File No: LTD/1361

April 2008

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Substance 1 in AKPT-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 the Environment, Water, Heritage and the Arts.

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 334-336 Illawarra Road, Marrickville NSW 2204.

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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FULL PUBLIC REPORT

Substance 1 in AKPT-1

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Epson Australia Pty Ltd (ABN: 91 002 625 783)
3 Talavera Road
North Ryde NSW 2113

NOTIFICATION CATEGORY
Limited-small volume: Chemical other than polymer (1 tonne or less 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; Import Volume.

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

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
LVC/740

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
AKPT-1 (for reaction mixture)
Ink Cartridge T0633 (containing ~1% notified chemical)

CAS NUMBER
Not assigned

MOLECULAR WEIGHT
>500 Da

ANALYTICAL DATA
Reference NMR, IR, GPC, UV-vis and MALDI-TOF spectra were provided.

3. COMPOSITION

DEGREE OF PURITY — Purity of complete reaction mixture, consisting of Substance 2 in AKPT-1 (see LTD/1340) and Substance 1 in AKPT-1, is typically ~82%. Substance 1 typically represents < 45% of the reaction mixture.

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (> 1% by weight)

Chemical Name	Quino[2,3-b]acridine-7,14-dione, 5,12-dihydro-2,9-dimethyl-		
CAS No.	980-26-7	*Typical concentration*	6%

Chemical Name Poly(oxy-1,2-ethanediyl), α-dodecyl-ω-hydroxy-
CAS No. 9002-92-0 *Typical concentration* 3.2%

Chemical Name Benzenesulfonic acid, 2-amino-
CAS No. 88-21-1 *Typical concentration* 1.6%

Chemical Name 1*H*-Isoindole-1,3(2*H*)-dione, 5-amino-
CAS No. 3676-85-5 *Typical concentration* 1.6 %

Chemical Name Water
CAS No. 7732-18-5 *Typical concentration* 5.2%

ADDITIVES/ADJUVANTS
None

4. PHYSICAL AND CHEMICAL PROPERTIES

NOTE: all studies were performed with the complete reaction mixture and not on Substance 1 in AKPT-1 individually as it cannot be separated from the reaction mixture.

APPEARANCE AT 20°C AND 101.3 kPa: Magenta powder

Property	**Value**	**Data Source/Justification**
Melting Point	No melting temperature observed	Measured
Boiling Point	No boiling temperature observed	Measured
Density	1451 kg/m^3 at 20°C	Measured
Vapour Pressure	< 1.47x10^{-11} kPa at 20°C	Measured
Water Solubility	<0.6 mg/L at pH 5.3-5.9	Measured
Hydrolysis as a Function of pH	Not determined	Due to the low water solubility. There is one hydrolysable functionality but this is not expected to be hydrolysed in the environmental pH range of 4-9.
Partition Coefficient (n-octanol/water)	Not determined	Due to the limited solubility in water and octanol. Expected to partition to octanol phase.
Adsorption/Desorption	Not determined	Due to the lack of solubility in the solvent system tested. Expected to associate with soils/sediments.
Dissociation Constant	Not determined	Due to the low water solubility. Several functionalities that could become cationic in environmental pH range of 4-9.
Particle Size	Inhalable fraction (<100 μm): ~98.5% Respirable fraction (<10 μm): 54.37% MMAD* = 10.409 μm	Measured
Flash Point	Not determined	Not expected to flash under normal conditions of use.
Flammability	Not highly flammable	Measured
Flammability in Contact with Water	Not predicted to be flammable in contact with water	Estimated
Pyrophoric Properties	Not predicted to be pyrophoric	Estimated
Autoignition Temperature	253°C	Measured
Explosive Properties	Not predicted to be explosive	Estimated
Oxidising Properties	Not predicted to be oxidising	Estimated

* MMAD = Mass Median Aerodynamic Diameter

DISCUSSION OF PROPERTIES

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

Reactivity
The notified substance is expected to be stable under normal conditions.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified substance will be imported as a component of inkjet printer inks (~1% concentration) in ink cartridges.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	<1	<1	<1	<1	<1

PORT OF ENTRY
Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
Potentially, the inkjet printer cartridges containing the notified substance will be supplied to retailers and offices nationwide.

TRANSPORTATION AND PACKAGING
The notified substance will be packaged within plastic inkjet cartridges of 5-100 mL volumes. The cartridges are likely to be transported by road.

USE
The notified substance will be used as a component of imported inkjet printer inks (~1%).

The inks will be used by office workers and the public for various printing operations. Sealed ink cartridges containing the notified substance will be used as necessary to replace spent cartridges in inkjet printers.

OPERATION DESCRIPTION
No reformulation or repackaging of the notified chemical will occur in Australia. The products containing the notified chemical will be delivered to the end-user in the same form in which they are imported. The cartridges will be installed or replaced into the inkjet printer by office workers, service technicians or consumers.

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)*
Importation/Waterside workers	10	4 hours per day	70 days per year
Storage and transport	100	6 hours per day	240 days per year
Office worker/Service technician	10000	<0.1 hours per day	20 days per year

EXPOSURE DETAILS
Exposure to the notified chemical during the importation, transport and storage of the printer cartridges is not expected, except in the unlikely event of an accident where the cartridge and its packaging may be breached.

Both office workers and service technicians may be exposed (dermal or ocular) to the notified chemical in ink while changing printer cartridges, and service technicians may additionally be exposed during printer maintenance. Dermal exposure to small quantities of the notified chemical may occur if the print heads are touched while replacing the cartridges. In addition, dermal and possibly ocular exposure could occur when handling faulty or ruptured cartridges.

Inhalation exposure to the notified chemical may occur during use of printing inks (>50% of the notified chemical is of respirable particle size). However, such exposure is expected to be very low, given its presence at low concentrations within ink solutions, its low vapour pressure, and the containment of the printing process.

Dermal exposure of workers may also occur when handling printed media before the ink is adequately dried, especially when printing on non-absorbent materials.

6.1.2. Public exposure

The exposure of the public to the notified chemical in inkjet printer inks is expected to be identical or of a lesser extent than that experienced by office workers using the same ink, due to the possible lower frequency of use.

6.2. Human health effects assessment

The results from toxicological investigations conducted on the complete reaction mixture containing 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	LD50 >2000 mg/kg bw low toxicity
Rat, acute dermal toxicity	LD50 >2000 mg/kg bw low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating
Mouse, skin sensitisation – Local lymph node assay	no evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days	NOAEL > 1000 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro mammalian chromosomal aberration test	non genotoxic

The notified chemical was of low acute oral and dermal toxicity in rats (LD50 > 2000 mg/kg bw). In addition, it was not shown to cause sensitisation or mutagenic/genotoxic effects. No toxicologically significant changes were observed during the 28 day repeat dose oral study, which resulted in an NOAEL of >1000 mg/kg bw/day.

The notified chemical contains a number of functional groups that suggest the possibility that it may cause corrosive effects (Hulzebos, 2005). However, the skin and eye irritation studies provided for AKPT-1 indicated that the notified chemical is non-irritating to the skin and slightly irritating to the eyes. Therefore, the possibility of corrosivity can be ruled out.

The notified chemical also contains functional groups that may fall under a USEPA category of concern. Chemicals containing this functional group may be toxic to the immune system, liver, blood, the male reproductive system, and the gastrointestinal (G.I.) tract, mainly via inhalation (USEPA, 2002). However, the absence of toxicologically significant changes during the 28 day repeat dose oral study suggest that the notified chemical is unlikely to cause effects of this kind.

Based on its molecular weight (>500) and low water solubility, the notified chemical is not expected to be readily absorbed transdermally or from the gastrointestinal tract. This is supported by the low acute dermal and oral toxicity, the lack of dermal reactions during the skin irritation study, and the absence of significant effects following repeated oral exposure.

Classification

Based on the available data the notified chemical is not classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

Dermal and accidental ocular exposure will be the main routes of worker exposure to the notified chemical at concentrations of ~1%. Such exposure is expected to be infrequent and of short duration and low concentrations. Skin or eye irritation is unlikely to occur during such exposure, particularly given that the notified chemical is non-irritating to the skin and only slightly irritating to the eyes of animals, and is present at concentrations below the irritation cut off (ie. ≤20%). Acute effects from exposure to the notified chemical

are unlikely to occur, given its low acute toxicity (oral and dermal).

Given that the notified chemical is of low toxicity and exposure of workers is expected to be low, the OHS risk is not considered to be unacceptable.

6.3.2. Public health

The risk to the health of the public during the use of inkjet printers containing the notified chemical are expected to be identical or similar to that experienced by office workers, and therefore is expected to be low.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

Printer ink will be imported in ready-to-use cartridges (containing ~1% of the notified chemical). No release is expected as manufacturing and reformulation of the ink containing the notified chemical will not take place in Australia. Environmental release of the notified chemical is unlikely during importation, storage and transportation. Spillage during a transport accident is the most likely reason for environmental release. Individual container capacity, container and packaging specifications would limit the extent of release.

RELEASE OF CHEMICAL FROM USE

The ink cartridges are designed to prevent leakage and will not be opened during transport, use, installation or replacement. Therefore, release of ink containing the notified chemical to the environment is not expected under normal conditions of use. In the unlikely case of spills arising during installation and replacement, it is expected that the ink containing the notified chemical will be contained and collected with absorbent materials and be subsequently disposed of to landfill. Cartridges are contained within the printer until the contents are used then they are removed and sent to a recycling and disposal centre or directly to landfill.

Most of the notified chemical (>98%) will be bound to the printed paper, which will be disposed of to landfill, recycled or incinerated. Recycling of treated paper may result in the release of a proportion of the notified chemical to the aquatic compartment. Waste paper is repulped using a variety of chemical treatments, which result in fibre separation and ink detachment from the fibres. The waste is expected to go to trade waste sewers. Approximately 50% of the ink printed on paper will enter paper recycling of which a proportion of the ink is expected to be recovered during recycling. While some may partition to water, due to the low percentage of the notified chemical in these inks and the widespread use, release to the aquatic compartment from any given recycling plant will still be low based on worst case assumptions. Most of the notified chemical will be absorbed to sludge during the recycling process and will be disposed of to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

The majority of the annual import volume of the notified chemical will ultimately be disposed of as normal office/domestic waste that will end up in either landfill or be incinerated. Some waste paper printed with the ink may be disposed of directly to landfill with the notified chemical bound to the paper, while some will enter the paper recycling process. Used cartridges may be sent to recycling and disposal centres or directly to landfill. The cartridges may be broken down into component parts for recycling. Residual ink (<0.1% of the notified chemical) left in the empty cartridges will be separated from the cartridges and incinerated during the recycling of the cartridges.

The notified chemical that is incinerated is expected to thermally decompose to form predominantly simple organic compounds. Similarly, the notified chemical that is disposed of to landfill should eventually degrade to form predominantly simple organic compounds.

7.1.2 Environmental fate

The notified chemical is practically insoluble in water and has relatively low vapour pressure. It is not considered to be readily biodegradable. In landfill, the residue is expected to degrade by biotic and abiotic processes to oxides of carbon and nitrogen, and water. For the details of the environmental fate studies please refer to Appendix C.

7.1.3 Predicted Environmental Concentration (PEC)

In Australia, approximately 50% of printed paper is recycled. The following Predicted Environmental Concentration calculation assumes this 50% recycling, and as a worst case scenario assumes no recovery within STPs.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	1000	kg/year
Proportion expected to be released to sewer	50%	
Annual quantity of chemical released to sewer	1000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	2.74	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	21.161	million
Removal within STP	0%	
Daily effluent production:	4,232	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.32	µg/L
PEC - Ocean:	0.03	µg/L

7.2. Environmental effects assessment

The results from ecotoxicological investigations conducted on the complete reaction mixture containing 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	LL50 >100 mg/L	Non-toxic up to limit of water solubility
Daphnia Toxicity	LL50 >100 mg/L	Non-toxic up to limit of water solubility
Algal Toxicity	LL50 >100 mg/L	Non-toxic up to limit of water solubility
Inhibition of Bacterial Respiration	EC50 >100 mg/L	Practically non-toxic

The Predicted No-Effect Concentration has been calculated from the toxicity of the notified chemical, which is not toxic up to its limit of water solubility (0.6 mg/L). Therefore, a toxicity of >0.6 mg/L is used in the calculation. As the results are available for three trophic levels, the assessment factor of 100 has been used.

7.2.1 Predicted No-Effect Concentration

The Predicted No-Effect Concentration has been calculated from the toxicity of the notified chemical, which is not toxic up to its limit of water solubility (0.6 mg/L). Therefore, a toxicity of >0.6 mg/L is used in the calculation. As the results are available for three trophic levels, the assessment factor of 100 has been used.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
	>0.6	mg/L
Assessment Factor	100	
Mitigation Factor	1.00	
PNEC:	>6	µg/L

7.3. Environmental risk assessment

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	0.32	>6	**<0.05**
Q - Ocean	0.03	>6	**<0.005**

As the risk quotients are <1 for both the river and ocean scenarios, the notified chemical is not expected to pose

an unacceptable risk to the aquatic environment based on the current use pattern, noting no allowance for the expected adsorption to sludge has been made.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available data the notified chemical is not classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

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 PEC/PNEC ratio and the reported use pattern, the notified chemical is not considered to pose a risk to the environment.

Recommendations

CONTROL MEASURES
Occupational Health and Safety

- No specific engineering controls or work practices are required for the safe use of the notified chemical itself, however, these should be selected on the basis of all ingredients in the formulation.
- 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 by 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(1) of the Act; if

- the importation volume exceeds one tonne per annum notified chemical; or
- the notified chemical is imported in any form other than in inkjet cartridges.

or

(2) Under Section 64(2) of the Act; if

- the function or use of the chemical has changed from being a component of imported inkjet printer inks, or is likely to change significantly;
- the amount of chemical being introduced has increased from 1 tonne per annum, or is likely to increase, significantly;
- if 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 a 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.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

All studies were performed with the complete reaction mixture (AKPT-1) containing the notified chemical.

Melting Point Not observed

Method	OECD TG 102 Melting Point/Melting Range. EC Directive 92/69/EEC A.1 Melting/Freezing Temperature. Differential scanning calorimetry.
Remarks	Melting of the test substance was not observed below 400 ºC, at which reaction and/or decomposition of the test substance occurred. In addition, the decreased sample weight observed at lower temperatures was attributed to evaporation of a small fraction of the test substance.
Test Facility	NOTOX (2007a)

Boiling Point Not observed

Method	OECD TG 103 Boiling Point. EC Directive 92/69/EEC A.2 Boiling Temperature. Differential scanning calorimetry.
Remarks	Boiling of the test substance was not observed below 400 ºC, at which reaction and/or decomposition of the test substance occurred. In addition, the decreased sample weight observed at lower temperatures was attributed to evaporation of a small fraction of the test substance.
Test Facility	NOTOX (2007a)

Density 1451 kg/m^3 at 20^{o}C

Method	OECD TG 109 Density of Liquids and Solids. EC Directive 92/69/EEC A.3 Relative Density. Gas comparison stereo pycnometer.
Test Facility	NOTOX (2007a)

Vapour Pressure < $1.47x10^{-11}$ kPa at 20^{o}C

Method	OECD TG 104 Vapour Pressure. EC Directive 92/69/EEC A.4 Vapour Pressure. Isothermal thermogravimetric effusion method
Test Facility	NOTOX (2007a)

Water Solubility <0.6 mg/L at 20^{o}C

Method	OECD TG 105 Water Solubility. EC Directive 92/69/EEC A.6 Water Solubility.
Remarks	Based on the preliminary testing, the column method was used for the determination of the water solubility. The test substance was mixed with the column material, which was used to fill the column. The system was allowed to equilibrate for 2 h prior to eluting with distilled water at flow rates of 12 and 24 mL/h. Ten consecutive samples were taken for analysis. No undissolved particles were detected in the eluates using the Tyndall effect. The pH of the aqueous samples was 5.3-5.9.
Test Facility	NOTOX (2007a)

Hydrolysis as a Function of pH Not determined

Remarks	The notifier indicated that, given that the notified chemical consists of a large number of components with molecular weights ranging from 100 to 3000 and has a low water solubility, it renders the analysis difficult. The notifier also indicated that the hydrolysis needs to be performed at half the saturated concentration level. At this low level (0.012 mg/L) the analytical method is insufficiently precise and accurate to determine significant changes in concentration. Consequently, the measurement of hydrolysis as a function of pH for the notified chemical is impractical.

Particle Size

Method Laser Diffraction Test, CTL SOP No.417 (internal method)
Results

Range (μm)	*Mass (%)*
< 0.956	10
< 8.644	50
< 42.045	90

Mass Median Aerodynamic Diameter (MMAD) = 10.409 μm
Volume weighted mean = 16.632 μm
Median = 8.644 μm
Mode = 11.624 μm
54.37% by volume of sample was <10 μm
Test Facility Chilworth (2007)

Flammability Not highly flammable

Method EC Directive 92/69/EEC A.10 Flammability (Solids).
Remarks The test substance did not ignite or propagate combustion. In contact with the flame, the test substance glowed and was reduced to a charred residue.
Test Facility NOTOX (2007b)

Flammability in Contact with Water Not predicted to be flammable

Method EC Directive 92/69/EEC A.12 Flammability (Contact with Water).
Remarks A statement provided by the testing laboratory indicates that the notified substance does not contain chemical groups likely to lead to flammability in contact with water or damp air.
Test Facility NOTOX (2007b)

Pyrophoric Properties Not predicted to be pyrophoric

Method EC Directive 92/69/EEC A.10 Flammability (Solids).
Remarks A statement provided by the testing laboratory indicates that the notified substance does not contain chemical groups likely to lead to spontaneous combustion in contact with air.
Test Facility NOTOX (2007b)

Autoignition Temperature 253 °C

Method EC Directive 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Test Facility NOTOX (2007a)

Explosive Properties Not predicted to be explosive

Method EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks Oxygen balance calculations performed individually on each component of Substance 2 resulted in values of approximately -200%), with two of the values being <-200%. This suggests that there may be potential for explodability (GHS, 2003). However, the absence of chemical groups within the notified substance known to confer or enhance explosive properties indicates that the notified substance is unlikely to be explosive.
Test Facility NOTOX (2007a)

Oxidizing Properties Not predicted to be oxidising

Method EC Directive 92/69/EEC A.17 Oxidizing Properties (Solids).
Remarks A statement provided by the testing laboratory indicates that the notified substance does

not contain chemical groups that are expected to result in oxidising properties.

Test Facility NOTOX (2007a)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

All studies were performed with the complete reaction mixture (AKPT-1) containing the notified chemical

B.1. Acute toxicity – oral

TEST SUBSTANCE	AKPT-1
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method. EC Directive 2004/73/EC B.1tris Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/Wistar strain Crl:WI (outbred, SPF-Quality)
Vehicle	Water (Milli-U)
Remarks - Method	No significant protocol deviations

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	3 F	2000	0/3
II	3 F	2000	0/3

LD50	> 2000 mg/kg bw
Signs of Toxicity	Hunched posture was observed in all animals on day 1. In three animals, purple urine and faeces were noted on day 2, which was probably caused by the staining properties of the test substance.
Effects in Organs	None
Remarks - Results	None
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	NOTOX (2007c)

B.2. Acute toxicity – dermal

TEST SUBSTANCE	AKPT-1
METHOD	OECD TG 402 Acute Dermal Toxicity. EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal).
Species/Strain	Rat/Wistar strain Crl:WI (outbred, SPF-Quality)
Vehicle	Water (Milli-U)
Type of dressing	Occlusive
Remarks - Method	No significant protocol deviations.

RESULTS

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

LD50	>2000 mg/kg bw
Signs of Toxicity - Local	Purple staining was observed in the treated skin area of all animals between Days 2 and 4.
Signs of Toxicity - Systemic	Chromodacryorrhea was observed in three males and three females between Days 1 and 6. One female showed hypothermia and/or hunched posture on Days 2 and/or 3.
Effects in Organs	None
Remarks - Results	None

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

TEST FACILITY NOTOX (2007d)

B.3. Irritation – skin

TEST SUBSTANCE AKPT-1

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	Water (Milli-U)
Observation Period	72 hours
Type of Dressing	Semi-occlusive.
Remarks - Method	One animal was exposed to the test substance for 4.5 hours instead of 4 hours. This was not considered to have influence the conclusion of the test the irritation scores were similar to the other animals.

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	0	0	1	24 hr	0
Oedema	0	0	0	0	-	0

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

Remarks - Results Pink staining of the treated skin by the test substance was observed throughout the study period. This did not hamper the scoring of the skin reaction.

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

TEST FACILITY NOTOX (2007e)

B.4. Irritation – eye

TEST SUBSTANCE AKPT-1

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
EC Directive 2004/73/EC B.5 Acute Toxicity (Eye Irritation).

Species/Strain	Rabbit/New Zealand White
Number of Animals	3 males
Observation Period	7 days
Remarks - Method	No significant protocol deviations

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	0.7	1.3	1.3	2	<7 days	0
Conjunctiva: chemosis	0.3	0	0.3	2	<48 hr	0
Conjunctiva: discharge	0	0.3	0.7	2	<72 hr	0
Corneal opacity	0	0	0	0	-	0
Iridial inflammation	0	0	0	1	<24 hr	0

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

Remarks - Results	Some irritation of the iris was observed in two animals and had resolved within 24 hours. Irritation of the conjunctivae was observed in all animals and was completely resolved in one animal within 72 hours, and in the other two animals within 7 days. Purple staining of the lower eyelid and nictitating membrane was noted on Day 1.
CONCLUSION	The notified chemical is slightly irritating to the eye.
TEST FACILITY	NOTOX (2007f)

B.5. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE	AKPT-1
METHOD	OECD TG 429 Skin Sensitisation: Local Lymph Node Assay. EC Directive 2004/73/EC B.42 Skin Sensitisation: Local Lymph Node Assay.
Species/Strain	Mouse/CBA strain, inbred, SPF quality
Vehicle	Acetone/olive oil (4:1 v/v)
Remarks - Method	No significant protocol deviations

RESULTS

Concentration (% w/w)	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
0 (vehicle control)	327 ± 125	1.0 ± 0.5
2.5	301 ± 102	0.9 ± 0.5
10	734 ± 89	2.2 ± 0.9
25	363 ± 100	1.1 ± 0.5

Remarks - Results	Red/purple staining by the test substance prevented scoring for erythema. No oedema was observed in any of the animals examined.
CONCLUSION	There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical.
TEST FACILITY	NOTOX (2007g)

B.6. Repeat dose toxicity

TEST SUBSTANCE	AKPT-1
METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents. EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral).
Species/Strain	Rat, Wistar Crl:(WI) Br (outbred, SPF quality)
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 7 days per week
Vehicle	Water (Milli-U)
Remarks - Method	No significant protocol deviations

RESULTS

Dose mg/kg bw/day	*Number and Sex of Animals*	*Mortality*
control	5/sex	0

50	5/sex	0
150	5/sex	0
1000	5/sex	0

Mortality and Time to Death
No mortality was observed during the treatment period.

Clinical Observations
From day 2 or 3 onwards, red faeces were observed from all animals treated at 150 mg/kg/day and 1000 mg/kg/day. Two females treated with 1000 mg/kg/day showed red staining of skin or fur during the observation period. These findings were considered to have been caused by staining of the test substance and not to be an indication of toxicity.

Functional observations, body weight and food consumption were also observed during the treatment. Each of the measured parameters was considered normal.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
Slight changes were observed in a small number of haematological and biochemical parameters. The changes were not considered to be of toxicological significance due to the absence of dose related responses, the values falling within expected ranges, or the absence of corroborative findings.

Effects in Organs
Some changes were observed in adrenal weights of male animals. However, these were not considered to be an indication of toxicity, given the absence of a dose related response, the values being within the range of the control values, and the lack of corroborative evidence of organ dysfunction.

Reddish contents of several parts of the gastro-intestinal tract were observed in most animals treated with 150 mg/kg/day and in all animals treated with 1000 mg/kg/day. These observations were considered to be due to the staining properties of the test substance and were not of toxicological relevance.

Incidental findings, including dark red foci on the right kidney, fluid in the uterus, and enlargement of the thymus were observed in some control and treated animals during this study. Such findings are occasionally seen among rats used in similar studies. These were not considered to be of toxicological significance.

Remarks – Results
No toxicologically relevant changes were noted in any of the parameters examined during this study.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as >1000 mg/kg bw/day in this study, based on the lack of toxicologically relevant observations throughout the duration of the study.

TEST FACILITY NOTOX (2007h)

B.7. Genotoxicity – bacteria

TEST SUBSTANCE AKPT-1

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	Rat liver S9-mix induced by a combination of Phenobarbital and β-naphthoflavone
Concentration Range in Main Test	a) With metabolic activation: 3, 10, 33, 100, 333 µg/plate b) Without metabolic activation: 1, 3, 10, 33, 100 µg/plate
Vehicle	Dimethyl sulfoxide
Remarks - Method	2-Aminoanthracene was the only positive control substance used in the

presence of metabolic activation. The Test Guideline recommends against this.

The positive control substance used for TA100 in the absence of metabolic activation was not that recommended by the Test Guideline.

Selection of adequate range of doses was based on a dose range finding test with the tested strain TA 100 (in the absence and presence of S9-mix).

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	>100	>33	Negative
Test 2		>100	>33	Negative
Present				
Test 1	>5000	>333	>100	Negative
Test 2		>333	>100	Negative

* Only performed for TA 100.

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

TEST FACILITY NOTOX (2007i)

B.8. Genotoxicity – in vitro

TEST SUBSTANCE AKPT-1

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/Cell Line	Cultured peripheral human lymphocytes
Metabolic Activation System	Rat liver S9-mix induced by a combination of phenobarbital and β-naphthoflavone
Vehicle	Dimethyl sulfoxide
Remarks - Method	No significant protocol deviations.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	10*, 33*, 100*	3h	24h
Test 2	10*, 33*, 100, 333*	24h	24h
Test 3	10*, 33*, 100, 333*	48h	48h
Present			
Test 1	10*, 33*, 100*	3h	24h
Test 2	10*, 33*, 100*	3h	48h

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	>100	>100	>33	Negative

Test 2	>1000	>333	>33	Negative
Test 3	>1000	>333	>33	Negative
Present				
Test 1	>100	>100	>33	Negative
Test 2	-	>100	>33	Negative

CONCLUSION	The notified chemical was not clastogenic to human lymphocytes treated in vitro under the conditions of the test.
TEST FACILITY	NOTOX (2007j)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

All studies were performed with the complete reaction mixture (AKPT-1) containing the notified chemical.

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	AKPT-1
METHOD	OECD TG 301 B Ready Biodegradability: CO2 Evolution Test. EC Directive 92/69/EEC C.4-C Biodegradation: Determination of the " Ready" Biodegradability: Carbon Dioxide Evolution Test
Inoculum	Activated sludge
Exposure Period	29 days
Auxiliary Solvent	None
Analytical Monitoring	CO_2
Remarks - Method	No significant protocol deviations. Test substance was added to test bottles containing medium with microbial organisms and mineral components followed by the addition of water. After vigorous shaking, the resulting suspension was added quantitatively to the test medium.

RESULTS

Test substance		*Sodium acetate*	
Day	*% Degradation*	*Day*	*% Degradation*
2	0	2	10
5	0	5	30
7	0	7	44
9	1	9	52
14	1	14	69
19	2	19	77
23	4	23	84
27	5	27	87
29	8	29	89

Remarks - Results	10% degradation was not achieved after 12 days. In addition, 60% degradation was not reached after 29 days incubation. Therefore, the test substance did not satisfy the ready biodegradation criterion. No inhibitory effects of the test item were observed (more than 25% degradation occurred within 14 days in the toxicity control). The degradation of the reference substance had reached 69% within 14 days, thus validating the test.
CONCLUSION	The notified chemical is not considered to be readily biodegradable.
TEST FACILITY	NOTOX (2007b)

C.1.2. Bioaccumulation

While the notified chemical is practically insoluble in water and is expected to partition to octanol, aquatic release will be low and together with a relatively high molecular weight, bioaccumulation is unlikely to occur.

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical

METHOD	OECD TG 203 Fish, Acute Toxicity Test - limit test/static EC Directive 92/69/EEC C.1 Acute Toxicity for Fish - limit test/static
Species	*Cyprinus carpio* (Carp)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	180 mg $CaCO_3$/L
Analytical Monitoring	UV-visible spectrometer
Remarks – Method	Preparation of the test concentration was performed at a loading rate of 100 mg/L with stirring for 24 h. The mixture was then filtered using a metal-filter stone. A pink-purple dispersion was observed after a stabilisation period of 24 h. This was then filtered through a membrane filter (0.45 µm) and the resulting clear and colourless filtrate was used for the testing. Fish were not fed from 48 hours before the start of the test. The test groups were inadvertently not sampled after 24 hours of exposure.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*2 1/4 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control	<detection limit	7	0	0	0	0	0
100	<detection limit	7	0	0	0	0	0

LL50	>100 mg/L at 96 hours (nominal)
NOEC	100 mg/L at 96 hours (nominal WAF))
Remarks – Results	Temperatures, dissolved oxygen and pH were within acceptable limits. Analysis of the samples taken from the filtrate at the start and the end of the test showed that the actual concentration was below the limit of detection (i.e. below 0.6 mg/L). Analysis of an aliquot of the filtered residue (2nd filtration) confirmed that the test substance was present and used for the preparation of the test concentration. No mortality or other clinical effects were observed at either test groups during the 96-hours test period.
CONCLUSION	The notified chemical is considered non-toxic to fish up to its limit of water solubility.
TEST FACILITY	NOTOX (2007c)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	AKPT-1
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – limit test/static. EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia – limit test/static.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	180 mg $CaCO_3$/L
Analytical Monitoring	UV-visible spectrometer
Remarks - Method	No significant protocol deviations. Preparation of the test concentration was performed at a loading rate of 100 mg/L with stirring for 24 h. The mixture was then filtered using a metal-filter stone. A pink-purple dispersion was observed after a stabilisation period of 24 h. This was then filtered through a membrane filter (0.45 µm) and the resulting clear and colourless filtrate was used for the testing.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
Control	<detection limit	20	0	0
100	<detection limit	20	0	0

LL50	>100 mg/L at 48 hours (nominal)
NOEC	100 mg/L at 48 hours (nominal WAF)
Remarks - Results	Temperatures, dissolved oxygen and pH were within acceptable limits. Analysis of the samples taken from the filtrate at the start and the end of the test showed that the actual concentration was below the limit of detection (i.e. below 0.6 mg/L). Analysis of an aliquot of the filtered residue (2nd filtration) confirmed that the test substance was present and used for the preparation of the test concentration. No immobility was observed at either test groups during the 48 hours test period.
CONCLUSION	The notified chemical is considered non-toxic to daphnia up to its limit of water solubility.
TEST FACILITY	NOTOX (2007d)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE	AKPT-1
METHOD	OECD TG 201 Alga, Growth Inhibition Test. EC Directive 92/69/EEC C.3 Algal Inhibition Test.
Species	*Pseudokirchneriella subcapitata*
Exposure Period	48 hours
Concentration Range	0 and 100 mg/L
Auxiliary Solvent	None
Water Hardness	24 mg $CaCO_3$/L
Analytical Monitoring	UV-visible spectrometer
Remarks - Method	No significant protocol deviations. Preparation of the test concentration was performed at a loading rate of 100 mg/L with stirring for 24 h. The mixture was then filtered using a metal-filter stone. A pink-purple dispersion was observed after a stabilisation period of 24 h. This was then filtered through a membrane filter and the resulting clear and colourless filtrate was used for the testing.

RESULTS

Biomass		*Growth*	
EbC50	*NOEC*	*ErC50*	*NOEC*
mg/L at 48 h (nominal)	*mg/L (nominal)*	*mg/L at 48 h (nominal)*	*mg/L (nominal)*
>0.6 mg/L	0.6 mg/L	>0.6 mg/L	0.6 mg/L

Remarks - Results	Temperatures and pH were within acceptable limits. Analysis of the samples taken from the filtrate at the start and the end of the test showed that the actual concentration was below the limit of detection (i.e. below 0.6 mg/L). Analysis of an aliquot of the filtered residue (2nd filtration) confirmed that the test substance was present and used for the preparation of the test concentration.

	No significant differences were recorded between the values for growth rate or yield in the filtrate when compared to the control. Microscopic observations at the end of the test revealed a normal and healthy appearance of the exposed cells when compared to the control. The reference test indicates that the system responded within an acceptable range.
CONCLUSION	The notified chemical is considered to be non-toxic to alga up to its limit of water solubility.
TEST FACILITY	NOTOX (2007e)

C.2.4. Inhibition of microbial activity

TEST SUBSTANCE	AKPT-1
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test. EC Directive 67/548/EEC Part C: Biodegradation: Activated Sludge Respiration Inhibition Test
Inoculum	Municipal sewage treatment plant
Exposure Period	3 hours
Concentration Range	Nominal: 100 mg/L
Remarks – Method	No significant protocol deviations. Test concentrations were prepared separately in Milli-RO water. The concentration was prepared at 200 mg/L by stirring for 24 h. Subsequently, synthetic sewage feed and sludge were added resulting in a final loading rate of 100 mg/L. Optimal contact between the test substance and test medium was ensured by continuous aeration and stirring.
RESULTS	
IC50	>100 mg/L (nominal)
NOEC	100 mg/L (nominal)
Remarks – Results	The temperature and pH were within acceptable range. No significant inhibition of respiration rate of sludge was recorded at 100 mg/L. The test reference 3,5-dichlorophenol allowed for a reliable determination of EC values.
CONCLUSION	The notified chemical is considered to be practically non-toxic to micro-organisms.
TEST FACILITY	NOTOX (2007f)

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