File No: STD/1405

December 2011

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Phosphoric acid compound in ADK STAB FP-2200

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

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

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

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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 SUBSTANCE	INTRODUCTION VOLUME	USE
STD/1405	Marubeni Australia Ltd	Phosphoric acid compound in ADK STAB FP-2200	Yes	≤70 tonnes per annum	Flame retardant in polymeric resins

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available data the notified chemical is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)]. The classification and labelling details are:

R36 Irritating to eyes

and

The classification of the notified chemical using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2009) 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	Category 2A	Irritating to eyes
Aquatic Environment	Acute Category 3	Harmful to aquatic life
	Chronic Category 3	Harmful to aquatic life with long lasting effects

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

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

Environmental risk assessment
On the basis of the limited aquatic exposure and the assessed use pattern, the notified chemical is not considered to pose an unreasonable 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:
  - Xi R36 Irritating to eyes
- Use the following risk phrases for products/mixtures containing the notified chemical:

- ≥20%: Xi; R36 Irritating to eyes

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:
  - Avoid contact with eyes
  - Do not inhale dust

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced in powdered form:
  - Eye protection
  - Appropriately fitted respiratory protection
  - Coveralls
  - Gloves

  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.

Emergency procedures

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

Regulatory Obligations

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

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

(1) Under Section 64(2) of the Act; if
  - the function or use of the chemical has changed from a flame retardant in polymeric resins, or is likely to change significantly;
  - the amount of chemical being introduced has increased from 70 tonnes per annum, or is likely to increase, significantly;

- the chemical has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

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

Material Safety Data Sheet
The MSDS of the product containing 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.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Marubeni Australia Ltd (ABN 53 000 329 699)
Level 19, 367 Collins Street
Melbourne VIC 3000

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: chemical name, other names, CAS number, molecular formula, structural formula, molecular weight, spectral data, purity, residual impurities, import volume, and site of reformulation.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: Acute inhalation toxicity, boiling point, flash point, and chronic toxicity to aquatic invertebrates.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Canada (2005), Korea (2009), Philippines (2009)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
ADK STAB FP-2200 (powder preparation containing the notified chemical at 35-45 % concentration)

MOLECULAR WEIGHT
<500 Da

ANALYTICAL DATA
Reference NMR, IR, HPLC, UV/Vis spectra were provided.

3. COMPOSITION

DEGREE OF PURITY >90%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None

ADDITIVES/ADJUVANTS
None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 ºC AND 101.3 kPa: White powder

Property	Value	Data Source/Justification
Melting Point	>360ºC	Measured
Boiling Point	Not determined	As the test material did not melt up to 360ºC.
Density	1.82 x 10^3 kg/m^3 at 21ºC	Measured
Vapour Pressure	<9.5 x 10^{-9} kPa at 25ºC	Measured
Water Solubility	0.225 g/L at 20ºC ± 0.5 ˚C (organic component) 0.150 g/L at 20˚C ± 0.5 ˚C (inorganic component)	Measured. The notified chemical is a salt with inorganic and organic components.
Hydrolysis as a Function of pH	$t_{½}$ >1 year at 25 ºC, pH 4-9 for organic and inorganic components	Measured
Partition Coefficient (n-octanol/water)	Log Pow = -1.48 at 22 ± 0.5ºC (organic component) Log Pow = <-4.18 at 22 ± 0.5˚C (inorganic component)	Measured
Adsorption/Desorption	log Koc = 2.11 at 40°C (organic component, partially ionised, pH 5.5) log Koc = 1.43 at 40ºC (organic component, unionised, pH 7.5) log Koc < 1.25 at 30ºC (inorganic component, ionised, pH 5.5)	Measured
Dissociation Constant	pKa = 5.16 (organic component) pKa_1 = ~1.0 (inorganic component) pKa_2 = ~ 1.8 (inorganic component) pKa_3 = ~ 6.57 (inorganic component) pKa_4 = ~ 9.64 (inorganic component)	Measured
Particle Size	Inhalable fraction (<105 μm): 76.4%* Respirable fraction (≤10 μm): 0.7%	Measured
Flash Point	Not determined	The notified chemical is solid.
Flammability	Not highly flammable	Measured
Autoignition Temperature	>400ºC	Measured
Explosive Properties	Not explosive	Measured
Oxidizing Properties	Non-oxidising.	Measured

*Although inhalable fraction is up to <100 μm, particle size distribution results were available up to 105 μm.

DISCUSSION OF PROPERTIES

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

Reactivity

The notified chemical contains no metals or metalloids and it is not expected to react on contact with water. Furthermore, during prolonged storage, the notified chemical did not show signs of instability in contact with air. Also, the notified chemical is non-oxidising and the chemical structure gives no indication of pyrophoric properties.

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. Therefore, consideration of all endpoints should be undertaken before a final decision on the Dangerous Goods classification is made by the introducer of the chemical.

5. INTRODUCTION AND USE INFORMATION

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

The notified chemical will be imported as a component (35-45%) of a powder preparation.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	<15	<30	<60	<70	<80

PORT OF ENTRY
Sydney and Melbourne

TRANSPORTATION AND PACKAGING
The notified chemical will be imported by sea in sealed aluminium bags on pallets. It will be transported from the port by road directly to the notifier's warehouse, where it will be dispatched to the downstream user (polymer compounds formulation site).

USE
The main use of the notified chemical will be as a flame retardant in polymeric resins to make various plastic articles such as electric appliances and electric cables. It is possible that the notified chemical may also be used in making building materials and stadium chairs.

OPERATION DESCRIPTION
During reformulation, the powder preparation containing the notified chemical (35-45%) will be manually weighed and added to a mixing vessel, along with other ingredients such as plastic powder, fillers, colour pigments and other additives. The mixture containing the notified chemical at <14% will then be transferred to a closed system preheated extruder, to produce plastic pellets. The plastic pellets, containing the notified chemical at <14%, will be automatically weighed and packed into plastic bags or bulk bags for delivery to customer sites.

At the customer sites, it is expected that the plastic pellets will be fed into the hopper of an injection moulding machine, in many cases manually. The plastic pellets containing the notified chemical at <14% will be heated in a cylinder, which is a closed system, and no vapours are expected to be released into the environment.

The heated polymer melt containing the notified chemical will be injected into a mould to form the shape of the required plastic article, containing the notified chemical at <14% concentration. Although this process is a closed system, the injection of plastic into mould will be an open system temporarily and negligible vapours are expected to be released. Local exhaust ventilation will be in place during moulding operations.

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	1-2	<8	5-10
Warehouse	1-3	1	10-20
Material handling	1-2	1	60-100
Mixing	1-2	1-2	60-100
Cleaning of mixer, hopper, floor	1-2	1-2	60-100
Extruder operation	1-2	3-5	60-100
Quality Control Testing	1-2	1-2	60-100
Maintenance of extruder	1-2	1	12
Finished article moulding	2-5	6-8	60-100
Maintenance of moulding machinery	1-2	1	12

EXPOSURE DETAILS

Transport and warehousing

Worker exposure to the notified chemical during the importation, transport and storage is not expected, except in the unlikely event of an accident where the packaging may be breached.

Reformulation/Pellets formulation

At the reformulation sites where the powder preparation containing the notified chemical (35-45%) will be converted to pellets, the main potential for exposure to the notified chemical via dermal, ocular or inhalation routes will be during manual weighing of the powder preparation and its transfer into the mixing vessel. The notifier has indicated that the powder preparation containing the notified chemical (35 - 45%) will be weighed in a dedicated additive preparation room, equipped with a dust extraction system and isolated from the rest of the factory. In addition, the operator performing this task will be required to wear comprehensive personal protective equipment (PPE) including particle-filter mask, safety glasses, gloves and protective clothing.

Due to the high potential for dermal and inhalation exposure to the notified chemical during manual weighing and transfer tasks, systemic toxicity is of concern from repeated exposure. The Estimation and Assessment of Exposure (EASE) exposure model from the European Chemicals Bureau (ECB) *Technical Guidance Document on Risk Assessment* (ECB 2003) estimated dermal exposure as 'very low', based on the following assumptions:

- Temperature: 25°C
- Physical state: Solid
- Dust inhalation: No
- Mobile solid: No
- Solid Vapour pressure: No
- Exposure type: Dermal
- Use pattern: Non-dispersive use
- Pattern of control: Not direct handling

The above estimates do not assume PPE for the user. The notifier has indicated that coveralls and gloves will be worn during reformulation processes. Therefore, based on the estimated 'very low' dermal exposure, and the required PPE, dermal exposure to the notified chemical is expected to be minimal.

Inhalation exposure is considered to be likely, resulting from inhalation of particulates during manual weighing and transfer processes. The EMKG-EXPO-TOOL (REACH 2009) was used to estimate an inhalation exposure range of 0.1-1 mg/m^3 based on the following assumptions:

- Definition of dustiness: High (fine powders)
- Scale of use: Medium (1 to 1000 kg)
- Control Strategies: Engineering control (local exhaust ventilation)
- Short term exposure: No (i.e., >15 minutes per day is likely)

The maximum estimated exposure concentration of 1 mg/m^3 powder preparation containing the notified chemical at 34-45% is then used to determine a typical daily systemic inhalation exposure for workers, based on the following assumptions:

- Inhalation absorption: 100% (default)
- Average Australian male bodyweight: 80 kg (ABS 2005)
- Respiration rate: 1.3 mg/m^3
- Duration of exposure: 1 hour/day (material handling – notifier's information)
- Concentration of notified chemical: 45% (maximum)

Systemic dose = (concentration powder × respiration rate × duration × concentration chemical) / bodyweight
= (1 mg/mg^3 × 1.3 mg/m^3/hour × 1 hour/day × 100% absorption × 45%) / 80 kg bw
= 0.00731 mg/kg bw/day

As the mixing vessel will be sealed during the mixing operation, exposure is expected to be minimal. Similarly, the extruder feeding system will be sealed and is equipped with dust extraction, thereby limiting any exposure during transfer of the mixture containing the notified chemical at <14% from the mixing vessel to the preheated extruder. During extrusion operations, exposure is not expected as this process takes place in a closed system equipped with both dust and fume extraction. Once the notified chemical has passed through the extruder, it will be encapsulated in a plastic resin and therefore, the potential for any exposure is significantly reduced. As the plastic pellets containing the notified chemical at <14% will be automatically weighed and packed into

plastic bags or bulk bags, exposure during packaging is also expected to be limited.

Manufacture of plastic articles, cleaning, maintenance and quality testing
During moulding operation, exposure is also possible as plastic pellets containing the notified chemical (<14%) are being fed into the hopper of an injection moulding machine manually. Although the actual moulding operation will be a closed system, the injection of heated plastic material into the mould will be an open system. Limited exposure is expected during the moulding process for the following reasons: the notified chemical is not considered to be bioavailable in the plastic pellets, the plastic pellets containing the notified chemical (<14%) are heated in a closed system, no vapours are expected to be released, and local exhaust ventilation protective glasses and protective gloves will be used.

Exposure to the notified chemical could also occur to a lesser degree during cleaning, maintenance and quality control testing. PPE such as safety glasses, gloves, dust masks and coveralls will be used by operators involved in these activities to minimize any expected exposure.

Workers could also be dermally exposed when touching finished articles containing the notified chemical at <14%. As the notified chemical will be trapped within the polymer matrix and no release of the notified chemical from finished articles is expected, exposure in this case is unlikely.

Overall, considering the use of engineering controls and PPE, exposure of workers to the notified chemical is expected to be low.

6.1.2. Public Exposure
As the powder preparation and plastic pellets containing the notified chemical (35-45% and <14%, respectively) will only be available to industrial end users, direct public exposure to the notified chemical is not expected. However, the public may come into contact with the finished articles containing the notified chemical at <14%. Public exposure, in this case, is unlikely as the notified chemical will be trapped within the polymer matrix, and no release of the notified chemical from finished articles is expected.

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.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD_{50}>2000 mg/kg bw; low toxicity
Rat, acute dermal toxicity	LD_{50}>2000 mg/kg bw; low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	irritating
Mouse, skin sensitisation – Local lymph node assay	non sensitising (under the study conditions)
Rat, repeat dose oral toxicity – 28 days	NOAEL=15 mg/kg bw/day LOAEL=150 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosome aberration	non clastogenic

Toxicokinetics, metabolism and distribution.
No toxicokinetic data on the notified chemical were submitted. Absorption of the notified chemical through the skin and gastrointestinal tract is expected to be limited by its low partition coefficient (<-4.18 and -1.48 for the inorganic and organic components, respectively), though its moderate water solubility (0.225 g/L and 0.150 g/L for the organic and inorganic components, respectively) and relatively low molecular weight (< 500 Da) suggest that some absorption may occur. This is supported by the systemic toxicity in the 28-day oral study in rats where effects in the kidneys were noted. Inhalation of powders of the notified chemical may occur, given that it contains ~76% of particles of inhalable size. However, respiration of the notified chemical is not expected to be significant, given that only a small proportion is of respirable size (0.7%). Upon deposition in the airways, due to its moderate water solubility, the notified chemical may dissolve/diffuse into the mucus lining the respiratory tract and subsequently be transported out of the respiratory tract. This also suggests that the notified chemical may be systemically absorbed following inhalation.

Acute toxicity.
The notified chemical has low acute oral (LD_{50}>2000 mg/kg bw) and dermal toxicity (LD_{50}>2000 mg/kg bw) in

rats. There is no data available on the acute inhalational toxicity of the notified polymer.

Irritation and Sensitisation.
The notified chemical is non-irritating to the skin but is an irritant to the eyes of rabbits. The notified chemical is unlikely to be a skin sensitiser based on an LLNA test in mice.

Repeated Dose Toxicity.
In a 28-day repeat dose gavage study, rats were administered the notified chemical at 0, 15, 150 or 1000 mg/kg bw/day. The NOAEL was 15 mg/kg bw/day based on histopathological changes in the kidney in males at the LOAEL of 150 mg/kg bw/day (tubular basophilia/dilation). These kidney effects were dose dependent at 150 and 1000 mg/kg bw/day and additional effects observed at 1000 mg/kg bw/day include interstitial inflammation of the papilla, cortical and medullary mineralisation, pelvic transitional cell hyperplasia, tubular casts and tubular necrosis. The tubular necrotic effects were minimal in severity, though they highlight the potential for severe effects in the kidneys following exposures longer than 28 days (i.e., subchronic or chronic exposure).

Mutagenicity.
The notified chemical was not mutagenic in a bacterial reverse mutation study, and not genotoxic in an *in vitro* chromosome aberration study in human lymphocytes.

Health hazard classification
Based on the conjunctival chemosis scores of >2 observed in two of the three test animals during the eye irritation study, 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

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
The main toxicological effects of concern are eye irritation following ocular exposure and systemic toxicity following repeated dermal or inhalation exposure. Eye irritation is likely to occur from ocular exposure to the notified chemical when present in concentrations greater than 20%, based on the cut-off for the R36 statement set by the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004). Below this level the risk of eye irritation is expected to be low. Before reformulation, the notified chemical will be present in the imported product at 35-45%, therefore eye irritation may occur as a result of ocular exposure to the imported product. The notified chemical will be weighed in a dedicated additive preparation room equipped with dust extraction and isolated from the rest of the factory. In addition, the operator performing this task will be required to wear comprehensive personal protective equipment (PPE) including safety glasses, which will mitigate the risk from ocular exposure to the notified chemical. After reformulation, the notified chemical will be encapsulated in plastic resin and eye irritation will not be of concern. Ocular exposure during plastics manufacture may also occur but the notified chemical will be present at <20% and the notifier has indicated that protective eye wear is likely to be worn, therefore the risk to workers from ocular exposure is not considered to be unreasonable.

The estimate of 'very low' dermal exposure does not assume PPE for the user. The notifier has indicated that coveralls and gloves will be worn during reformulation processes. Therefore, based on the estimated 'very low' dermal exposure, and the likely PPE, the risk from dermal exposure to the notified chemical is not considered to be unreasonable. However, there is a potential for secondary exposure to the notified chemical from adhered particles on the clothing of workers. Coveralls and gloves are recommended when workers are handling the powder preparation to mitigate this risk. Therefore, the risk to workers from secondary exposure is not considered unreasonable when workers wear coveralls and gloves.

For systemic toxicity, the NOAEL of 15 mg/kg bw/day from the 28-day oral rat study based on kidney toxicity is the only study appropriate for risk assessment and calculation of a margin-of-exposure (MOE). A 10-fold safety factor to account for intraspecies variation and a 10-fold safety factor to account for interspecies extrapolation will be used when considering the MOE. There is the potential for long-term worker exposure to occur, and given the NOAEL is from a short-term study, an additional 10-fold safety factor will be applied to account for short-term to chronic extrapolation. Therefore, a MOE of 1000 or greater is considered acceptable for risk assessment of the notified chemical.

Based on the estimated inhalation exposure of 0.00731 mg/kg bw/day, the MOE is determined as follows:

MOE = NOEL / Systemic dose
= 15 mg/kg bw/day / 0.00731 mg/kg bw/day
= 2051

The MOE of 2051 is above the acceptable MOE of 1000 and thus there is no systemic toxicity concern for worker exposure from inhalation of the notified chemical. The notifier has stated that respiratory protection will be worn during manual weighing and transfer processes. Given the limited presence of inhalable particles (<0.7%), and in the absence of acute inhalation toxicity data for the notified chemical, respiratory protection is still recommended. Therefore, the risk to workers inside facilities with local exhaust ventilation and wearing respiratory protection during manual weighing and transfer processes is not considered to be unreasonable.

Dermal, inhalation and ocular exposure of workers to the notified chemical during other activities such as transport and warehousing; manufacture of plastics; and cleaning, maintenance and quality testing of machinery are likely to be low and the risk to workers exposed during these stages is not considered to be unreasonable.

6.3.2. Public Health

The public will only come into contact with the notified chemical when trapped within a polymer matrix in finished products and therefore is not expected to be bioavailable for exposure. The risk to the public from exposure to finished products is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical will not be manufactured in Australia; therefore, there will be no release from this activity. Release to the environment is unlikely during importation, transport and storage but may occur as a result of accidental spills or leaks. This is expected to be minor due to the packaging of the material. Releases that do occur as a result of accidents are expected to be physically contained, collected and disposed of in accordance with local regulations.

The notified chemical will be incorporated into plastic resins and, based on typical industrial processes and controls for the production of plastic pellets, release to the aquatic environment is not expected during reformulation activities. Residues in import packaging are estimated at up to 0.1% of the import volume and, along with an estimated 0.5% reformulation wastage generated by spillage, start up lump, pellet cuts, out of specification material and equipment cleaning, are expected to be collected and disposed of in accordance with local regulations, namely to landfill.

RELEASE OF CHEMICAL FROM USE

The notified chemical in plastic pellets is used in the production of plastic articles such as electrical appliances, building materials and stadium chairs, and, based on typical industrial processes for injection moulding, release to the aquatic environment is not expected due to these activities. It is expected that any wastes containing the notified chemical from these activities will be in solid form and disposed of in accordance with local regulations, namely to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

The majority of the notified chemical will share the fate of the plastic articles. At the end of the useful life of the plastic articles it is expected that disposal will be to landfill.

7.1.2. Environmental Fate

The majority of the notified chemical is expected to be disposed of to landfill and no significant release of the notified chemical to the aquatic environment is expected from the reported use pattern. The notified chemical is not readily biodegradable (refer to Appendix C) and does not hydrolyse under environmental conditions but it is not expected to bioaccumulate due to its low partition coefficient. Although the adsorption coefficient indicates that the notified chemical may be mobile in soils, when disposed of to landfill the notified polymer is largely expected to be trapped within the inert polymer matrix of pellets or finished articles and in this form it is not expected to leach or be bioavailable. In landfill, the notified chemical is expected to be slowly released from the polymer matrix over time and degrade to form water and oxides of carbon, nitrogen and phosphorous.

7.1.3. Predicted Environmental Concentration (PEC)

The PEC has not been calculated since no significant release of the notified chemical to the aquatic compartment is expected based on the reported use pattern.

7.2. Environmental Effects Assessment

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

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	96 h LC_{50} >74.96 mg/L	Unlikely to be harmful to fish
Daphnia Toxicity	48 h EC_{50} > 80 mg/L	Unlikely to be harmful to aquatic invertebrates
Algal Toxicity	72 h E_rC_{50} = 98 mg/L	Harmful to algae

Under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009) the notified chemical is unlikely to be harmful to fish and aquatic invertebrates but is harmful to algae, and is formally classified as 'Acute Category 3: Harmful to aquatic life'. On the basis of its toxicity to algae and since it is not rapidly degradable, the notified chemical is formally classified as 'Chronic Category 3: Harmful to aquatic life with long lasting effects'.

7.2.1. Predicted No-Effect Concentration

Calculation of the PNEC was not considered necessary since no significant release of the notified chemical to the aquatic compartment is expected from the reported use pattern.

7.3. Environmental Risk Assessment

The Risk Quotient (PEC/PNEC) was not calculated as limited release of the notified chemical to the aquatic compartment is expected based on the reported use pattern. The majority of the imported notified chemical will be trapped within an inert polymer matrix in plastic pellets and articles and in this form it is not expected to leach or be bioavailable. Therefore, on the basis of limited aquatic exposure and the assessed use pattern, the notified chemical is not considered to pose an unreasonable risk to the environment

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point/Melting range >360ºC

Method OECD TG 102 Melting Point/Melting Range.
Remarks Determination was carried out by differential scanning calorimetry (DSC).
Test Facility SafePharm (2004a).

Density 1.82 x 10^3 kg/m^3 at 21.0ºC ± 0.5

Method OECD TG 109 Density of Liquids and Solids.
Remarks Determined using a gas comparison pycnometer.
Test Facility SafePharm (2004a).

Vapour Pressure <9.5 x 10^{-9} kPa at 25ºC

Method OECD TG 104 Vapour Pressure.
Remarks Determined using a vapour pressure balance.
Test Facility SafePharm (2004b).

Water Solubility 0.225 g/L at 20ºC ± 0.5 ˚C (organic component)
0.150 g/L at 20˚C ± 0.5 ˚C (inorganic component)

Method OECD TG 105 Water Solubility.
Remarks Flask Method with HPLC/UV determination of the organic component and ion chromatographic determination of the inorganic component. The pH of the solution was determined but not reported.
Test Facility Safepharm (2004a)

Hydrolysis as a Function of pH

Method OECD TG 111 Hydrolysis as a Function of pH.
EC Directive 92/69/EEC C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH.

Organic component

pH	*T (°C)*	*t½*
4	25	>1 year
7	25	>1 year
9	25	>1 year

Inorganic component

pH	*T (°C)*	*t½*
4	25	1.49 years
7	25	>1 year
9	25	>1 year

Remarks Except for the inorganic component at pH 4, less than 10% hydrolysis occurred after 5 days at 50˚C, equivalent to a half- life of greater than 1 year at 25˚C.
Test Facility Safepharm (2004a)

Partition Coefficient (n-octanol/water) Log Pow = -1.48 at 22 ± 0.5ºC (organic component)
Log Pow = <-4.18 at 22 ± 0.5˚C (inorganic component)

Method OECD TG 117 Partition Coefficient (n-octanol/water).
EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks Flask Method
Test Facility Safepharm (2004a)

Adsorption/Desorption – screening test

log Koc = 2.11 at 40°C (organic component, partially ionised, pH 5.5)
log Koc = 1.43 at 40ºC (organic component, unionised, pH 7.5)
log Koc < 1.25 at 30ºC (inorganic component, ionised, pH 5.5)

Method OECD TG 121 Estimation of the Adsorption Coefficient (Koc) on soil and on sewage sludge using High Performance Liquid Chromatography (HPLC)
Remarks UV detection for organic component and MS detection for inorganic component. It was not possible to test the inorganic component in its unionised form as the required pH would be outside the specified pH range of the test.
Test Facility Safepharm (2004a)

Dissociation Constant

pKa = 5.16 organic component
pKa_1 = ~1.0 inorganic component
pKa_2 = ~ 1.8 inorganic component
pKa_3 = ~ 6.57 inorganic component
pKa_4 = ~ 9.64 inorganic component

Method N/A
Remarks No determination was performed due to the availability of literature values for each component of the test material.
Test Facility Safepharm (2004a)

Particle Size

0.7% w/w particles of notified chemical were <10 µm

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

Range (µm)	*Mass (%)*						
	Test 1	*Test 2*	*Test 3*	*Test 4*	*Test 5*	*Test 6*	*Mean*
105-130	39.3	25.0	31.1	19.7	18.2	8.4	23.6
60.0-105	27.5	36.8	44.8	46.5	50.4	56.5	43.8
30.0-60.0	18.6	23.8	15.9	21.0	22.7	26.2	21.4
10.4-30.0	13.9	13.5	7.6	11.9	7.8	8.5	10.5
0.5-10.4	0.7	0.9	0.5	0.8	0.9	0.4	0.7

Remarks The observed particles were predominantly irregularly-shaped, with some oblong in appearance.
Test Facility Huntingdon (2011).

Flammability

Not highly flammable

Method EC Directive 92/69/EEC A.10 Flammability (Solids).
Test Facility Huntingdon (2011).

Autoignition Temperature

>400ºC

Method EC Directive 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Remarks The notified chemical was found not to self-ignite below 400ºC.
Test Facility Huntingdon (2011).

Explosive Properties

Not explosive

Method EC Directive 92/69/EEC A.14 Explosive Properties.
Test Facility Huntingdon (2011).

Oxidizing Properties

Non-oxidising

Method EC Directive 92/69/EEC A.17 Oxidizing Properties (Solids).
Test Facility Huntingdon (2011).

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/Sprague-Dawley CD (Crl:CD(SD)IGS BR)
Vehicle Arachis oil BP
Remarks - Method Limit test at 2000 mg/kg bw/day. No protocol deviations noted.

RESULTS

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

LD_{50} >2000 mg/kg bw
Signs of Toxicity No signs of systemic toxicity.
Effects in Organs No abnormalities noted during necropsy.
Remarks - Results All animals gained weight over the 14 day observation period.

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

TEST FACILITY SafePharm (2004c)

B.2. Acute toxicity – dermal

TEST SUBSTANCE Notified chemical

METHOD OECD TG 402 Acute Dermal Toxicity – Limit Test.
Species/Strain Rat/CD(Crl:CD SD)
Vehicle Corn oil
Type of dressing Semi-occlusive
Remarks - Method No protocol deviations noted.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 males	2000	0/3
2	5 females	2000	0/3

LD_{50} >2000 mg/kg bw
Signs of Toxicity - Local Very slight erythema (grade 1) noted in one male and one female, which resolved by the end of the observation period.
Signs of Toxicity - Systemic No signs of systemic toxicity.
Effects in Organs No abnormalities noted at necropsy at completion of the study.
Remarks - Results No bodyweight gain was noted in one female. All other animals continued to gain weight over the study duration.

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

TEST FACILITY Huntingdon (2010a)

B.3. Irritation – skin

TEST SUBSTANCE Notified chemical

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.
EC Directive 2004/73/EC B.4 Acute Toxicity (Skin Irritation).

Species/Strain	Rabbit/New Zealand White
Number of Animals	3 males
Vehicle	Distilled water
Observation Period	72 hours
Type of Dressing	Semi-occlusive
Remarks - Method	pH of test material = 3.5

RESULTS

Remarks – Results	Scores of zero were observed in all three rabbits at 1, 24, 48 and 72 hours.

CONCLUSION The notified chemical is non-irritating to the skin.

TEST FACILITY SafePharm (2005a)

B.4. Irritation – eye

TEST SUBSTANCE Notified chemical

METHOD OECD TG 405 Acute Eye Irritation/Corrosion (2002)

Species/Strain	Rabbit/New Zealand White
Number of Animals	3 females
Observation Period	15 days
Remarks - Method	No protocol deviations noted.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	2	1.67	2	2	<15 days	0
Conjunctiva: chemosis	2.33	1	2.33	3	<8 days	0
Conjunctiva: discharge	1	0	2	3	<8 days	0
Corneal opacity	0.67	0.33	1	1	<8 days	0
Iridial inflammation	0	0	0	0	0 hrs	0

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

Remarks - Results

CONCLUSION The notified chemical is irritating to the eye.

TEST FACILITY Huntingdon (2011c)

B.5. Skin sensitisation

TEST SUBSTANCE Notified chemical

METHOD OECD TG 429 Skin Sensitisation – Local Lymph Node Assay (2002).

Species/Strain	Mouse (CBA/Ca (CBA/CaBkl)
Vehicle	Acetone:olive oil (4:1)
Remarks – Method	Doses were selected based on the results of a preliminary screening study conducted on one mouse treated with 25 µL of 25% w/w test material on three consecutive days. No signs of systemic toxicity were noted after 6 days. The concentrations of 5, 10 and 25% w/w were selected for the main story on this basis. The selection of 25% w/w concentration as the highest dose tested in this study may not have maximized exposure, as required by the test protocol. Given that no signs of toxicity or excessive irritation

were recorded during the preliminary test at 25% concentration

This protocol deviation is not expected to adversely affect the results, however, the conclusion may be of limited significance given that the employed test method did not maximise initial sensitization to the test material. It should also be noted that irritation was not reported or discussed.

A concurrent positive control was not conducted during this study, however, the laboratory provided results of positive controls conducted within six months of the present study, thus confirming the sensitivity of the laboratory.

RESULTS

Concentration (% w/w)	*No. animals*	*Proliferation response (DPM/Node)*	*Stimulation index (Test/control)*
0	4	1251.20	-
5	4	980.72	0.78
10	4	1000.85	0.80
25	4	725.79	0.58

Remarks - Results

CONCLUSION There was no evidence of induction of lymphocyte proliferation response indicate of skin sensitisation to the notified chemical, under the study conditions.

TEST FACILITY SafePharm (2005b)

B.6. Repeat dose toxicity

TEST SUBSTANCE Notified chemical

METHOD OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents (2008).
OPPTS 870-3050, Repeated Dose 28-day Oral Toxicity Study in Rodents. (2000).

Species/Strain Rat/Crl:CD(SD)
Route of Administration Oral – gavage
Exposure Information Total exposure days: 28 days
Dose regimen: 7 days per week
Post-exposure observation period: None
Vehicle Corn oil
Remarks - Method Urinalysis was not conducted. Seminiferous tubules were evaluated for the spermatogenic cycle. The vagina was examined for the stage of menstrual cycle.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
control	5/sex	0	0/5
low dose	5/sex	15	0/5
mid dose	5/sex	150	0/5
high dose	5/sex	1000	0/5

Mortality and Time to Death
There were no unscheduled deaths.

Clinical Observations

There were no treatment related clinical signs or arena observations. There were no treatment related findings in the sensory reactivity and grip strength assessments. There were sporadic changes in the motor activity but there was no dose dependent relationship and most measurements were similar to controls, thus these findings are not considered treatment related.

There was a statistically significant reduction in body weight gain in 1000 mg/kg bw/day males (↓30%) and females (↓22%) over the treatment period. The food consumption was reduced in 1000 mg/kg bw/day males (↓14%) and females (↓8%) over the treatment period. Water consumption was markedly increased over the treatment period in 1000 mg/kg bw/day males (↑87%) and females (↑88%).

Laboratory Findings – Clinical Chemistry and Haematology

Effects on haematology include statistically significant changes compared to controls in mean corpuscular haemoglobin concentration (MCHC) (↑2%), mean cell volume (↓5%) and leukocyte count (↓34%) in 1000 mg/kg bw/day males, and neutrophils (↑460%), eosinophils (↑100%) and monocytes (↑150%) in 1000 mg/kg bw/day females. Other non-statistically significant changes at 1000 mg/kg bw/day include platelet count (↑18%) in males and white blood cell count (↑36%) in females. There was also a slight decrease in activated partial prothrombin time in 1000 mg/kg bw/day males (↓15%) and females (↓15%). The change in MCHC in males is considered to be small and within the limits of biological variability. There were no clear dose dependent trends and there is no clear trend between sexes, but are considered treatment related in the absence of evidence to dismiss the effects.

Statistically significant changes in clinical chemistry parameters included alanine aminotransferase (ALT) (↑46%), aspartate aminotransferase (↑25%), total bile acid content (↓52%), urea (↑460%), creatinine (↑436%), clolesterol (↑21%) and total protein (↓7%) in 1000 mg/kg bw/day males, and ALT (↑64%), urea (↑399%), creatinine (↑292%), total protetin (↑8%) and albumin/globulin ratio (↓14%) in 1000 mg/kg bw/day females. Some of these effects did not show clear dose related trends though they are considered to be treatment related. There was a statistically significant decrease in sodium (↓1%) in 1000 mg/kg bw/day males but the change was within expected biological variation for this parameter and is unlikely to be treatment related.

Effects in Organs

KIDNEYS: Absolute kidney weights were statistically increased in 1000 mg/kg bw/day males (↑33%) and females (↑86%), which given the decreased body weight gains, were accompanied by changes in relative kidney weights (↑52% in males and ↑103% in females). Associated treatment related macroscopic kidney observations in 1000 mg/kg bw/day males and females were enlarged, granular, pale and pale areas. Histopathology revealed treatment related changes in 1000 mg/kg bw/day males and females, and in 150 mg/kg bw/day males (see following Table for incidence and severity). The histopathological findings in the kidney appear to be the main treatment related systemic toxicity effect and indicate the LOAEL of 150 mg/kg bw/day based on the increased incidence and severity of tubular basophilia/dilation and tubular casts in males. These pathological kidney changes likely explain the marked changes in urea and creatinine in 1000 mg/kg bw/day males and females.

Necrosis only occurred at 1000 mg/kg bw/day in males and females, thus the NOAEL of 15 mg/kg bw/day is likely to be protective of these effects. The tubular necrotic effects were minimal in severity, though they highlight the potential for severe effects in the kidneys following exposures longer than 28 days (i.e., subchronic or chronic exposure).

	Males (mg/kg bw/day)				*Females (mg/kg bw/day)*			
	0	*15*	*150*	*1000*	*0*	*15*	*150*	*1000*
Cortical cysts	0	0	0	0	0	0	0	1
Interstitial inflammation, papilla	0	0	0	5(2.0)	0	0	0	5(1.8)
Mineralisation, cortex	0	0	0	4(1.0)	0	0	0	0
Mineralisation, medulla	0	0	0	5(1.8)	0	0	1(1.0)	5(2.6)
Transitional cell hyperplasia, pelvis	0	0	0	5(2.0)	0	0	0	5(1.6)
Tubular basophilia/dilation	0	0	3(1.0)	5(3.0)	0	0	0	5(3.4)
Tubular casts	1(1.0)	1(1.0)	2(1.0)	5(2.0)	1(1.0)	0	0	5(1.2)
Tubular necrosis/degeneration	0	0	0	5(1.0)	0	0	0	5(1.4)

( ) Average severity of affected animals: 1=minimal, 2=slight, 3=moderate, 4=marked.

ADRENALS: There was a slight non-statistically significant increase in absolute adrenal weights in 1000

mg/kg bw/day males (↑12%), with associated increases in relative adrenal weights (↑28%). No pathological changes were observed.

REPRODUCTIVE ORGANS: In males, absolute epididymus weights were decreased at the high dose (↓11%) but the relative epididymus weights were similar to controls. The absolute seminal vesicles, prostate and coagulating gland (weighed together) weight was decreased at 150 mg/kg bw/day (↓6%) and at 1000 mg/kg bw/day (↓17%) but there was no associated relative weight decreases. No cell or stage specific abnormalities were noted in the seminiferous tubules.

In females, there was a non-statistically significant increase in the absolute uterus and cervix weights (weighed together) at 1000 mg/kg bw/day (↑39%), with an associated increase in relative weights (↑50%). Fluid distension in the uterus was noted during necropsy in all treatment groups (1/5, 1/5 and 3/5 at 15, 150 and 1000 mg/kg bw/day females, respectively) and is likely to be treatment related at 1000 mg/kg bw/day. Luminal dilation was also observed in 3/5 females at 1000 mg/kg bw/day but was also observed in 1/5 females in the control, 15 and 150 mg/kg bw/day groups. There were no notable differences in the oestrus cycle stage between the control and 1000 mg/kg bw/day groups.

LIVER: In males only, there was a decrease in absolute liver weights (↓16%) but there was only a slight decrease in relative liver weights (↓4%). There were no treatment related macroscopic or microscopic changes.

THYMUS: Absolute thymus weights were decreased in 1000 mg/kg bw/day males (↓31%) and an associated decrease in relative thymus weights (↓22%) and is therefore possibly treatment related. The decrease in absolute thymus weights in 1000 mg/kg bw/day females (↓18%) is unlikely to be treatment due to the lack of a marked decreased in relative thymus weights (↓11%). Thyroid hormone levels were not measured in this study.

BRAIN: Absolute brain weights were similar to controls.

Remarks – Results

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established at 15 mg/kg bw/day in this study, based on histopathological changes in the kidney (tubular basophilia/dilation in males) at 150 mg/kg bw/day and above.

TEST FACILITY Huntingdon (2011d)

B.7. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical

METHOD
OECD TG 471 Bacterial Reverse Mutation Test.
EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria.
Plate incorporation procedure

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100, *E. coli*: WP2uvrA
Metabolic Activation System	S9 fraction from rat liver induced with phenobarbitone/β-naphthoflavone
Concentration Range in Main Test	a) With metabolic activation: 50 to 5000 µg/plate b) Without metabolic activation: 50 to 5000 µg/plate
Vehicle	Dimethyl sulfoxide
Remarks - Method	No significant protocol deviations

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
Test 2	-	>5000	-	Negative

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

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

TEST FACILITY SafePharm (2004d)

B.8. Genotoxicity – in vitro

TEST SUBSTANCE

METHOD OECD TG 473 In vitro Mammalian Chromosome Aberration Test.
EC Directive 2000/32/EC B.10 Mutagenicity - In vitro Mammalian Chromosome Aberration Test.

Cell Type: Human lymphocytes
Metabolic Activation System: S9 rat liver faction
Vehicle: Aqueous culture medium
Remarks - Method: 190 µL/mL was the maximum achievable solubility

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0*, 1.91, 3.19, 5.32, 8.86, 14.77, 24.63, 41.04, 68.4*, 114*, 190* and MMC*	3	21
Test 2	0*, 8.86, 14.77, 24.63, 41.04, 68.40*, 114*, 190* and MMC*	21	21
S9 mix present			
Test 1 (2%)	0*, 1.91, 3.19, 5.32, 8.86, 14.77, 24.63, 41.04, 68.4*, 114*, 190* and CP*	3	21
Test 2 (5%)	0*, 8.86, 14.77, 24.63, 41.04, 68.40*, 114*, 190* and CP*	3	21

*Cultures selected for metaphase analysis.
MMC = Mitomycin C, CP = Cyclophosphamide

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	n/a	>190	>190	Negative
Test 2	n/a	>190	>190	Negative
Present				
Test 1	n/a	>190	>190	Negative
Test 2	n/a	>190	>190	Negative

Remarks - Results

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

TEST FACILITY Huntingdon (2011e)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 310 Ready Biodegradability - CO_2 in sealed vessels (Headspace Test).
Inoculum	Activated sludge, domestic sewage treatment
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Method (b), total inorganic carbon (TIC)
Remarks - Method	The test was conducted in accordance with the above guidelines and in compliance with GLP standards and principles. The test was conducted using CO_2 free ultrapurified water. There were no significant deviations from the protocol.

RESULTS

Notified chemical		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
7	0	7	64.9
14	0	14	63.2
21	0	21	63.6
28	0	28	61.7

Remarks - Results

CO_2 evolved by the blank controls were slightly above the validity criterion of 3 mg C/L (equivalent to ≤15% of the applied organic load) but all results were below 4 mg C/L (equivalent to 20% of the applied organic load). The reference substance was degraded by 63.8% in the presence of the notified chemical; therefore, the notified chemical was considered to be non-inhibitory to the microbial activity of the inoculum. As sodium benzoate showed acceptable biodegradation after 14 days in the reference substance control and after 7 days in the inhibition check, and there was no evidence of biodegradation of the test substance, only the precision of some results were considered to have been affected to a minor extent and the test result is still considered to be reliable.

There was no evidence of CO_2 production in samples containing the notified chemical above that evolved by the blank controls. Therefore, the notified chemical was not considered readily biodegradable under the conditions of the test.

CONCLUSION	The notified chemical is not readily biodegradable.
TEST FACILITY	Huntingdon (2011b)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test – Semi-Static. EC Directive 92/69/EEC C.1 Acute Toxicity for Fish – Semi-static.
Species	Rainbow Trout (*Oncorhynchus mykiss*)
Exposure Period	96 hours

Auxiliary Solvent	None
Water Hardness	34 mg $CaCO_3$/L (calculated from labelled data)
Analytical Monitoring	Ion Chromatography
Remarks – Method	The test was conducted in accordance with the guideline above and in compliance with GLP standards and principles. After a range finding test over 0.1-100 mg/L in static conditions, a limit test was conducted at 100 mg/L in dechlorinated tap water, however, only 7% recovery of the notified chemical was achieved. Therefore, the definitive limit test at 100 mg/L was conducted in bottled natural spring water with improved recovery (70.1-81.5%) under semi-static conditions.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*0 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control	(0)	7	0	0	0	0	0
100	74.96	7	0	0	0	0	0

LC50	>74.96 mg/L at 96 hours
NOEC	74.96 mg/L at 96 hours
Remarks – Results	The validity criteria were met. In accordance with the test guideline the results are based on the mean of the measured concentration as the measured concentration deviated from the nominal concentration by more than 20%. No effects were observed up to the highest tested concentration of 74.96 mg/L and, therefore, the EC50 could not be calculated. The 96 h LC50 was estimated to be greater than 74.96 mg/L based on the results of the test. The no-observed effect concentration (NOEC) was 74.96 mg/L. The lowest observed (lethal) effect concentration (LOEC) could not be determined as there were no mortalities or abnormal behaviour recorded.

CONCLUSION The notified chemical is unlikely to be harmful to fish.

TEST FACILITY Chemex (2005a)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified chemical

METHOD OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – Semi-static.
EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia – Semi-static.

Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	156 mg $CaCO_3$/L
Analytical Monitoring	Ion Chromatography
Remarks - Method	After a range finding test a definitive test was conducted in accordance with the guideline above and in compliance with GLP standards and principles. There were no significant deviations from the protocol.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
Control	(0)	20	0	0
10	<0.42	20	0	0
18	<0.42	20	0	0
32	7	20	0	0
56	33	20	0	0
100	80	20	0	0

EC50	>80 mg/L at 24 hours >80 mg/L at 48 hours
NOEC	80 mg/L at 48 hours
Remarks - Results	The validity criteria were met. At the highest exposure concentration (100 mg/L) the measured concentration of the notified chemical were 86 mg/L and 88 mg/L for the freshly prepared 0 and 24 hour solutions, respectively. The measured concentrations in the aged solutions decreased to 75 mg/L and 69 mg/L after 24 hours. At all the lower exposure concentrations the percent recovery was less than 80% for both fresh and aged solutions. It is noted that the percentage recovery dropped in fresh solutions as the nominal concentration decreased and as the solutions aged. In accordance with the test guideline, the results are based on the measured concentration as the concentration of the test substance was not maintained within ±20% of the nominal concentration, or initial measured concentration, throughout the test. No effects were observed up to 80 mg/L and, therefore, the EC50 could not be calculated. The 48 hour EC50 was estimated to be >80 mg/L. The no observed effect concentration (NOEC) after 48 hours was 80 mg/L. The lowest test concentration that immobilised all twenty *daphnia* within 48 hours could not be determined as there was 0% immobilisation at the highest test concentration.
CONCLUSION	The notified chemical is unlikely to be harmful to aquatic invertebrates.
TEST FACILITY	Chemex (2005bc)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE

METHOD	OECD TG 201 Alga, Growth Inhibition Test. EC Directive 92/69/EEC C.3 Algal Inhibition Test.
Species	*Pseudokirchneriella subcapitata,* strain CCAP 278/4
Exposure Period	72 hours
Concentration Range	Nominal: Control (0), 10, 18, 32, 56 and 100 mg/L Actual: Control (not measured), 1.4, 7.6, 17.1, 46.6 and 93.9 mg/L
Auxiliary Solvent	None
Water Hardness	156 mg $CaCO_3$/L
Analytical Monitoring	Ion Chromatography
Remarks - Method	After a range finding test a definitive test was conducted in accordance with the guideline above and in compliance with GLP standards and principles. There were no significant deviations to the protocol.

RESULTS

Biomass		*Growth*	
E_bC_{50} mg/L at 72 h	*NOEC mg/L*	*E_rC_{50} mg/L at 72 h*	*NOEC mg/L*
44	<10	98	<10

Remarks - Results

The validity criteria were met. The EC50 values were determined using a logarithm-linear or logarithm probit plot. The 72 hour NOEC was estimated as <10mg/L as determined by the Bonferroni T test.

At the two highest exposure concentrations (56 and 100 mg/L) the initial measured concentrations of the notified chemical were within 20% of the nominal concentration. This was not the case for the solutions containing 32 mg/L or less with as little as 27% of the nominal concentration measured in the 10 mg/L solution. It is noted that the percentage recovery dropped in line with decreasing nominal concentration. The measured concentrations after 72 hours did not vary by more than 20% compared to the initial measured concentration, with the exception of lowest concentration solution which was below the limit of detection.

In accordance with the test guideline, the results should therefore be based on the measured concentration as the concentration of the test substance varied by more than 20% from the nominal concentration throughout the test. However, the reported results were calculated using the nominal concentrations. Therefore, the results should be treated with caution. For example, effects on both biomass integral and growth rate were observed at all tested concentrations. The geometric mean of measured concentrations for the lowest exposure concentration was 1.4 mg/L and therefore the NOEC would be expected to be <1.4 mg/L.

CONCLUSION

The notified chemical is harmful to algae.

TEST FACILITY

Chemex (2005de)

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