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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Phosphoric acid, potassium salt (2:1)

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

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This Full Public Report is also available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

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NICNAS

TABLE OF CONTENTS

FULL PUBLIC REPORT **3**

1. APPLICANT AND NOTIFICATION DETAILS 3
2. IDENTITY OF CHEMICAL 3
3. COMPOSITION ALL 4
4. PHYSICAL AND CHEMICAL PROPERTIES 4
5. INTRODUCTION AND USE INFORMATION 5
6. HUMAN HEALTH IMPLICATIONS 6
   - *6.1 Exposure assessment* *6*
   - *6.2. Human health effects assessment* *7*
   - *6.3. Human health risk characterisation* *9*
7. ENVIRONMENTAL IMPLICATIONS 10
   - *7.1. Environmental Exposure & Fate Assessment* *10*
   - *7.2. Environmental effects assessment* *10*
   - *7.3. Environmental risk assessment* *11*
8. CONCLUSIONS AND REGULATORY OBLIGATIONS 11

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES **14**

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS **16**

- *B.1. Acute toxicity – oral* *16*
- *B.2. Acute toxicity – dermal* *16*
- *B.3. Irritation – skin* *17*
- *B.4. Irritation – eye* *17*

BIBLIOGRAPHY **19**

FULL PUBLIC REPORT

Phosphoric acid, potassium salt (2:1)

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Redox Pty Ltd (ABN 92 999 762 345)
2 Swettenham Road Minto, NSW 2566

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: Spectral data, purity, non-hazardous residual impurities, and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: Acute inhalation toxicity, skin sensitisation, repeat dose toxicity, mutagenicity, hydrolysis as a function of pH, partition coefficient, adsorption/desorption, ready biodegrability, bioaccumulation, acute toxicity to fish, acute/chronic toxicity to aquatic invertebrates, and algal growth inhibition test.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Potassium pentahydrogen bis(phosphate)
PeKacid (product containing the neat notified chemical with a purity of >90%)
Novacid (formulated powder blend containing the notified chemical up to 10%)

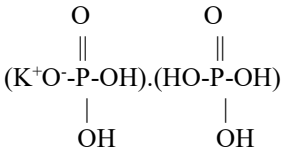
CAS NUMBER
14887-42-4

CHEMICAL NAME
Phosphoric acid, Potassium salt (2:1)

OTHER NAME(S)
Potassium phosphate - $KH_5(PO_4)_2$

MOLECULAR FORMULA
H_3O_4 P.1/2 K

STRUCTURAL FORMULA



MOLECULAR WEIGHT

234.08 Da

ANALYTICAL DATA
X Ray Diffraction and X Ray Fluorescence data were provided for the notified chemical.

3. COMPOSITION ALL

DEGREE OF PURITY >90%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS None

ADDITIVES/ADJUVANTS None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Solid, white, crystalline and odourless substance.

Property	Value	Data Source/Justification
Melting Point/Melting Range	127-135°C	Measured
Boiling Point	Not determined	Notified chemical is solid
Density	2119 kg/m^3 at 20°C	Measured
Vapour Pressure	<1.47 x 10^{-6} kPa at 20°C	Measured
Water Solubility	583 g/L at 20°C	Measured
Hydrolysis as a Function of pH	Not determined	Expected to be hydrolytically stable
Partition Coefficient (n-octanol/water)	Not determined	Expected to be low due to the high water solubility of the notified chemical
Adsorption/Desorption	Not determined	Expected to be relatively immobile in soil and sediment
Dissociation Constant	pKa_1 = 2.752, pKa_2 = 6.960, 20 °C	Measured.
Particle Size	Inhalable fraction (<100 μm): 1% Respirable fraction (<10 μm): 0 %	Measured
Flash Point	Not determined	The notified chemical is solid.
Flammability (Solid)	Not determined to be flammable	Measured
Autoignition Temperature	Did not ignite up to 400°C	Measured
Explosive Properties	Unlikely to have explosive properties	Based on chemical structure
Oxidizing Properties	Not an oxidant	Measured

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

Reactivity

The notified chemical is hygroscopic and forms phosphoric acid (which is corrosive) on contact with water. A 1% solution of the notified chemical was reported to have a pH of 2.2.

Test showed that the notified chemical is not an oxidising agent.

Dangerous Goods classification
Based on the submitted physical-chemical data in the above table, the notified chemical is not classified according to the Australian Dangerous Goods Code (NTC, 2007). However, the data above do not address all Dangerous Goods endpoints.

The notifier has classified the notified chemical as a dangerous goods on the product MSDS, with a Dangerous Goods Class 8 (corrosive substance), on the basis of its corrosive properties on contact with water.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical and finished products containing the notified chemical will be imported and will not be manufactured in Australia.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	30-100	30-100	30-100	30-100	30-100

PORT OF ENTRY
Sydney, Melbourne, Adelaide, Brisbane and Perth.

IDENTITY OF RECIPIENTS
Redox Pty Ltd in Sydney, Melbourne, Adelaide, Brisbane and Perth.

TRANSPORTATION AND PACKAGING
The notified chemical and finished products containing the notified chemical will be imported mainly in 25 kg polyethylene bags. However, bulk big bags or IBCs may be considered in the future. The 500 and 1000 kg big bags are made of polyethylene lined with polyester. In the future, formulated blends containing the notified chemical up to 10% may be imported.

The 25 kg bags will be packed to a pallet (42 bags) and the pallets will be transported in a container from the wharf to the notifier's warehouses. Pallets will be mainly distributed to local rural areas but some will also be distributed to stock and station agents and local hardware stores. Farmers may buy from these sources.

USE
The notified chemical will be used as an agricultural fertiliser.

OPERATION DESCRIPTION
The notified chemical will be imported and will not be manufactured in Australia. Initially, it is expected that only the neat notified chemical will be imported and no reformulation will take place in Australia. However, in the future, blends of finished products containing the notified chemical at up to 10% may be imported and also local reformulation may take place where the notified chemical may be mixed with other fertiliser ingredients for end use applications. No information was available as to whether farmers may carry out further mixing of the notified chemical with other commercial products at their farms.

Local Reformulation
At customer's blending sites, the chemist would sample and test the notified chemical for QC purposes. Quantities of the notified chemical would be issued to the compounder for production as required once cleared by the chemist.

Once cleared for reformulation, the notified chemical will be reformulated by mixing with other fertiliser ingredients. The bags containing the notified chemical will be transferred into a mixing vessel, such as an enclosed and process controlled Nauta mixer (2-10,000 L) under local exhaust ventilation, with flame proof mixers and pumps designed not to create a dust hazard. When mixing is complete, the fertilisers containing the notified chemical at concentrations of < 650 g/L of water (the solubility limit for the notified chemical) will be decanted into containers (20 L pails, 200 L drums and 1,000 L IBCs). Workers would monitor the line filler and the bagging operation where the finished product was filled into containers. The chemist would sample and test the final products containing the notified chemical for QC purposes.

End Use Applications
The end use applications will include either a product containing the neat notified chemical, a blended imported product (powder or solution), or a locally reformulated product containing a mixture of fertilisers (powder or solution).

The farmers will dissolve the neat notified chemical, or fertiliser blend (powder or solution) in water to give a final dilute solution (concentration dependent on soil requirements, notified chemical at typically 0.65%), which will be applied to the soil. The fertiliser mix containing the notified chemical will only be used by commercial farming operations and will be applied by drip irrigation systems or boom spray. The maximum frequency for use is 5 months/year.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

Category of Worker	*Number*	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and Storage	10	4	12
Professional Compounder	1	8	12
Chemist	1	3	12
Packers	2	8	12
Store Persons	2	4	12
End Users	2000	8	140

EXPOSURE DETAILS
The main route of exposure will be dermal. Inhalation exposure is not expected to be significant (due to the low vapour pressure and granular nature of the notified chemical) except in situations where dust formation could occur i.e during reformulation processes. Ocular exposure to dust is also possible during reformulation.

Transport and Storage
Worker exposure to the notified chemical in neat form or in blended form during importation, transportation and storage is not expected, except in the unlikely event of an accident where the packaging may be breached.

QC Sampler and Laboratory Analyst
Dermal and ocular exposure to the notified chemical is possible during testing and sampling by QC workers and laboratory analysts. Exposure is minimised by using a scoop and it is expected that tests may be conducted in a forced ventilation extraction booth. Furthermore, workers are expected to wear safety glasses, protective gloves, coveralls and shoes to protect eyes, hands, and body (skin) and feet.

Reformulation
At customer facilities, compounder and formulation workers may be exposed to the notified chemical during handling of the containers containing the notified chemical, pouring the notified chemical into the dispensary for weighing and transferring the notified chemical directly into a powder mixing plant such as a Nauta mixer for reformulation. During these processes, dermal, inhalation and ocular exposure to the notified chemical are likely to be the main routes of exposure. However, exposure is expected to be minimised by local exhaust ventilation, safety glasses with shields, gloves, coverall and shoes. Respiratory protection is not expected to be used, as reformulation would be done in an enclosed system with appropriate dust extraction system. In cases, where exposure to dust could occur, appropriate respiratory masks are expected to be worn.

Exposure is also possible during line filler and the bagging operation where the finished product is filled into containers. Exposure would be minimised by the use of safety glasses, gloves, and coveralls and with the use of dust extraction.

End Use Applications
Dermal and ocular exposure to the neat notified chemical or fertiliser blends (solution with up to 65% notified chemical, or granules) is possible when the farmer is preparing the fertiliser solutions for application. Exposure will be minimised by the use of safety glasses, protective clothing and gloves.

Dermal and ocular exposure to the notified chemical at dilute concentrations of typically 0.65% is possible during the application of fertilisers containing the notified chemical by drip irrigation systems or boom spray.

Exposure will be minimised if safety glasses, protective clothing and gloves are used. Inhalation exposure to the notified chemical in fertiliser solutions is not expected to be significant due to the method of spraying and the dilute concentrations used.

6.1.2. Public exposure

The notified chemical and the blend containing the notified chemical will not be sold to the general public. Therefore, the general public will not be exposed to the notified chemical as such. Furthermore, as the notified chemical will be used in agricultural settings, the general public is unlikely to come into contact with the notified chemical. As the product will be applied by drip irrigation systems or boom spray, bystander exposure is not expected. Therefore, based on the above, exposure to the general public is expected to be low.

6.2. Human health effects assessment

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

Limited data were submitted for toxicology end points of the notified chemical. The notified chemical is an inorganic chemical and a double salt of monopotassium phosphate and phosphoric acid. When dissolved in water phosphoric acid is formed. Therefore, read across data from the analogue phosphoric acid, wherever available, were used for the remaining toxicology end points (SIDS, 2009).

Endpoint	*Test substance*	*Result and Assessment Conclusion*
Rat, acute oral toxicity	Notified chemical (50%)	LD50 >2000 mg/kg bw; low toxicity
Rat, acute dermal toxicity	Notified chemical (>90%)	LD50 >2000 mg/kg bw; low toxicity
Rat, acute inhalation toxicity	-	Not determined
Rabbit, skin irritation	Notified chemical (>90%)	slightly irritating
Rabbit, eye irritation	Notified chemical (>90%)	irritating
Mouse, skin sensitisation tests	-	Not determined
Rat, repeat dose oral toxicity – 40-52 days	Analogue chemical*	NOAEL for repeat dose effects = 250 mg/kg bw/day NOAEL for reproductive and developmental effects = 500 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	Analogue chemical*	non mutagenic
Genotoxicity–in vitro-Chinese hamster lung cell	Analogue chemical*	non genotoxic
Reproductive effects	Analogue chemical*	ay

* Phosphoric acid

Toxicokinetics, metabolism and distribution.

No data were provided to assess the absorption, distribution, metabolism and excretion of the notified chemical. Based on high water solubility and a relatively low molecular weight of the notified chemical (238 Da), absorption following ingestion is expected.

As the notified chemical is in granular form and has high water solubility dermal absorption is expected to be low due to limited penetration into the stratum corneum. However, as phosphoric acid is likely to be formed on contact with water dermal absorption of notified chemical solutions should consider the likely uptake of the acid, especially at corrosive concentrations.

The notified chemical has a low vapour pressure and is introduced in a granular form, with 99% of the particles having a diameter of greater than 100 μm. Therefore the notified chemical is not expected to be inhaled.

The analogue chemical, phosphoric acid, can be absorbed by ingestion, inhalation and dermal contact. Absorbed phosphoric acid is distributed widely in the body as phosphate. Phosphate is present in plasma and extracellular fluid in cell membranes and intracellular fluid, and in collagen and bone tissue. More than 90% of plasma phosphate is filterable, of which 80% is actively reabsorbed. Phosphate excreted in the urine represents the difference between the amount filtered and that reabsorbed.

Acute toxicity.
The notified chemical is of low acute oral and dermal toxicity, with oral and dermal LD50 of >2000 mg/kg bw. It is noted that the acute oral toxicity test was conducted only with 50% of the notified chemical, as mixtures in excess of 50% (i.e., 60-70% of notified chemical) were too viscous to be administered properly.

No data were provided to assess the acute inhalation toxicity potential of the notified chemical due to the low vapour pressure and granular nature. However, in solution phosphoric acid is formed, which has been found to be irritating to the respiratory tract and of moderate to low acute inhalation toxicity [LC50 values ranging from 193 mg/m^3 in guinea pig to 5,337 mg/m^3 in rabbit (SIDS, 2009)].

Irritation and Sensitisation.
The notified chemical was slightly irritating to the skin of rabbit and was irritating to the eyes of rabbit. There is no structural alert for skin sensitisation for the notified chemical. Therefore, the notified chemical is unlikely to be a skin sensitiser. No data were provided to assess the skin sensitisation potential of the notified chemical.

Repeated Dose Toxicity and Toxicity for Reproduction.
No data were provided to assess the potential for repeat dose toxicity of the notified chemical.

In a combined repeated dose toxicity study with the reproduction-developmental screening test (OECD TG 422) the analogue phosphoric acid at dose levels of 125, 250, and 500 mg/kg bw/day was administered via gavage to 13 animals/sex/dose, once a day to male rats from 2 weeks prior to mating to 2 weeks after mating (42 days) and to female rats from 2 weeks prior to mating to Day 4 post partum (40–52 days).

No adverse effects were observed in all males and females at doses of 250 mg/kg bw/day or less. Two females in the 500 mg/kg bw/day treatment group died and findings of gaseous distension of gastrointestinal tract were observed. Also, mucous stool, soft stool, and dirty nose were observed in one male of the 500 mg/kg bw/day treatment group. Therefore, the NOAEL for repeat dose toxicity was determined to be 250 mg/kg bw/day in males and females.

No effects of the test substance were observed on mating, conception, parturition, neonate body weights and survival rate and external examination of neonates. Therefore the NOAEL for reproductive and developmental toxicity was determined to be 500 mg/kg bw/day (SIDS 2009).

Mutagenicity.
No data were provided to assess the potential for mutagenicity of the notified chemical.

For the analogue chemical (phosphoric acid), a bacterial reverse mutation assay (Ames test) was conducted with *Salmonella typhimurium* strains TA 1535, TA 1537, TA 98, TA 100 and *Escherichia coli* WP2*uvr*A in the presence and absence of a metabolic activation containing S9 mix, at concentrations of 156.3 to 5,000 µg/plate. The test substance didn't induce the increase in the frequency of revertant colonies in a dose-dependent manner (SIDS 2009).

The mutagenic potential of phosphoric acid was further investigated in the chromosome aberration test system using Chinese hamster lung cell (CHL/IU). The treatment levels were 112.5, 225.0 and 450 µg/mL, regardless of application of metabolic activation system, due to cytotoxicity at higher concentrations. The structural and numerical chromosome aberrations were not observed in both the short time treatment without and with metabolic activation system and the continuous treatment. In the positive control, the structural chromosome aberration was significantly increased (SIDS 2009).

Therefore, based on *in vitro* results for the analogue chemical, the notified chemical is unlikely to be genotoxic.

Health hazard classification
Based on the eye irritation effects, the notified chemical is classified as hazardous, according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phrase:

R36: Irritating to eyes

The notified chemical imported as a solid and crystalline substance is not a skin irritant. However, the notifier has classified the notified chemical as 'R34: Causes burns', on the product MSDS, due to the formation of phosphoric acid on contact with water and the low pH of the solution (pH of 2.2 of 1% solution). Therefore, based on the data provided, solutions containing the notified chemical at concentrations of ≥ 1% should be considered as though classified as hazardous, with the following risk phrase:

R34: Causes burns

6.3. Human health risk characterisation

6.3.1. Occupational health and safety
The primary risk to workers from exposure to the notified chemical is skin and eye irritation (as a solid) and corrosive potential (in solution).

During reformulation dermal, ocular and inhalation exposure to the neat notified chemical and reformulated products may occur, Exposure during reformulation will be minimised by the use of local exhaust ventilation, safety glasses with shields, gloves, coverall and shoes. As the particle size of 99% of the notified chemical is above 100 microns, a significant percentage of particles is not in the inhalable or respirable particle size range. Furthermore, reformulation would be done in an enclosed system with an appropriate dust extraction system, and although respiratory protection is not expected to be used routinely, the notifier has stated that appropriate respiratory masks would be worn where exposure to dust is expected to occur.

Therefore, based on the use of safe work practices, PPE and local exhaust ventilation, the risk of skin and eye irritation during reformulation, is not considered to be unacceptable.

During end use applications, there is potential for dermal and ocular exposure to the neat notified chemical, reformulated products (up to 65% concentration), and dilute fertiliser solutions (containing typically 0.65% notified chemical). The highest potential for exposure is during transfer of neat notified chemical (or concentrated solutions) to vessels for dilution. During transfer, exposure will be minimised by the use of safety glasses, protective clothing and gloves. Exposure is expected to be minimal during application by drip irrigation systems or boom spray, as the diluted fertiliser will be delivered through the pipes close to the ground to have minimal spray drift. If fertiliser solutions with ≥ 1% notified chemical are prepared by farmers, safety glasses, protective clothing and gloves are recommended to reduce the risk of skin or eye irritation.

Therefore, based on the use of PPE, drip irrigation systems or boom spray, the risk of skin or eye injury during end use applications, is not considered to be unacceptable.

6.3.2. Public health
The notified chemical and the blend containing the notified chemical will not be sold to the general public. Furthermore, as the notified chemical will be used in agricultural settings, the general public is unlikely to come into contact with the notified chemical. As the product will be applied by drip irrigation systems or boom spray, bystander exposure is not expected. Therefore the risk to the general public from the use of notified chemical is not considered to be unacceptable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE
The notified chemical will not be manufactured in Australia. It will be imported in blends of finished fertiliser products or as a raw granular material to be dissolved in water during reformulation or by farmers before use. Accidental spills during transport are expected to be collected and recycled or disposed of to landfill.

RELEASE OF CHEMICAL FROM USE
The notified chemical will be a component in fertilisers used by farmers. The fertiliser will be applied to topsoil by drip irrigation systems or potentially by ground boom spraying. Residues of the notified chemical in empty product containers are likely to be disposed of to landfill. Notified chemical residues remaining in application equipment will remain *in situ* and are expected to be delivered to soil during subsequent use of the equipment.

RELEASE OF CHEMICAL FROM DISPOSAL
During use, all the notified chemical is expected to be applied to the soil as the fertiliser. However, unwanted unused fertiliser is likely to be disposed of by an authorised waste disposal company.

7.1.2 Environmental fate

No environmental fate data were submitted. All the notified chemical is expected to be applied to topsoil as fertiliser. In soil, the notified chemical is expected to be relatively immobile, and is therefore not likely to leach into groundwater. Phosphates are generally retained on soil particles and loss to surface waters is usually related to run-off or erosion of soil particles, which carry the attached phosphates.

Biodegradation and bioaccumulation are not relevant environmental processes in the case of phosphate fertiliser products. In the environment the notified chemical will dissociate into potassium and orthophosphate. Orthophosphates are naturally present in the environment, and both phosphorous and potassium are essential nutrients required for plant growth and development. Consequently, notified chemical released to the environment are expected to be eventually taken up by plants and crops.

The notified chemical may reach aquatic environments from overspray, spray-drift or run-off. However, efficient and economic use of the fertilisers, in addition to good farming practices, are expected to minimise loss of the notified chemical to the aquatic environment.

7.1.3 Predicted Environmental Concentration (PEC)

Of the potential 100 tonnes of notified chemical imported, it can be assumed for the purpose of the risk assessment, that all of the notified chemical will be applied to soil as fertiliser. The notified chemical is intended as part of a nutrient replacement program for agricultural land and actual application rates will depend on specific crop nutrient requirements. As indicated by the notifier, farmers are expected to match fertiliser application rates to crop needs. The recommended application rates of up to 6 kg of notified chemical/ha/month for up to 5 months/year reflect typical phosphate fertiliser application rates. Phosphate fertilisers are ubiquitously used to improve soil conditions for crop maximisation and the notified chemical will contribute to less than 0.01% of the total phosphorus fertiliser consumption in Australia.

Therefore, given these factors, the Predicted Environmental Concentration for soil (PEC_{soil}) will not be calculated for the notified chemical as no significant increase in environmental levels of phosphorous and related inorganic compounds is expected from the use of the notified chemical as a fertiliser.

Similarly, edge of field concentrations cannot be calculated as the worst case models do not consider the uptake by crops, topography of the land and the mobility of the notified chemical. Additionally, good agricultural practices should ensure that the potential wastage from run-off, overspray or drift are minimised.

7.2. Environmental effects assessment

No ecotoxicity data for the notified chemical were submitted. Orthophosphate is considered to be non-toxic and is not expected to have adverse effects on aquatic or soil dwelling organisms. However, excessive quantities of the notified chemical or its dissociation products in the aquatic environment may lead to eutrophication, i.e. an increase in the quantity of organic matter in the environment from rapid growth from plants and algae. The growth and subsequent decay of the organisms can reduce dissolved oxygen concentrations in aquatic environments which may indirectly adversely affect aquatic organisms.

7.2.1 Predicted No-Effect Concentration

The notified chemical is expected to be used in agricultural regions where the application of fertiliser-type products is already high. The efficient and economic use of the fertilisers, in addition to good farming practices, are expected to minimise loss of the notified chemical to the aquatic environment and therefore limit the potential for eutrophication. As the nation wide use of phosphorous in fertilisers is approximately 282,000 tonnes/year (FIFA, 2009), the use of the notified chemical as a fertiliser will not significantly contribute to the environmental levels of phosphorous and inorganic phosphorous compounds. Therefore, the increased risk from the use of the notified chemical as a fertiliser to the potential phenomenon of eutrophication in water bodies is considered to be low.

7.3. Environmental risk assessment

The notified chemical will be used as a fertiliser and is intended for uptake from the environment by the crops to which it is applied. The notified chemical is not expected to be harmful to soil-dwelling or aquatic organisms. The notified chemical is a minor source of phosphorous compounds for use in the agricultural markets and the increased risk to the potential phenomenon of eutrophication in water bodies is considered to be low. Additionally, good agricultural practice should ensure that the wastage and potential eutrophication of water bodies from overspray, drift or runoff are minimised. On the basis of the reported use pattern and total import volume, the notified chemical is not expected to significantly increase the environmental levels of inorganic phosphates and is therefore not considered to pose an unacceptable risk to the environment.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the data provided, the notified chemical is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)], with the following risk phrase:

R36: Irritating to eyes

Furthermore, based on the formation of phosphoric acid on contact with water, the following risk phrase should be considered for solutions containing the notified chemical at concentrations ≥ 1%:

R34: Causes burns

The classification of the notified chemical using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

	Hazard category	***Hazard statement***
Eye irritation	2B	Causes eye irritation

Human health risk assessment

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

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

Environmental risk assessment

On the basis of the reported use pattern and total import volume, the notified chemical is not expected to pose an unacceptable risk to the environment.

Recommendations

REGULATORY CONTROLS
Hazard Classification and Labelling

- Safe Work Australia should consider the following health hazard classification for the notified chemical:
  - R36 Irritating to eyes

- Use the following risk phrase for solid products/mixtures containing the notified chemical:
  - Conc ≥ 20%: Xi; R36

- Due to the formation of phosphoric acid on contact with water, the following risk phrase should be considered for solutions containing the notified chemical:
  - Conc ≥ 1%: C; R34 Causes severe burns

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical as introduced:
  - Local exhaust ventilation during reformulation

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced and in solutions with ≥ 1% notified chemical:
  - Avoid contact with skin and eyes
  - Do not inhale dust/vapour

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced and in solutions with ≥ 1% notified chemical:
  - Chemical resistant gloves
  - Safety glasses or face mask
  - Coveralls

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

- A copy of the MSDS should be easily accessible to employees.

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified chemical should be disposed of to landfill.

Storage and Handling

- The following precautions should be taken regarding storage and handling of the notified chemical:
  - Avoid contact with water and unnecessary exposure to the atmosphere to prevent moisture pickup.

Emergency procedures

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

Transport and Packaging

- Transportation and packaging should take into consideration that solutions containing the notified chemical may be classified as Dangerous Goods under the ADG Code, with a Dangerous Goods Class 8 (corrosive substance) classification.

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 introduced in a form in which greater than 25% of particles have a diameter less than 10μm;

or

(2) Under Section 64(2) of the Act; if
   - the function or use of the chemical has changed from an agricultural fertiliser applied by drip irrigation or boom spray, or is likely to change significantly;
   - the amount of chemical being introduced has increased from 100 tonnes/annum, or is likely to increase, significantly;
   - the chemical has begun to be manufactured in Australia;
   - additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

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

No additional secondary notification conditions are stipulated.

Material Safety Data Sheet
The MSDS of the notified chemical provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point/Melting Range 127-135°C

Method	OECD TG 102 Melting Point/Melting Range. EC Directive 92/69/EEC A.1 Melting/Freezing Temperature. US EPA, OPPTS 830.7200 Melting Point/Melting Range.
Remarks	Determined by the capillary method using an electronically controlled heating system.
Test Facility	Institute fur Biologische Analytik and Consulting IBACON GmbH (2009a)

Density 2119 kg/m^3 at 20°C

Method	OECD TG 109 Density of Liquids and Solids. EC Directive 92/69/EEC A.3 Relative Density. US EPA, OPPTS 830.7300
Remarks	Determined using the gas comparison pycnometer method.
Test Facility	Institute fur Biologische Analytik and Consulting IBACON GmbH (2009b)

Vapour Pressure <1.47 x 10^{-6} kPa at 20°C

Method	OECD TG 104 Vapour Pressure. EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks	Determined using isothermal thermogravimetric effusion method.
Test Facility	NOTOX B.V. (2010)

Water Solubility 583 g/L at 20°C

Method	OECD TG 105 Water Solubility.
Remarks	Flask Method. Pure water (~5 mL) was added to the test substance (15 g) and replicates were agitated for 24 h, 48 h, or 72 h at 30 ± 1°C, then for a further 24 h at 20 ± 1°C. The mixtures contained a small amount of undissolved test substance. Aliquots were taken, filtered, and the concentration of test substance was determined using a titration method. As no differences higher than 8% were found between samples, the test is considered to be valid.
Test Facility	Institute fur Biologische Analytik and Consulting IBACON GmbH (2009c)

Dissociation Constant $pKa_1 = 2.752$, $pKa_2 = 6.960$ at 20 °C ± 0.9 °C.

Method	OECD TG 112 Dissociation Constants in Water.
Remarks	The dissociation constant of the test substance (0.01 M) was determined using the titration method. After each addition of the titrant (standard base solution) the pH was measured potentiometrically. The pKa values were determined at the half neutralization point.
Test Facility	Institute fur Biologische Analytik and Consulting IBACON GmbH (2009d)

Particle Size

Method OECD TG 110 Particle Size Distribution/Fibre Length and Diameter Distributions.

Range (μm)	*Cummulative Mass (%)*
<10	0
<20	0
<50	0
<100	1
<200	6
<448	35
<1002	83
<1416	90

	<2000	100

Remarks Determined by laser diffraction (light scattering). The median particle sizes were: L_{10}: 254.4 µm, L_{50}: 512.4 µm, L_{90}: 923.6 µm.
Test Facility Siemens AG (2009)

Flammability (Solid) Not determined to be flammable.

Method EC Directive 92/69/EEC A.10 Flammability (Solids).
Remarks The notified chemical could not be ignited in the preliminary test. Therefore, it was not considered to be flammable.
Test Facility Institute fur Biologische Analytik and Consulting IBACON GmbH (2009e)

Autoignition Temperature Did not auto-ignite.

Method EC Directive 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Remarks Using a linear increase in temperature of 0.5ºC/min up to 400ºC, the notified chemical showed no self-ignition reaction, At the end of the experiments, the test item was a liquid.
Test Facility Institute fur Biologische Analytik and Consulting IBACON GmbH (2009f)

Oxidizing Properties Not an oxidant

Method EC Directive 92/69/EEC A.17 Oxidizing Properties (Solids).
Remarks The notified ingredient is chemically stable and will not decompose under normal ambient conditions. It is further considered to be inert in terms of oxidizing properties.
Test Facility Institute fur Biologische Analytik and Consulting IBACON GmbH (2009g)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical (50%)
METHOD	OECD TG 425 Acute Oral Toxicity: Up-and-Down Procedure. US EPA Health Effects Test Guidelines, OPPTS 870.1100 (2002)
Species/Strain	Rat/ Sprague-Dawley albino
Vehicle	Distilled water
Remarks - Method	No significant protocol deviations. An initial limit dose of 2,000 mg/kg bw was administered to one healthy female rat by oral gavage. Due to the absence of mortality in this animal, four additional females received the same dose level, sequentially. Since these animals survived, no additional animals were tested. Preliminary solubility testing conducted by the laboratory indicated that mixture in excess of 50% (i.e., 60-70%) were too viscous to be administered properly.
RESULTS	
LD50	> 2000 mg/kg bw
Signs of Toxicity	All animals observed survived, gained weight and were active and healthy during the study. There were no signs of gross toxicity, adverse pharmacological effects, or abnormal behaviour.
Effects in Organs	No gross abnormalities were noted for any of the animals when necropsied at the conclusion of the 14-day observation period.
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	Product Safety Laboratories (2006a)

B.2. Acute toxicity – dermal

TEST SUBSTANCE	Notified chemical (>90%)
METHOD	OECD TG 402 Acute Dermal Toxicity. EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal). US EPA Health Effects Test Guidelines, OPPTS 870.1200 (1998).
Species/Strain	Rat/ Sprague-Dawley albino
Vehicle	Distilled water used to form a dry paste (90% w/w/ mixture)
Type of dressing	Occlusive.
Remarks - Method	No significant protocol deviations. The test substance was moistened with distilled water and applied to the skin of ten healthy rats for 24 hrs.
RESULTS	
LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	None
Signs of Toxicity - Systemic	All animals observed survived, gained weight and were active and healthy during the study. There were no signs of adverse pharmacological effects, or abnormal behaviour.
Effects in Organs	No gross abnormalities were noted for any of the animals when necropsied at the conclusion of the 14-day observation period.
CONCLUSION	The notified chemical is of low toxicity via the dermal route.

TEST FACILITY Product Safety Laboratories (2006b)

B.3. Irritation – skin

TEST SUBSTANCE Notified chemical (>90%)

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.
EC Directive 2004/73/EC B.4 Acute Toxicity (Skin Irritation).
US EPA Health Effects Test Guidelines, OPPTS 870.2500 (1998).

Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	Distilled water used to form a dry paste (90% w/w/ mixture)
Observation Period	72 hrs
Type of Dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations. The test substance was moistened with distilled water and applied to the skin of three healthy rabbits for 4 hrs.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0.33	0	0	1	< 48 hrs	0
Oedema	0	0	0	0	0	0

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

Remarks - Results	All animals appeared active and healthy during the study. Apart from the slight dermal irritation noted above, there were no other signs of gross toxicity, adverse pharmacologic effects, or abnormal behaviour. There was no oedema observed at any treated site during this study. All 3 animals exhibited very slight erythema within one hour of patch removal. The overall incidence and severity of irritation decreased with time. All animals were free of dermal irritation by 48 hrs.

CONCLUSION The notified chemical is slightly irritating to the skin.

TEST FACILITY Product Safety Laboratories (2006c)

B.4. Irritation – eye

TEST SUBSTANCE Notified chemical (>90%)

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
EC Directive 2004/73/EC B.5 Acute Toxicity (Eye Irritation).
US EPA Health Effects Test Guidelines, OPPTS 870.2400 (1998).

Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Observation Period	7 days
Remarks - Method	The test substance was instilled into the right eye of three healthy rabbits. The left eye remained untreated and served as a control.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period (7 days)*
	1	2	3			
Conjunctiva: redness	2.0	2.0	1.67	2.0	< 7 days	0
Conjunctiva: chemosis	1.67	2.0	1.67	2.0	< 7 days	0
Conjunctiva: discharge	2.0	1.33	1.33	3.0	< 7 days	0
Corneal opacity	0.67	0.67	0.67	1.0	< 72 hrs	0
Iridial inflammation	1.0	1.0	0.67	1.0	< 4 days	0

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

Remarks - Results

Within 24 hrs of test substance instillation, all three treated eyes exhibited corneal opacity, iritis, and conjunctivitis. The overall incidence and severity of irritation decreased gradually thereafter. All animals were free of ocular irritation by Day 7 (at study termination).
Apart from the eye irritation noted, all animals appeared active and healthy during the study and there were no signs of gross toxicity, adverse pharmacologic effects, or abnormal behaviour.

CONCLUSION

The notified chemical is irritating to the eye.

TEST FACILITY

Product Safety Laboratories (2006d)

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