt (1:?:?)

OTHER NAME(S)
Calcium ammonium nitrate

MOLECULAR FORMULA
$Ca.xH_3N.xHNO_3$

STRUCTURAL FORMULA



MOLECULAR WEIGHT
120.12 Da

ANALYTICAL DATA
Reference NMR and IR spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 90%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: White granule

Property	Value	Data Source/Justification
Melting Point/Freezing Point	> 400 °C	Measured
Boiling Point	Not determined	The notified chemical does not melt below 400 °C
Density	2,050 kg/m^3 at 20 °C	Measured
Vapour Pressure	Not determined	The notified chemical is a solid inorganic chemical. It did not melt up to 400 °C.
Water Solubility	100 g/L at 20 °C	(M)SDS
Hydrolysis as a Function of pH	Not determined	The chemical is a salt and will predominately exist as Ca^{2+}, NH_4^+ and NO_3^- in environmental waters. Significant hydrolysis of these ions is not expected at environmental pH range.
Partition Coefficient (n-octanol/water)	Not determined	The chemical is expected to stay in water phase as it is highly soluble in water
Adsorption/Desorption	Not determined	The chemical is a salt and will predominately exist as Ca^{2+}, NH_4^+ and NO_3^- in environmental waters. These cations or anions are mobile in water and not expected to absorb to soil or sediment significantly.
Dissociation Constant	Not determined	The chemical is a salt and will predominately exist as Ca^{2+}, NH_4^+ and NO_3^- in environmental waters
Particle Size (Granulometry)	Inhalable fraction (< 100 μm): < 0.1% Respirable fraction (< 10 μm): ND > 2000 μm fraction at 99.3%	Measured
Flash Point	Not determined	Estimated. The notified chemical did not melt at 400 °C and is not highly flammable
Flammability	Not highly flammable	Measured
Autoignition Temperature	Not self-ignitable (> 400 °C)	Measured
Pyrophoric Properties	Non pyrophoric	Measured
Explosive Properties	Non explosive	Measured
Oxidising Properties	Non oxidising	Measured
Self-Heating Temperature	Not a self-heating substance	Measured

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

Reactivity
The notified chemical is expected to be stable under normal conditions of use.

Physical hazard classification
Based on the submitted physico-chemical data depicted in the above table, the notified chemical is not recommended for hazard classification according to the *Globally Harmonised System 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, reformulated or repackaged in Australia. It will be shipped in neat form into Australia in 1.2 tonne bulk bags and in break bulk.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 20,000	< 20,000	< 20,000	< 20,000	< 20,000

PORT OF ENTRY
Fremantle, Brisbane, Sydney and Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
Yara Australia Pty Ltd

TRANSPORTATION AND PACKAGING
The notified chemical will be shipped into Australia in 1.2 tonne bulk bags and in break bulk. The notified chemical will be transported by road to end-users warehouses.

USE
It will be used as an oxidising agent in explosives in the mining industry. The notified chemical will be also used as an emulsifying agent in offshore oil and gas operations (secondary recovery processes). The notified chemical will not be used in Coal Seam Gas operations or in drilling mud operations.

OPERATION DESCRIPTION
The notified chemicals will be imported from overseas for end-use in Australia and will not be manufactured, reformulated or repacked in Australia.

At end-use sites (both offshore and onshore), the blending operators will weigh the notified chemical and then dissolve it in water to create a solution containing ions of calcium, nitrate and ammonium.

Oil and gas applications:
Dissolution and solution transfer processes occur within a containment compound. The notified chemical will be injected with sea water into injection lines linked to offshore oil and gas wells and will not return to the surface after it has been pumped into the formations of producing wells.

Mining applications:
The aqueous solution containing the notified chemical will be used as an oxidising agent in explosives. The notified chemical will be present in aqueous emulsions and undergo a rapid decomposition when combusted. The residual will be dissolved in the surrounding water as ions of nitrate, calcium and ammonium.

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)*
Forklift/truck driver	8	10
Warehouse operators	2	12
Blending operators	8	80

EXPOSURE DETAILS
Transport and warehouse workers may come into contact with the notified chemical (at up to 100% concentration) only in the event of accidental rupture of packaging.

Dermal and ocular exposure to the notified chemical at concentrations up to 100% may occur during blending operations. Exposure is expected to be reduced by the use of appropriate personal protective equipment (PPE) such as chemical resistant gloves, eye protection and long sleeved overalls as stated by the notifier.

Inhalation exposure to the notified chemical at 100% concentration is unlikely due to the notified chemical being imported as granules with low levels of respirable material and negligible expected vapour pressure.

6.1.2. Public Exposure
The notified chemical will be used in industrial settings only and will not be sold to the public. Therefore, public exposure to the notified chemical is not expected.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified chemical and an analogue 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[1]	300 < LD50 < 2000 mg/kg bw; harmful
Rat, acute dermal toxicity[2]	LD50 > 2000 mg/kg bw; low toxicity
Rabbit, skin irritation[2]	non-irritating
Rabbit, eye irritation[1]	corrosive
Eye irritation (Bovine)[1]	non-irritating
Mouse, skin sensitisation – Local lymph node assay[1]	no evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days[2].	NOAEL 150 mg/kg bw/day
Genotoxicity – in vitro Mammalian Cell Gene Mutation Test - L5178Y mouse Lymphoma cells[1]	non genotoxic
Genotoxicity – Bacterial Reverse Mutation Test [1]	non mutagenic

1 Test has been done using the notified chemical
2 Test has been done using the analogue (nitric acid, calcium potassium salt, hydrate CAS No. 905593-70-6)

Toxicokinetics, metabolism and distribution
The notified chemical is an inorganic compound with relatively high water solubility. Absorption across the gastrointestinal tract and dermal absorption may occur. Animal studies indicated, that ammonium ions absorbed by intestine are converted to urea in the liver, and excreted in urine within 6 hours (SIAM, 2007). Nitrate will be partly reduced to nitrite after ingestion (in the saliva in the mouth and the gastro-intestinal tract) in humans. Nitrite is less efficiently absorbed in the rat than in humans. In humans most of ingested nitrate is excreted via the urine (65-75%) (SIAM, 2007). The absorption, the distribution and the excretion of the calcium ions in animals are regulated. Calcium (cation) will enter the body electrolyte pool, and is not expected to play a significant toxicological role at low doses (SIAM, 2007). Calcium is also an essential constituent for all animal bodies such as for the formation of skeletons, neural transmission, muscle contraction, and coagulation of the blood (SIDS, 2002).

Acute toxicity
The notified chemical was harmful to rats in an acute oral toxicity study. No acute dermal and inhalation toxicity data were provided for the notified chemical. However, the analogue nitric acid, calcium potassium salt, hydrate was of low acute dermal toxicity in rats. No acute inhalation data was provided.

Irritation and sensitisation
The analogue nitric acid, calcium potassium salt, hydrate was non-irritating to the skin of rabbits under the conditions of the test. The notified chemical was non irritating in a bovine eye irritation test but was severely

irritating when tested in the eyes of rabbits. The notified chemical was not a skin sensitiser in mice (local lymph node skin sensitisation test).

Repeated dose toxicity
The No Observed Effect Level (NOEL) was established for the analogue nitric acid, calcium potassium salt, hydrate by the study authors as 150 mg/kg bw/day in rats based on the effects noted in male and female at 1,000 mg/kg bw/day (the highest dose tested).

Mutagenicity/Genotoxicity
The notified chemical was not mutagenic in a bacterial reverse mutation test and was not genotoxic in an *in vitro* mammalian cell gene mutation test (L5178Y mouse Lymphoma cells).

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

Hazard classification	*Hazard statement*
Acute Toxicity (Category 4)	H302 - Harmful if swallowed.
Serious eye damage/eye irritation (Category 1)	H318 - Causes serious eye damage

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
The notified chemical is expected to be harmful following oral exposure and also a severe eye irritant. Adverse effects from inhalation cannot be ruled out, due to lack of data on the notified chemical, however as the vapour pressure is expected to be negligible and it is imported as granules with a large particle size, exposure may only occur if aerosols are formed after it is dissolved in water.

Workers may be exposed to the imported notified chemical at up to 100% concentration during blending operations. The use of PPE is expected to minimise dermal and ocular exposure and therefore the risk of eye irritation or systemic effects.

Provided that control measures are in place to minimise worker exposure to the notified chemical, the risk to the health of workers from use of the notified chemical is not considered to be unreasonable.

6.3.2. Public Health
The notified chemical is only intended for use in industrial settings, and hence public exposure is not expected. Therefore, when used in the proposed manner, the risk to public health from the notified chemical is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE
The notified chemical will be imported for end-use in Australia and will not be manufactured, reformulated or repacked in Australia. Therefore, environmental release of the notified chemical from these processes is not expected.

RELEASE OF CHEMICAL FROM USE
The notified chemical will be imported into Australia for offshore oil and gas operation or mining industries. At the end-use sites (both offshore and onshore), the notified chemical is dissolved in water to create a solution containing ions of calcium, nitrate and ammonium. The dissolution of the notified chemical will be used in:

Offshore Oil and Gas applications (50%, up to 10,000 tonnes per annum):
The notified chemical will be injected with sea water into injection lines linked to offshore oil or gas wells. The notified chemical is not expected to return to the surface after it has been pumped into the producing wells. Significant environmental release of the notified chemical is not expected during this process.

Onshore Mining Applications (50%, up to 10,000 tonnes per annum):
The aqueous solution containing the notified chemical will be used as an explosive agent in mining industries. The majority of the notified chemical will be combusted after explosion. No significant release of the notified chemical is expected.

RELEASE OF CHEMICAL FROM DISPOSAL

For offshore oil and gas application, the notified chemical is expected to be utilised by the microorganisms in the reservoir during the water flood, as indicated in the provided additional information. Very little amount of the notified chemical is expected to breakthrough in the production wells together with produced fluids. Therefore, the notified chemical is not expected to be significantly discharged to ocean along with the production fluids from the wells.

For onshore mining applications, most of the notified chemical is expected to be combusted at the end of its useful life. Residual ions of nitrate, calcium and ammonium are expected to be dissolved in the surrounding water.

Residue of the notified chemical in empty containers may share the fate of the container and be disposed of to landfill, or be washed to sewer where containers are rinsed before recycling.

7.1.2. Environmental Fate
The notified chemical is a water-soluble salt and will readily dissociate to form ions of nitrate, ammonium and calcium upon release into environment.

Ammonium ion will exist as ammonia/ammonium equilibrium depending on the media pH. However, under typical environmental conditions, the predominant form will be ammonium.

Nitrate is denitrified by micro-organisms to nitrogen and nitrous oxide. Nitrate can be taken up by plants or denitrified again to yield nitrogen and nitrous oxide gas. Nitrates form a pivotal part the global nitrogen cycle, and are an essential plant nutrient (Barsanti and Gualtieri, 2014).

Calcium is ubiquitous in the environment and is essential for proper functioning of cells (Campbell et al, 1999). Calcium is an essential element in the animal diet. However, high calcium concentrations may cause phosphorus deficiency by interfering with phosphorus absorption in the gastrointestinal tract.

It is not currently possible to categorise the environmental hazards of metals and other inorganic chemicals according to standard bioaccumulation hazard criterion, which was developed for organic chemicals and do not take into account the unique properties of inorganic substances and their behaviour in the environment.

7.1.3. Predicted Environmental Concentration (PEC)
The notified chemical is not expected to be discharged to the aquatic compartment significantly based on its intended use in drilling wells to be utilised by the bacteria in the reservoir. Therefore, the predicted environmental concentration (PEC) was not calculated.

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	48 h LC50 = 447 mg/L	Not harmful to fish
Daphnia Toxicity	48 h LC50 > 100 mg/L	Not harmful to aquatic invertebrate
Algal Toxicity	72 EC50 > 100 mg/L	Not harmful to algae
Inhibition of Bacterial Respiration	3 h EC50 > 1000 mg/L	Not inhibitory to microbial respiration

Based on the above ecotoxicological endpoints, the notified chemical is not expected to be harmful to aquatic life. Therefore, the notified chemical is not formally classified under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009) for acute and chronic toxicities.

7.2.1. Predicted No-Effect Concentration

The PNEC has been calculated by using the most toxic endpoint of 100 mg/L for daphnia for a more conservative prediction. A safety factor of 100 was used since endpoints for three trophic levels were available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment	
EC50 (daphnia)	447 mg/L
Assessment Factor	100
PNEC:	4.47 mg/L

7.3. Environmental Risk Assessment

The notified chemical is not expected to be discharged to the aquatic compartment and the predicted environmental concentration (PEC) was not calculated. Therefore, the Risk Quotient, Q (= PEC/PNEC), has not been calculated.

The notified chemical is not harmful to aquatic life and bioaccumulation is not applicable for the inorganic chemical such as the notified chemical. On the basis of the low toxicity to aquatic organisms and low potential for exposure to the aquatic environment, the notified chemical is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point/Freezing Point > 400 °C

Method OECD TG 102 Melting Point/Melting Range.
EC Council Regulation No 440/2008 A.1 Melting/Freezing Temperature.
Remarks The melting temperature of the test substance was determined using differential scanning calorimetry (DSC). No melting of the test substance was observed up to 400 °C.
Test Facility NOTOX B.V. (2010a)

Density 2,050 kg/m^3 at 20 °C

Method OECD TG 109 Density of Liquids and Solids.
EC Council Regulation No 440/2008 A.3 Relative Density.
Remarks The density (ρ) and relative density (D_4^{20}) of the test substance were determined using a gas comparison stereopycnometer. The volume of the test substance is measured in helium gas in a calibrated cylinder of variable volume. The mass of the sample is determined and the density calculated. The density of the test substance at 20 °C was 2.05 g/cm^3 (2.05 x 10^3 kg/m^3). The relative density was 2.05.
Test Facility NOTOX B.V. (2010a)

Particle Size (Granulometry)

Method CIPAC, Physico-chemical Methods for Technical and Formulated Pesticides, MT 59: "Sieve Analysis"; CIPAC Handbook Volume F, 1995.

Range (μm)	*Mass (%)*
< 100	< 0.1
100 -180	< 0.1
180 -250	< 0.1
250-500	< 0.1
500-2000	0.7
> 2000	99.3

Remarks The amount of material retained on the sieves and in the receiver pan was weighed to the nearest 0.1 g, and expressed as percentages of the sample to the nearest 0.1 %.
Test Facility NOTOX B.V. (2010a)

Flammability Not highly flammable

Method EC Council Regulation No 440/2008 A.10 Flammability (Solids) and "Flammability (Contact with Water)".
Remarks In contact with the flame of the gas burner, the test substance melted. After removal of the ignition source, no propagation of combustion of the test substance along 200 mm length of the pile within 4 minutes was observed. The test substance was considered 'not highly flammable'.
The test substance contains a Ca^{2+} group. The group is ionized and poses no risk on ignition in contact with water and/or to the evolution of a flammable gas. Moreover the test substance contains water. The test substance is considered 'not highly flammable' in contact with water.
Test Facility NOTOX B.V. (2010a)

Autoignition Temperature Not self-ignitable (> 400 °C)

Method EC Council Regulation No 440/2008 A. "Relative Self-Ignition Temperature for Solids ".
Remarks No endothermic or exothermic effect of the test substance was observed. After the experiment, the test substance had turned into a white, sticky residue and was still in the cube. The test substance is not self-ignitable.
Test Facility NOTOX B.V. (2010a)

Pyrophoric Properties

Method	EC Council Regulation No 440/2008 A.13: "Pyrophoric Properties of Solids and Liquids".
Remarks	In none of the six tests, spontaneous ignition of the test substance (2 cm^3 of the test substance was poured from about 1 meter height onto a non-combustible solid surface) occurred during dropping or within five minutes of settling. The test was performed at 20 °c ± 5 °C. The test substance has no pyrophoric properties
Test Facility	NOTOX B.V. (2010a)

Explosive Properties Not explosive

Method	EC Council Regulation No 440/2008 A.14 Explosive Properties.
Remarks	To confirm that the test substance is "not explosive" as expected based on the structural formula, two experiments were performed using differential scanning calorimetry (DSC). The test substance was considered not explosive.
Test Facility	NOTOX B.V. (2010a)

Oxidizing Properties Not oxidising

Method	EC Council Regulation No 440/2008 A.17 Oxidizing Properties (Solids).
Remarks	The burning time of the test substance was significantly longer than the burning time of the reference mixture (potassium bromated and cellulose). The test substance has no oxidizing properties.
Test Facility	NOTOX B.V. (2010a)

Self-Heating Temperature Not a self-heating substance

Method	United Nations, UN no. ST/SG/AC.10/11/Rev.4: Recommendations on the Transport of Dangerous Goods, Part III: Classification Procedures. Test Methods and Criteria Relating to Explosives of Class 3, Class 4, Division 5.1 and Class 9, Test N.4>: “Test Method for Self-heating Substances”, 2003
Remarks	The ability of the test substance to undergo oxidative self-heating was determined by Test 1 of the Modified Bowes-Cameron Cage test. No exothermic effect of the test substance was observed. The test substance is considered "not a self-heating substance”.
Test Facility	NOTOX B.V. (2010a)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/Wistar
Vehicle	Water
Remarks - Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3F	300	0/3
2	3F	300	0/3
3	3F	2000	3/3

LD50	Between 300 and 2000 mg/kg bw
Signs of Toxicity	Hunched posture was observed in animals treated at 300 mg/kg bw. Dark red discolouration of glandular mucosa were found in the animals dosed at 2000 mg/kg bw that died during the study in addition to lethargy, hunched/flat posture, laboured respiration, piloerection, ptosis, and hypothermia.
Effects in Organs	No abnormalities were found in the surviving animals.
Remarks - Results	Bodyweight gains in the surviving animals were considered to be normal.
CONCLUSION	The notified chemical harmful via the oral route.
TEST FACILITY	NOTOX B.V. (2007a)

B.2. Acute toxicity – dermal

TEST SUBSTANCE	Analogue chemical: nitric acid, calcium potassium salt, hydrate
METHOD	OECD TG 402 Acute Dermal Toxicity.
Species/Strain	Rat/5M, 5F Wistar
Vehicle	Corn oil
Type of dressing	Occlusive
Remarks - Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5F	2000	0/5
2	5M	2000	0/5

LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	Lethargy, flat/hunched posture, uncoordinated movements, shallow respiration, piloerection, chromodacryorrhoea (snout), ptosis and/or hypothermia were noted in all male animals. In female animals effects were limited to hunched posture and chromodacryorrhoea (snout). Scales, scabs and/or maculate erythema were also seen in the treated skin-area of the animals during the observation period.
Signs of Toxicity - Systemic	No abnormalities were found at macroscopic post mortem examination of the animals.
Effects in Organs	No abnormalities were found at macroscopic post mortem examination of the animals.

Remarks - Results	Bodyweight gains were as expected.
CONCLUSION	The test substance is of low toxicity via the dermal route.
TEST FACILITY	NOTOX B.V. (2007b)

B.3. Irritation – skin

TEST SUBSTANCE	Analogue chemical: nitric acid, calcium potassium salt, hydrate
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	Water
Observation Period	1, 24, 48 and 72 hours
Type of Dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations.

RESULTS

Remarks - Results	No skin irritation was caused by 4 or 4.5 hours exposure to the test substance. No staining of the treated skin by the test substance or corrosion was observed.
CONCLUSION	The test substance is non-irritating to the skin.
TEST FACILITY	NOTOX B.V. (2007c)

B.4. Irritation – eye (in vitro)

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 437 Bovine Corneal Opacity and Permeability Test Method for Identifying Ocular Corrosives and Severe Irritants
Vehicle	Water
Remarks - Method	The test substance was applied as a 20% (w/w) solution (750 µL) directly on top of the corneas for 240 ± 10 minutes.

RESULTS

Test material	*Mean opacities of triplicate tissues (SD)*	*Mean permeabilities of triplicate tissues (SD)*	*IVIS (SD)*
Vehicle control	0	0.000	0
*Test substance**	5	0.018	5.3
*Positive control**	77	1.324	97

SD = Standard deviation; IVIS = in vitro irritancy score
*Corrected for background values

Remarks - Results	A test substance induction of an IVIS ≥ 55.1 is defined as a corrosive or severe irritant. In vitro irritancy score (IVIS) = mean opacity value + (15 × mean OD490 value). The negative control did not induce irritancy on the corneas and its opacity and permeability values were less than the upper limits of the laboratory historical range (Irritancy scores 0.0 to 1.0). The mean in vitro irritancy score of the positive control (20% w/w Imidazole) was 97 and within the historical positive control data range.

As the mean in vitro irritancy score for the test substance was below 55.1 after 240 minutes treatment (opacity values ranging from 3 to 8 and permeability values ranging from 0.006 to 0.035)., the test substance is considered to be a non-irritant.

The test conditions were adequate and the test system functioned properly.

CONCLUSION The notified chemical was a non-irritant under the conditions of the test.

TEST FACILITY NOTOX B.V. (2010b)

B.5. Irritation – eye

TEST SUBSTANCE Notified chemical

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
EC Council Regulation No 440/2008 B.5 Acute Toxicity (Eye Irritation).

Species/Strain	Rabbit/New Zealand White
Number of Animals	1M
Observation Period	21 days
Remarks - Method	There were no deviations from the protocol.

RESULTS

Lesion	*Mean Score* Animal No.* 1	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	3	3	21 days	2
Conjunctiva: chemosis	1.7	4	21 days	1
Conjunctiva: discharge	2	2	21 days	1
Corneal opacity	1	4	21 days	4
Iridial inflammation	1	1	< 14 days	0

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

Remarks - Results Corneal injury consisted of opacity (maximum grade 4) and epithelial damage (maximum 75% of the corneal area). As a result of the corneal injury, pannus (neovascularization of the cornea) was apparent 7 days after instillation up to the end of the observation period. The corneal injury did not resolve within the observation period of 21 days.
Iridial irritation resolved within 14 days. The irritation of the conjunctivae consisted of redness, chemosis and discharge and did not resolve within the observation period of 21 days.

CONCLUSION The notified chemical is severely irritating to the eye.

TEST FACILITY NOTOX B.V. (2010c)

B.6. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE Notified chemical

METHOD OECD TG 429 Skin Sensitisation: Local Lymph Node Assay
EC No 440/2008; B.42 Skin Sensitisation (Local Lymph Node Assay)

Species/Strain	Mouse/ CBA/J
Vehicle	Ethanol/water 7:3
Preliminary study	Yes
Positive control	1-Chloro-2,4-dinitrobenzene
Remarks - Method	No significant protocol deviations.

RESULTS

Concentration (% w/w)	*Number and sex of animals*	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance			
0 (vehicle control)	5F	124 ± 39	1.0 ± 0.5
10	5F	89 ± 37	0.7 ± 0.4
25	5F	163 ± 58	1.3 ± 0.6
50	5F	313 ± 48	2.5 ± 0.9
Positive Control			
	5F	4497 ± 594	36.4 ± 12.6

Remarks - Results

The positive control group added to the study showed that the vehicle is suitable for eliciting an SI > 3 in this batch of animals and with the procedures used for this study used.

There was no indication that the test substance elicits an SI ≥ 3 when tested at concentrations up to 50%, the test substance was considered to be a non skin sensitizer.

Erythema was observed for all animals at a concentration of 50% and for one animal at 25%. No oedema was observed for any of the animals treated with the test substance.

CONCLUSION

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

TEST FACILITY

NOTOX B.V. (2010d)

B.7. Repeat dose toxicity

TEST SUBSTANCE

Analogue chemical: nitric acid, calcium potassium salt, hydrate

METHOD

OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.
EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral).

Species/Strain: Rats/Wistar Crl:(WI) BR (outbred, SPF)
Route of Administration: Oral – gavage
Exposure Information: Total exposure days: 28 days
Dose regimen: Once daily (7 days per week)
Post-exposure observation period: none
Vehicle: Water
Remarks - Method: No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
control	5M, 5F	0	0/10
low dose	5M, 5F	50	0/10
mid dose	5M, 5F	150	0/10
high dose	5M, 5F	1000	0/10

Mortality and Time to Death

No unscheduled mortality was observed in any treatment group.

Clinical Observations

There were no clinical signs of toxicity noted over the 28-day observation period.
Salivation was noted in a several males and all females treated at 1000 mg/kg between days 6 and 15, this was considered to be a physiological response rather than a sign of systemic toxicity as salivation is often noted in

rats of this age (6 weeks) and strain following oral gavage.

Hearing ability, pupillary reflex, static righting reflex and grip strength were normal in all animals. The variation in motor activity did not indicate a relation with treatment.

Body weights and body weight gain of treated animals remained in the same range as control groups over the 4-week study period.

Food consumption before or after allowance for body weight was similar in both treated and control group animals.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Reticulocytes percentage and red blood cell distribution width (RDW) were increased in male animals treated at 1000 mg/kg bw/day. Red blood cell count and haematocrit level were decreased in female animals treated at 1000 mg/kg bw/day.

Minor statistically significant decrease in mean corpuscular haemoglobin concentration (MCHC) and prothrombin time (PT) arising between control groups and treated animals receiving 50 and/or 150 mg/kg bw/day. The changes occurred in the absence of a dose response relation and were within the historical physiological range and therefore were not considered biologically significant by the study authors.

Inorganic phosphorus levels were increased in female rats treated at 1000 mg/kg bw/day. This finding was considered to have arisen by chance, since all values were within the physiological range and no corroborative findings were seen. No toxicological significance was ascribed to this finding by the study authors. No other changes occurred in clinical biochemistry parameters of treated rats.

Effects in Organs

Organ weights and organ to body weight ratios of treated animals were similar to those of control group animals.

Thickened limiting ridge and/or foci in glandular mucosa were noted in the stomach of two males and three females treated at 1000 mg/kg bw/day.

Incidental findings among control and treated animal groups included pelvic dilation of the kidney, enlarged testis, agenesis of testes and epididymides, reddish foci in thymus, discolouration of the thymus, uterus containing fluid and constricted spleen. These findings are occasionally seen among rats used in these types of studies. In the absence of a treatment-related distribution they were considered changes of no toxicological significance. In the spleen there was a slight increase in the severity of hemopoietic foci, primarily erythroid from minimal or slight to minimal to moderate in both sexes treated at 1000 mg/kg bw/day.

Remarks – Results

The effects in the haematological parameters and in the organs of both male and female rats treated at 1000 mg/kg bw/day are considered to be test substance related adverse effects. No toxicologically relevant effects were observed at lower doses in either sex.

CONCLUSION

The No Observed Adverse Effect Level (NOAEL) was established as 150 mg/kg bw/day in this study, based on the effects noted in males and females at 1000 mg/kg/day.

TEST FACILITY	NOTOX B.V. (2007d)

B.8. Genotoxicity – bacteria

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria.

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP_2uvrA
Metabolic Activation System	Rat liver S9--mix induced by a combination of phenobarbital and β-naphthoflavone
Concentration Range in Main Test	a) With metabolic activation: 100-5000 µg/plate b) Without metabolic activation: 100-5000 µg/plate
Vehicle	Dimethyl sulfoxide
Remarks - Method	No significant protocol deviations. Dose range finding (Preliminary) test, the notified chemical was tested up to concentrations of 5000 µg/plate in the absence and presence of S9-mix in the strains TA100 and WP2uvrA. The notified chemical was tested in the first mutation assay (Test1) at a concentration range of 100 to 5000 µg/plate in the absence and presence of 5% (v/v) S9-mix in tester strains TA 1535, TA 1537 and TA98. In the independent repeat of the assay with additional parameters, the notified chemical was tested (Test2) at the same concentration range as the first assay in the absence and presence of 10% (v/v) S9-mix in tester strains TA1535, TA1537, TA98, TA 100 and WP_2uvrA.

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	> 5000	Negative	Negative
Test 2		> 5000	Negative	Negative
Present				
Test 1	> 5000	> 5000	Negative	Negative
Test 2		> 5000	Negative	Negative

Remarks - Results	The negative and strain-specific positive control values were within the laboratory historical control data ranges indicating that the test conditions were adequate. No toxicologically significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains, with any dose of the test substance up to 5000 µg/plate either with or without metabolic activation. The positive controls induced the appropriate responses in the corresponding strains.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	NOTOX B.V. (2006)

B.9. Genotoxicity – in vitro

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 476 In vitro Mammalian Cell Gene Mutation Test. European Community (EC). Commission regulation (EC) No. 440/2008, Part B: Methods for the Determination of Toxicity and other health effects, Guideline B.17: "Mutagenicity – In Vitro Mammalian Cell Gene Mutation Test".
Species/Strain	L5178Y/TK+/- Mouse Lymphoma cells
Metabolic Activation System	S9 preparation (Rat liver S9--mix induced by a combination of phenobarbital and β-naphthoflavone)
Vehicle	Dimethyl sulfoxide
Remarks - Method	No significant protocol deviations Positive controls: MMS (Methyl methane sulfonate) (-S9-mix) and CP

(Cyclophosphamide) (+S9).

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Expression Time*	*Selection Time*
Absent				
Test 1	50, 100, 200, 300, 350, 375, 400 and 450	3 h	2 d	11-12 d
Test 2	300, 320, 350, 360, 370, 380, 390 and 400	24 h	2 d	11-12 d
Present				
Test 1	10, 100, 600, 1000, 2000, 2500, 2750 and 3000	3 h	2 d	11-12 d
Test 2	10, 100, 600, 1000, 2000, 2750, 3000 and 3250	3 h	2 d	11-12 d

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 333	> 450	> 450	Negative
Test 2	> 333	> 300	> 300	Negative
Present				
Test 1	> 333	> 1000	> 1000	Negative
Test 2		> 1000	> 1000	Negative

Remarks - Results

There were no concentration-related increases in mutant frequency, in the presence or absence of metabolic activation.

The positive and vehicle controls gave satisfactory responses confirming the validity of the test system.

CONCLUSION

The notified chemical was not clastogenic to mouse lymphoma cells treated in vitro under the conditions of the test.

TEST FACILITY

NOTOX B.V. (2010e)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Major component of the notified chemical
METHOD	Short-term Toxicity for Fish - static
Species	*Cyprinus carpio*
Exposure Period	48 h
Auxiliary Solvent	None
Water Hardness	160.14 – 167.15 mg $CaCO_3$/L
Analytical Monitoring	Not applicable
Remarks – Method	The test guideline used for this study is not clear and the good laboratory practice is not compliance. Therefore, the test results has not been relied upon.
RESULTS	
LC50	447 mg/L at 48 hours
Remarks – Results	Only study summary was provided and the validity of the results is undetermined.
CONCLUSION	The notified chemical is not toxic to fish
TEST FACILITY	NOTOX B.V. (2010f)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test - Static
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	180 mg $CaCO_3$/L
Analytical Monitoring	Not applicable
Remarks - Method	The test was conducted in accordance with the test guideline above. No significant deviations from the test guidelines were reported.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
Control	-	20	0	0
0.1	-	10	0	0
1.0	-	10	0	0
10	-	10	0	0
100	-	20	0	0

LC50	> 100 mg/L at 48 hours
NOEC	100 mg/L at 48 hours
Remarks - Results	All validity criteria for the test were satisfied. The results were based on nominal concentration, which is considered to be acceptable given the test substance is soluble in water and the inorganic salts present in the test substance are all stable in aquatic media.
CONCLUSION	The notified chemical is not harmful to aquatic invertebrate.
TEST FACILITY	NOTOX B.V. (2007e)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 201 Alga, Growth Inhibition Test - Static
Species	*Pseudokirchneriella subcapitata*
Exposure Period	72 hours
Concentration Range	Nominal: Control, 0.1, 1.0, 10 and 100 mg/L Actual: Not applicable
Auxiliary Solvent	None
Water Hardness	24 mg $CaCO_3$/L
Analytical Monitoring	Not applicable
Remarks - Method	The test was conducted in accordance with the test guideline above. No significant deviations from the test guidelines were reported.

RESULTS

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

Remarks - Results	All validity criteria for the test were satisfied. The results were based on nominal concentration, which is considered to be acceptable given the test substance is soluble in water and the inorganic salts present in the test substance are all stable in aquatic media. No reduction of growth rate or inhibition of yield was observed at any of the test concentrations.
CONCLUSION	The notified chemical is not harmful to algae
TEST FACILITY	NOTOX B.V. (2007f)

C.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Analogue
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test.
Inoculum	Activated sludge
Exposure Period	3 hours
Concentration Range	Nominal: Control, 62.5, 125, 250, 500 and 1000 mg/L Actual: Not determined
Remarks – Method	
RESULTS	
EC50	> 1000 mg/L
Remarks – Results	The test substance was determined to have no significant inhibitory effect on the respiration rate of activated sludge at all the test concentrations (nominal) in 3 hours. The validation criteria for the control respiration rates and reference material, (3,5-dichlorophenol) EC_{50} were satisfied.
CONCLUSION	The analogue and, by inference the notified chemical are not expected to inhibit microbial respiration.
TEST FACILITY	BASF (2008)

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