File No STD/1120

22 October 2004

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Phosphonic acid, (4-morpholinylmethylene)bis-, sodium salt

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 and Heritage.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at:

Library
National Occupational Health and Safety Commission
25 Constitution Avenue
CANBERRA ACT 2600
AUSTRALIA

To arrange an appointment contact the Librarian on TEL + 61 2 6279 1161 or + 61 2 6279 1163.

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

Street Address:	334 - 336 Illawarra Road MARRICKVILLE NSW 2204, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 8577 8888.
Website:	www.nicnas.gov.au

Director
Chemicals Notification and Assessment

TABLE OF CONTENTS

Phosphonic acid, (4-morpholinylmethylene)bis-, sodium salt

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Kodak Australia Pty Ltd (ACN 004 057 621) of 173 Elizabeth St, Coburg, VIC, 3058.

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:
Detailed use

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:

- Melting Point
- Particle size
- Flammability
- Water Solubility
- Partition coefficient
- Acute Inhalation toxicity
- Induction of Germ Cell Damage
- Bioaccumulation

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
No

NOTIFICATION IN OTHER COUNTRIES
USA (2004) PMN P-04-0287
Canada (2003) NSN 12780
Japan (2004) low volume MITI/MHW

2. IDENTITY OF CHEMICAL

CHEMICAL NAME
Phosphonic acid, (4-morpholinylmethylene)bis-, sodium salt

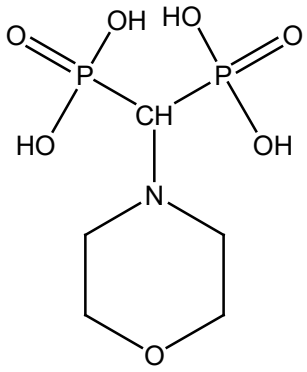
OTHER NAME(S)
Morpholinomethylenebisphosphonic acid, sodium salt (IUPAC)

MARKETING NAME(S)
The notified chemical cannot be isolated and does not have a marketing name. It is imported as a component of Budex 5103.

CAS NUMBER
94200-61-0

MOLECULAR FORMULA
$C_5H_{13}NO_7P_2.xNa$

STRUCTURAL FORMULA



.xNa

MOLECULAR WEIGHT

The molecular weight of the notified chemical could not be determined due to the unknown sodium content. The molecular weight of the free acid is 261.11.

SPECTRAL DATA

ANALYTICAL METHOD	Ion chromatography/mass spectrometric detection
Remarks	The mass spectrum of the test substance was consistent with the proposed structure of the notified chemical. The mass spectrum of the test substance peak shows the molecular ion at 260 m/z attributable to the fact that the sodium atoms would not be detected.
TEST FACILITY	Eastman Kodak (2003a)

SPECTRAL DATA

ANALYTICAL METHOD	UV-vis Spectroscopy
Remarks	λ_{max} (neutral) = 190*nm, λ_{max} (acidic) = 209*nm, λ_{max} (basic) = 216*nm * No absorbance peak was observed. Absorbance maximum reflects the point at which the solvents UV-cut off interferes with the test substance absorbance spectrum or at the minimum wavelength scanned (190nm)
TEST FACILITY	Eastman Kodak (2003b)

SPECTRAL DATA

ANALYTICAL METHOD	^{1}H NMR Spectroscopy (one and two dimensional)
Remarks	1-D Peaks: 3.36, 3.76, 4.02 ppm The 1-D and 2-D ^{1}H NMR spectra are consistent with the known molecular structure for the notified chemical.
TEST FACILITY	Eastman Kodak (2003c)

SPECTRAL DATA

ANALYTICAL METHOD	^{13}C NMR Spectroscopy
Remarks	Peaks: 55.1, 66.1, 67.6 ppm The ^{13}C NMR spectrum is consistent with the known molecular structure for the notified chemical.
TEST FACILITY	Eastman Kodak (2003c)

METHODS OF DETECTION AND DETERMINATION

ANALYTICAL METHOD	Ion chromatography/conductivity detection
Remarks	The retention time of the principal test substance peak was approximately 14.4 minutes.

TEST FACILITY Eastman Kodak (2003d)

3. COMPOSITION

DEGREE OF PURITY **Non-Confidential**

The notified chemical is imported as an aqueous solution with the following composition
notified chemical 43-45%
impurities 5-7%
water 48-52%
Therefore the purity of the notified chemical is ~85%.

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

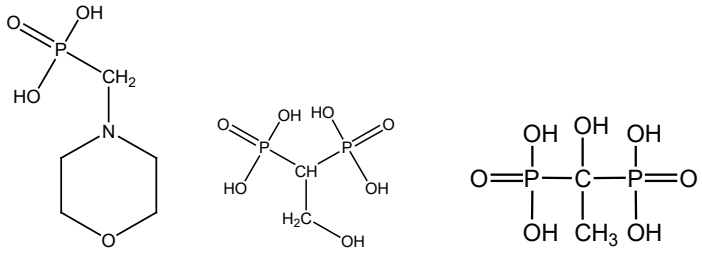
Chemical Name	Phosphoric acid		
CAS No.	7664-38-2	*Weight %*	3-5
Hazardous Properties	Classification (NOHSC, 2003) R22: Harmful if swallowed, R35: causes severe burns		
	Concentration cut-off Conc≥25%: R22; R35 ≥10%Conc<25%: R35 ≥5%Conc<10%: R34 ≥1%Conc<5%: Xi; R36/38		

Chemical Name	Phosphorus acid		
CAS No.	10294-5-61	*Weight %*	1-3
Hazardous Properties	Classification (NOHSC, 2003) R22: Harmful if swallowed, R35: causes severe burns		
	Concentration cut-off Conc≥25%: R22; R35 ≥10%Conc<25%: R35 ≥5%Conc<10%: R34 ≥1%Conc<5%: Xi; R36/38		

Chemical Name	See below*		
CAS No.	N/A	*Weight %*	2-6
Hazardous Properties	Not known		

* The identity of the other impurities have not been fully determined. Proposed structures for the major impurities shown below are based solely on the known chemistry and the interpreted mass spectrum (Eastman Kodak (2000d))

Possible impurities



MW181 MW206 MW206

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight)
None known

ADDITIVES/ADJUVANTS

Chemical Name	Water		
CAS No.	7732-18-5	*Weight %*	50-60

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported as an aqueous solution at a concentration of 43-45% of Budex 5103.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	1.2	1.2	1.2	1.2	1.2

USE
Photographic processing chemical

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Not specified

IDENTITY OF MANUFACTURER/RECIPIENTS
Formulation of the photographic processing solution using Budex 5103 (containing 43-45% notified chemical) will occur at Kodak Australia Pty Ltd, Coburg, VIC. The formulated product will be distributed to photoprocessing laboratories throughout Australia.

TRANSPORTATION AND PACKAGING
Budex 5103 will be imported into Australia in 250kg high density polyethylene (HDPE) drums. The formulated photoprocessing solution will be bottled in 1.3-5L HDPE bottles and packaged in multi-bottle cartons for sale to customers in Australia as well as in the greater Asia region.

5.2. Operation description

Formulation
Budex 5103 containing 43-45% notified chemical is weighed and transferred to a mix vessel containing water. A drum lifter will be used to dispense the chemical from the original drum into the weighing vessel (usually an empty, clean drum). The chemical is then dispensed from the weighing vessel into the mix tank using a drum lifter. The drums are then rinsed out with water and the rinse waters added to the mix vessel. The addition to the mix vessel is conducted using air extractors with mechanical ventilation. Other chemicals are then added and the resulting mixture is stirred in a closed vessel. Samples are manually taken and tested in the QC laboratory. The final formulated product containing the notified chemical at a concentration of <5% is filled into bottles. The bottling operation is an enclosed automated system.

End Use
There are two types of photoprocessing customers that will use the final formulated product, mini-lab customers and large lab customers.
Mini-lab: Workers will place the bottle of photoprocessing solution in the photoprocessor. The mini-lab equipment employs a probe to remove the solution from the bottle. The empty bottle is rinsed prior to disposal.

Large-lab: The photoprocessing solution is poured into a mix tank containing water. This diluted product (containing the notified chemical at <<5%) is mechanically added to the photoprocessor.

5.3. Occupational exposure

Number and Category of Workers

Exposure Details
Formulation
Incidental exposure to drips and splashes of the notified chemical at a concentration of 43-45% may occur during the mechanical weighing and transfer of Budex 5103 to the mixing vessel. No exposure is expected during the automated filling process, except in the event of a machine malfunction. During sampling and analysis of the formulated product there may be skin contact. The notified chemical is at a concentration of <5% in the formulated product. The laboratory testing will take a few minutes per batch.

When handling the notified chemical, the following equipment is available for employee use: overalls, safety glasses and disposable vinyl gloves.

End Use
Mini-lab: Exposure to splashes of the notified chemical at a concentration of <5% could occur upon the opening of the photoprocessing solution. Exposure could also occur during the rinsing of the spent bottle prior to exposure.

Large-lab: Exposure to drips and splashes of the notified chemical at a concentration of <5% could occur during the opening of the photoprocessing solution and transfer of the solution to the mix tank. Exposure could also occur during the rinsing of the spent bottle prior to exposure or the occasional mix tank cleaning.

5.4. Release

RELEASE OF CHEMICAL AT FORMULATION SITE
Environmental release of the notified chemical is unlikely during importation, storage and transportation, and accidental spills, leaks and catastrophic mechanical failure during a transport accident is the most likely reason for environmental release.

The aqueous solution containing the notified chemical will be transported by road directly from the point of import to the notifier's facility. Engineering controls such as container specifications, personnel training, storage requirements and emergency clean-up procedures (i.e. spill response instructions on Safety Data Sheet and label) will limit the impact on the environment of such incidents. There is no anticipated environmental release during transportation or storage.

In the formulation process, there are no anticipated releases to the environment of the notified chemical and no waste is routinely generated during solution preparation. Any chemical released from the automated bottling equipment is collected for wastewater treatment.

Emptied imported containers will be rinsed and rinsate is added to the finished product formulation. Rinsed drums are likely to contain only trace quantities of the notified chemical.

RELEASE OF CHEMICAL FROM USE
The notifier anticipates that practically all of the notified chemical will be bound to processing solution constituents and recovered during the customer's recovery process; however, not all operations may have such recovery facilities. Thermal treatment for refinement of recovered solutions containing the notified chemical will destroy the notified chemical, resulting in the formation of oxides of carbon, nitrogen and phosphorus. A small but unspecified fraction of the notified chemical used, that is unreacted or not collected in the in the recovery process may potentially be discharged to the sewerage system. Emptied bottles containing the notified chemical are likely to be rinsed clean with rinsate added to the process. The notifier estimates that <3 kg/year of notifier chemical may be sent to landfill in emptied containers.

5.5. Disposal

Aqueous wastes from blending and manufacture of the finished product containing the notified chemical will be sent to sewer for disposal. Emptied drums and containers are likely to be rinsed with wastewater added to subsequent batches and consequently very limited quantities may be present in these containers. Emptied containers will be either recycled or sent to landfill for disposal.

5.6. Public exposure

The photoprocessing solution is sold to professional customers only. Therefore, no exposure to the general public is expected.

6. PHYSICAL AND CHEMICAL PROPERTIES

The notified chemical cannot be isolated out of water and appears to decompose when attempted. Therefore the following physico-chemical studies were conducted on an aqueous solution of the notified chemical with the following composition:
notified chemical 34%
impurities 11%
water 55%

Appearance at 20ºC and 101.3 kPa Yellow liquid

Freezing Point <-20ºC

METHOD EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks No significant protocol deviations.
The test substance became increasingly viscous during cooling
TEST FACILITY Safepharm Laboratories (2003)

Boiling Point 106ºC ± 14ºC at 101.3 kPa

METHOD EC Directive 92/69/EEC A.2 Boiling Temperature; Differential Scanning Calorimetry
Remarks No significant protocol deviations.
An endothermic change in enthalpy was observed above 45 ºC in both trials, this is believed to be primarily due to the boiling of water in the test substance mix.
TEST FACILITY Eastman Kodak (2004a)

Density 1354 kg/m^3 at 24ºC

METHOD OECD TG 109 Density of Liquids and Solids; Air Comparison Pycnometer
Remarks Inert gas: Helium
Air Comparison Pycnometer is listed in the OECD test method for the determination of solid densities.
TEST FACILITY Eastman Kodak (2004b)

Vapour Pressure 2.3 kPa at 25ºC

METHOD EC Directive 92/69/EEC A.4 Vapour Pressure; Isoteniscope
Remarks The isoteniscope method is usually not suitable for multicomponent systems. It is considered this result reflects the water component of the formulation tested.
TEST FACILITY Safepharm Laboratories (2003)

Water Solubility Completely soluble

Remarks The notified chemical cannot be isolated out of water and therefore a quantitative value for water solubility could not be determined. An analogue of the free acid form of the notified chemical, morpholinomethane disulfonic acid (CAS 32545-75-8) has a water solubility of approximately 40g/L.

Hydrolysis as a Function of pH

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

pH	*T (°C)*	*$t_{½}$ hours*
4	25	Not calculated

7	25	Not calculated
9	25	1910

Remarks Preliminary (122 h) and definitive (72-483 h) tests were performed at pH 4, 7 and 9 (50°C). Stock solution was prepared by addition of test material (0.003 g) in 150 mL flasks and dilution with pH 4, 7, and 9 buffers. Working concentrations were ~14 to 32 mg/L. All tests were clear and colourless with no visible test substance.
Test solutions were held between 50-80°C and extrapolated to 25°C. Aliquots were analysed by ion chromatography. The test material showed <10% degradation in pH 4 and 7 solutions in the preliminary test and half lives were not calculated.

TEST FACILITY Eastman Kodak (2003e)

Partition Coefficient (n-octanol/water) log Pow = -1.68 (estimated)

METHOD USEPA QSAR Method, free acid form of the notified chemical (no further details).

Adsorption/Desorption – screening test log K_{oc} = <1.25 at 25°C

METHOD OECD TG 121: Estimation of the Adsorption Coefficient (Koc) on Soil and on Sewage Sludge using High Performance Liquid Chromatography (HPLC).

Remarks HPLC Method. The standard (acetanilide) and test substances were dissolved in 50:50 distilled deionised water/acetonitrile, at working concentrations of ~3600 mg/L and 19800 mg/L, respectively. The test substance eluted before the standard, which is the standard having the lowest literature Log Koc value. Therefore the Log Koc of the test material in its ionised form was estimated to be <1.25, which suggests high mobility in soils (McCall et al., 1980); however, the notified chemical's structure indicates a potential for binding to soil constituents and mobility is likely to be much less than suggested above. Due to the pH limits of the analytical column (pH range 2-8) it was not possible to analyse the test substance in its non-ionisable form, since this would require using a buffered water mobile phase at a pH <2. The test substance was analysed in an ionised form using a buffered water mobile phase at a pH of 6.5.

TEST FACILITY Eastman Kodak (2004c)

Dissociation Constant pKa1 = 4.80, pKa2 = 8.48

METHOD OECD TG 112 Dissociation Constants in Water: Titration method

Remarks No significant protocol deviations. In the determination of log Koc, it is stated that the notified chemical has four pKa values; 2.16, 4.91, 8.81 and 11.3.

TEST FACILITY Eastman Kodak (2004d)

Particle Size Not determined

Remarks The notified chemical could not be isolated as a solid.

Flash Point >106ºC

METHOD EC Directive 92/69/EEC A.9 Flash Point; Closed cup equilibrium

Remarks No significant protocol deviations.
The test material has been determined not to have a flash point below its boiling temperature.

TEST FACILITY Safepharm Laboratories (2003)

Flammability Limits Not determined

Remarks The notified chemical cannot be isolated as a solid. The notified chemical is imported as an aqueous solution. The notified chemical does not react with water.

Autoignition Temperature 471ºC

METHOD	92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases).
Remarks	No significant protocol deviations.
TEST FACILITY	Eastman Kodak (2004a)

Explosive Properties Not predicted to be explosive

Remarks	There are no chemical groups that would imply explosive properties, therefore the result has been predicted to be negative.

Reactivity

Remarks	The notified chemical appears to decompose upon isolation from solution. Based on its structure the notified chemical is not pyrophoric or oxidising. The UV-vis spectra (Eastman Kodak, 2003b) indicate that the notified chemical would not be susceptible to photochemical degradation.

7. TOXICOLOGICAL INVESTIGATIONS

The notified chemical cannot be isolated out of water and appears to decompose when attempted. Therefore the following toxicological studies were conducted on an aqueous solution of the notified chemical with the following composition:
notified chemical 34%
impurities 11%
water 55%

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral	low toxicity, LD50 >2038mg/kg bw
Rat, acute dermal	low toxicity, LD50 >2038mg/kg bw
Rat, acute inhalation	not submitted
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	very slightly irritating
Guinea pig, skin sensitisation – adjuvant test	no evidence of sensitisation.
Rat, repeat dose oral toxicity – 29/30 days.	NOAEL 1000 mg/kg bw/day
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosome aberration assay	non genotoxic
Genotoxicity – in vivo	not submitted

7.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical (34% aqueous solution)
METHOD	OECD TG 420 Acute Oral Toxicity - Fixed Dose Method - Limit Test. EC Directive92/69/EEC B.1bis Acute Toxicity (Oral) Fixed Dose Method - Limit Test.
Species/Strain	Rat/Sprague Dawley
Vehicle	Test substance administered as supplied.
Remarks - Method	Due to a calculation error, the initial group of animals was not administered the correct dose and an additional group of five females was added to the study.

RESULTS

Sighting Study 1

Dose mg/kg bw	*Administered*	*Evident Toxicity*	*Mortality*
2000*	Yes	No	No
500	No	-	-
50	No	-	-
5	No	-	-
<5	No	-	-

* Taking into account density of test substance and purity of notified chemical, the actual dose is 697 mg/kg bw

Sighting Study 2

Dose mg/kg bw	*Administered*	*Evident Toxicity*	*Mortality*
2000 *	Yes	No	No
500	No	-	-
50	No	-	-
5	No	-	-
<5	No	-	-

* Taking into account density of test substance and purity of notified chemical, the actual dose is 2038 mg/kg bw

Signs of Toxicity	Clinical signs limited to diarrhoea for both rats on the day following dosing. Both rats appeared normal between days 2 and 14.
Effects in Organs	There were no remarkable necropsy findings, and no tissue was collected for microscopic examination.

Main Study

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	4 females*	697**	0
II	4 females*	2038**	0

* does not include screening animal
**dose of notified chemical calculated from administered dose, using purity of 34% and the density of the test substance.

Discriminating Dose	>2038 mg/kg bw
Signs of Toxicity	Diarrhoea and decreased faecal volumes were observed for all group II main study rats on Days 0 to 1. All rats appeared normal between days 2 and 14. There were no clinical signs of toxicity in group I main study rats.
Effects in Organs	There were no remarkable necropsy findings, and no tissue was collected for microscopic examination.
Remarks - Results	

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

TEST FACILITY Eastman Kodak (2003f)

7.2. Acute toxicity - dermal

TEST SUBSTANCE Notified chemical (34% aqueous solution)

METHOD OECD TG 402 Acute Dermal Toxicity – Limit Test.
EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal) – Limit Test.

Species/Strain	Rat/Sprague Dawley
Vehicle	Test substance administered as supplied.
Type of dressing	Occlusive
Remarks - Method	No significant protocol deviations. The animals were administered 2000 mg/kg bw (4.44mL/kg bw) corrected for purity (34%) but not density. Actual dose was 2038 mg/kg bw when corrected for density.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5 per sex	2038*	0

*Dose of notified chemical

LD50	>2038 mg/kg bw
Signs of Toxicity - Local	There were no test substance-related dermal reactions.
Signs of Toxicity - Systemic	One female rat lost a small amount of weight during the first week but gained weight during the second week of the study. No other clinical signs of toxicity were observed.
Effects in Organs	There were no remarkable necropsy findings, and no tissue was collected for microscopic examination.
Remarks - Results	

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

TEST FACILITY Eastman Kodak (2003g)

7.3. Acute toxicity - inhalation

Not submitted.

7.4. Irritation – skin

TEST SUBSTANCE	Notified chemical (34% aqueous solution)
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion. EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	Test substance administered as supplied.
Observation Period	72 hours
Type of Dressing	Occlusive
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			
Erythema/Eschar	0	0	0	0	N/A	0
Oedema	0	0	0	0	N/A	0

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

Remarks - Results	There were no deaths or test substance-related clinical signs or remarkable body weight changes during the study period. No signs of erythema or oedema were observed at any time.
CONCLUSION	The notified chemical is non-irritating to the skin.
TEST FACILITY	Eastman Kodak (2003h)

7.5. Irritation - eye

TEST SUBSTANCE	Notified chemical (34% aqueous solution)
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion. EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	6
Observation Period	72 hours
Remarks - Method	The treated eyes of three rabbits were washed out with distilled water immediately after administration. The treated eyes of the remaining rabbits were not irrigated. Eyes were treated with a fluorescein dye at 24 hours and observed for staining.

RESULTS

Irrigated

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	0	0	1	24 hours	0
Conjunctiva: chemosis	0	0	0	0	N/A	0
Conjunctiva: discharge	-	-	-	-	-	-

Corneal opacity	0	0	0	0	N/A	0
Iridial inflammation	0	0	0	0	N/A	0

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

Non irrigated

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	0	0	1	24 hours	0
Conjunctiva: chemosis	0	0	0	0	N/A	0
Conjunctiva: discharge	-	-	-	-	-	-
Corneal opacity	0	0	0	0	N/A	0
Iridial inflammation	0	0	0	0	N/A	0

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

Remarks - Results

Signs of irritation consisted of redness (grade 1) for all non irrigated treated eyes and one irrigated eye. All eyes appeared normal from the 24-hour examination onwards. Immediate irrigation had a slight palliative effect on the minimal irritation caused by the test substance.

Staining was not evident in any eyes when tested with fluorescein dye.

Observations regarding discharge not recorded.

CONCLUSION

The notified chemical is very slightly irritating to the eye.

TEST FACILITY

Eastman Kodak (2003i)

7.6. Skin sensitisation

TEST SUBSTANCE

Notified chemical (34% aqueous solution)

METHOD

OECD TG 406 Skin Sensitisation – Guinea Pig Maximisation Test.
EC Directive 96/54/EC B.6 Skin Sensitisation - Guinea Pig Maximisation Test.

Species/Strain

Guinea pig/Crl:(HA)BR VAF/Plus

PRELIMINARY STUDY

Maximum Non-irritating Concentration:
intradermal: 6.7% (maximum concentration tested)
topical: test substance administered as supplied

MAIN STUDY

Number of Animals

Test Group: 20 Control Group: 10

INDUCTION PHASE

Induction Concentration:
intradermal: 5% test substance in distilled water
topical: test substance administered as supplied

Signs of Irritation

There were no signs of irritation following intradermal induction.
Discrete to moderate erythema were noted in the majority of the treated and control group animals after the application of sodium lauryl sulfate. Discrete erythema was noted in 14 test group and eight control group animals 24 hours after the topical induction phase, with moderate erythema being noted in one test animal.

CHALLENGE PHASE

1st challenge

topical: test substance administered as supplied

Remarks - Method

The intradermal induction concentration was lower than the maximum non-irritating concentration in the preliminary study. No justification for choice of concentration was given. No irritancy was observed at either concentration tested (3% and 6.7%) in the preliminary study.

As the test substance was determined to be a non irritant, the application

site of all animals was painted with approximately 0.5mL of 10% sodium lauryl sulfate in petrolatum prior to topical induction to induce local irritation.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*			
		1st challenge		*2nd challenge*	
		24 h	*48 h*	*24 h*	*48 h*
Test Group	100%	0/20	0/20	-	-
Control Group	100%	0/10	0/10	-	-

Remarks - Results

CONCLUSION There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.

TEST FACILITY Eastman Kodak (2003j)

7.7. 29/30-day repeat dose oral toxicity (rat)

TEST SUBSTANCE Notified chemical (34% aqueous solution)

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/Sprague Dawley

Route of Administration Oral – gavage

Exposure Information Total exposure days: 29 (male) or 30 (female) days;
Dose regimen: 7 days per week;
Post-exposure observation period: None

Vehicle Administered as supplied (high dose)
Distilled water (low and mid dose)

Remarks - Method No significant protocol deviations.
Prior to use in the study, the test solution was determined to be 34% of the notified chemical by weight. At study termination the test material was determined to be 44.2% notified chemical by weight.

The dose levels were chosen following a dose finding study. Twelve female rats were treated with 1349, 750, 500 or 0 mg/kg bw/day of the notified chemical in distilled water by gavage for four consecutive days. No mortality was observed and all animals appeared clinically normal throughout the study. Mean bodyweight, bodyweight gains, and feed consumption values were comparable among groups. Based on these results a limit dose of 1000 mg/kg bw/day was selected as the highest dose level with 300 and 100 mg/kg bw/day being selected to provide evidence of a dose response.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day**	*Mortality*
I (control)	5 per sex	0	0
II (low dose)	5 per sex	100	0
III (mid dose)	5 per sex	300	0
IV (high dose)	5 per sex	1000	1

* concentration is that of the notified chemical, based on the initial purity analysis. Based on the final purity analysis, the dose levels may have been as high as 1300, 390 and 130 mg/kg bw/day.

Mortality and Time to Death

One high dose group female died on day seven shortly after being dosed. No other mortality occurred during the study.

Clinical Observations

Clinical abnormalities observed exclusively for the female rat that died included prostration, moderate tremors and convulsions and moderately darker than normal eye colour. All of these abnormalities were observed immediately prior to death.

Eschars were observed in two low dose group males for three to six days of the study. Malocclusion of the teeth, minimal to minor reductions in the amount of faeces and ocular porphyrin discharges were observed for one to two rats from the control and/or low dose treated groups on one or two days of the study. A swelling of the ear was observed in one mid dose female on day 26 of the study.

All functional observations were comparable among groups during the dosing period and there were no significant differences detected in mean total ambulations or mean total motor activity counts among any of the groups.

There were no significant differences in feed consumption, mean body weight or body weight gain during the study.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Clinical Chemistry

Mean phosphorus levels were significantly lower in high dose male animals compared to controls. Mean sodium levels were significantly higher in both high dose males and mid dose animals.

Haematology

Mean corpuscular volume was significantly reduced in high dose males when compared with the control group.

Urinalysis

No urinalysis determinations were performed.

Effects in Organs

Organ weight

Mean absolute heart and liver weights were significantly lower in high dose males when compared to the control group. Lower mean absolute and relative to body weight liver weights were also observed in low dose males. Mean relative heart weights were higher for low dose female rats when compared to the control group.

Gross Pathology

For the high dose female rat that died shortly after being dosed on day seven, gross lesions observed at necropsy were limited to pink fluid in the abdominal cavity.

Minimal to minor haemorrhages of the thymus and/or cervical lymph nodes were observed in two control females, 3 low dose animals (2 male, 1 female) and one high dose male. Minimal ocular porphyrin discharges were observed in one control group male and one low dose group male. Minimal red discolouration of the lungs was observed in one control group female and one high dose group female and minor hydrometra of the uterus was observed in a control group female.

Histopathology

For the high dose female that died prior to study termination, microscopic lesions were limited to minimal hepatocellular cytoplasmic vacuolation. This lesion was also found in surviving animals from both treated and control groups.

Prostatitis was observed in all treated group males with the occurrence being statistically significant at the highest dose. The prostatitis was multifocal. There were no other microscopic evidence of histologic or cytologic alterations on the prostates. Microscopic findings were noted in a number of other organs including the heart, stomach, liver, thyroid gland, cervical lymph nodes, thymus, cervical spinal cord, sciatic nerve, prostate gland, uterus, trachea, kidneys and lungs. However, these were not considered treatment related

because they, either were only found in control group animals, were found in both treated and control animals with similar frequencies or only occurred sporadically.

Remarks – Results

The death of the high dose female on day seven may be due to gavage trauma and not from the toxicity of the substance. This was supported by the presence of pink fluid in the abdominal cavity. The convulsions observed were a likely consequence of hypoxia of the brain, occurring as a result of the dosing procedure and not the test substance. In addition, no mortality was observed in animals dosed up to 1349 mg/kg in the range finding study.

All other clinical observations were not observed in high does animals and were either only found in control group animals, found in both treated and control animals with similar frequencies or occurred only sporadically. Therefore these are not considered to be treatment related.

The changes in haematology values and clinical chemistry parameters were not considered toxicologically significant as the values measured were within the historical control limits.

The changes in mean absolute heart weight were not considered toxicologically significant because there were no microscopic alterations in the heart that correlated with a reduction in weight. Other organ weight changes were not considered toxicologically significant because they did not correlate with changes in histopathology and they did not occur in a dose dependant manner.

Prostatitis is reported to be a common background lesion in this strain of rat. In addition, since there were no other microscopic alterations in the prostate glands of these animals, and all other reproductive organs were microscopically normal, this prostatitis lesion is not considered to be test-substance related.

CONCLUSION

There were considered to be no toxicologically significant treated related effects, therefore the No Observed Adverse Effect Level (NOAEL) was established as 1000 mg/kg bw/day in this study.

TEST FACILITY Eastman Kodak (2004e)

7.8. Genotoxicity – bacteria

TEST SUBSTANCE	Notified chemical (34% aqueous solution)
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. Plate incorporation procedure
Species/Strain	*S. typhimurium*: TA1537, TA1535, TA98 and TA100. *E. coli*: WP2uvrA (pKM101).
Metabolic Activation System	Aroclor 1254 induced rat liver S9 fraction
Concentration Range in Main Test	a) With metabolic activation: 100-5000 µg/plate (76–3780 µg/plate) b) Without metabolic activation: 100-5000µg/plate (76–3780 µg/plate)
Vehicle	Deionised water
Remarks - Method	No significant protocol deviations. The notified chemical concentration listed in the report was calculated based on a purity of 45%. However, in other studies the purity was shown to be 34%. The concentration based on this purity is shown in brackets. An aliquot of the positive control 2-aminoanthracene was not added to one of the three positive control plates for tester strain TA100 in the presence of S9 mix. Therefore the test article was retested with tester strain TA100 in the presence of S9 mix in Test 3.

RESULTS

Metabolic	*Test Substance Concentration (µg/plate) Resulting in:*

Activation	*Cytotoxicity in Preliminary Test*	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent	>5000 (>3780)			
Test 1		>5000 (>3780)	>5000 (>3780)	negative
Test 2		>5000 (>3780)	>5000 (>3780)	negative
Present	>5000 (>3780)			
Test 1		>5000 (>3780)	>5000 (>3780)	negative
Test 2		>5000 (>3780)	>5000 (>3780)	negative
Test 3		>5000 (>3780)	>5000 (>3780)	negative

Remarks - Results: In all three studies, there were no positive increases in the mean number of revertants per plate with any of the tester strains in the presence or absence of S9 mix.

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

TEST FACILITY: Covance (2003a)

7.9. Genotoxicity – in vitro Chromosome Aberration assay

TEST SUBSTANCE: Notified chemical (34% aqueous solution)

METHOD: OECD TG 473 In vitro Mammalian Chromosome Aberration Test.

Species/Strain: Chinese Hamster
Cell Type/Cell Line: Ovary (CHO-WBL)
Metabolic Activation System: Aroclor 1254 induced rat liver S9 fraction
Vehicle: Cell culture grade water

Remarks - Method: No significant protocol deviations.

The notified chemical concentration listed in the report was calculated based on a purity of 45%. However, in other studies the purity was shown to be 34%. The concentration based on this purity is shown in brackets.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	33.9, 48.4, 69.2, 98.9, 141, 202, 288, 412, 588, 840, 1200, 1720*, 2450*, 3500* and 5000*. (25.6, 36.6, 52.3, 74.7, 107, 153, 218, 311, 438, 635, 907, 1300*, 1850*, 2640* and 3780*)	3 hours	20 hours
Test 2	120*, 240*, 480*, 960, 1920, 2880, 3480 and 4800 (90.7*, 181*, 363*, 725, 1450, 2180, 2630 and 3630)	20 hours	20 hours
Present			
Test 1	33.9, 48.4, 69.2, 98.9, 141, 202, 288, 412, 588, 840, 1200, 1720*, 2450*, 3500* and 5000*. (25.6, 36.6, 52.3, 74.7, 107, 153, 218, 311, 438, 635, 907, 1300*, 1850*, 2640* and 3780*)	3 hours	20 hours
Test 2	480, 960, 1920*, 2880*, 3480* and 4800* (363, 725, 1450*, 2180*, 2630* and 3630*)	3 hours	20 hours

*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	>5000 (>3780)	>5000 (>3780)	negative
Test 2	480 (363)*	>4800 (3630)	negative
Present			
Test 1	>5000 (>3780)	>5000 (>3780)	negative
Test 2	>4800 (>3630)	>4800 (3630)	negative

* based on a reduction in mitotic index of ~ 50%.

Remarks - Results

Test 1
There were no significant increases in cells with chromosomal aberrations, polyploidy, or endoreduplication in the cultures analysed in either the absence or presence of metabolic activation. A slight reduction in the mitotic index (6%) was observed in the presence of metabolic activation when treated with 5000µg/mL (3780µg/mL).

Test 2
There were no significant increase in cells with chromosomal aberrations, polyploidy, or endoreduplication in the cultures analysed in either the absence or presence of metabolic activation. A reduction in mitotic index was observed in cultures treated with 240µg/mL (181µg/mL) upwards in the absence of metabolic activation, the reduction ranged form 23% to 95%. A slight reduction (12%) in mitotic index was observed in the presence of metabolic activation in cultures treated with 4800µg/mL (3630µg/mL).

In both tests, the positive controls led to the expected increase in the number of cells with chromosomal aberrations.

CONCLUSION

The notified chemical was not clastogenic to Chinese Hamster Ovary (CHO) cells treated in vitro under the conditions of the test.

TEST FACILITY

Covance (2003b)

7.10. Genotoxicity – in vivo

Not submitted

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE

Formulation containing 34% notified chemical

METHOD

OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test (Modified Sturm).

Inoculum

Activated sludge mixed liquor from a sewage treatment plant receiving mostly domestic wastewater

Exposure Period

28 d

Auxiliary Solvent

None

Analytical Monitoring

Titration

Remarks - Method

Five test containers were used: 2 x test material, 1 x positive control and 2 x inoculum blank. The initial test material concentration was ~107.6 mg/L (20 mg DOC/L). The containers were filled with 2340 mL of basal salt medium (BSM) and 160 mL of prepared inoculum supernatant. The mixture was aerated with CO_2-free air for ~24 h to remove CO_2 prior to use. Microbial activity was checked using a positive control (sodium

benzoate 34.3 mg/L). To assess biodegradability, measured CO_2 evolution was compared to theoretical CO_2 ($ThCO_2$) evolution. CO_2 absorber bottles containing $Ba(OH)_2$ were collected periodically during the test for analysis by titration using HCl.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% TCO_2 degradation*	*Day*	*% TCO_2 degradation*
1	2	1	4
3	4.5	3	22
10	7.5	10	56
16	12	16	63
23	14	23	69
28	15	28	72

Remarks - Results: The pH of the test solution was 7.4-7.7. DOC in the positive control and test solutions were 98% and 30.5-34.1% less than the initial DOC. The reference substance achieved 72% degradation after day 14, validating the test conditions (≥60%). The test substance achieved only 15% degradation after 28 days contact time.

CONCLUSION: The test material is not ready biodegradable under the conditions of the test and OECD classification criteria.

TEST FACILITY: Eastman Kodak (2003k)

8.1.2. Bioaccumulation

Not determined.

Remarks: The notified chemical is estimated to be completely soluble in water and has an estimated negative octanol:water partition co-efficient (log Kow of -1.68) indicating a very low bioaccumulation potential.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE: Formulation containing 34% notified chemical

METHOD: OECD TG 203 Fish, Acute Toxicity Test – static and EC Directive 92/69/EEC C.1 Acute Toxicity for Fish - static.

Species	Fathead minnow (*Pimephales promelas*), juvenile. 0.18 g, 2.1 cm.
Exposure Period	96 h
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	Ion chromatographic (IC/CON) analysis of test solutions at 0 and 96 h.
Remarks – Method	The test was carried out as a limit test with one test concentration. Exposure solution was prepared by weighing 7.0588 g of the test substance into separate 10 mL beakers and transferring the contents to 22 L glass test vessels containing 20 L of laboratory dilution water. Dissolved oxygen range: 7.7-9.1 mg/L. Test temp: 20°C. Test water pH 8.1-8.3. Photoperiod: 16 h light: 8 h dark.

RESULTS

Concentration mg/L		*Number of Fish*	*Percent Mortality*				
Nominal	*Actual*		*4h*	*24h*	*48h*	*72h*	*96h*
Control	0	20 (2 replicates of 10)	0	0	0	0	0

120	110.9 (mean)	"	0	0	0	0	0

LC50	>110.9 mg notified chemical/L at 96 hours.
NOEC	110.9 mg notified chemical/L at 96 hours (highest concentration tested).
Remarks – Results	No mortalities or adverse behavioural effects were observed in fish in the control or test substance solutions during the study. No statistical analysis was required. No adverse effects were noted at the highest test concentration. Throughout the test, the test solutions appeared clear and colourless. Analysis of samples at 0 and 96 h indicated minor (7.6%) loss of the test substance.
CONCLUSION	The test formulation containing the notified chemical is practically acutely non-toxic to fish (L{E}C50 >100 mg/L, Mensink *et al*., 1995).
TEST FACILITY	Eastman Kodak (2003l)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Formulation containing 34% notified chemical
METHOD	OECD TG 202 *Daphnia* sp. Acute Immobilisation Test – static and EC Directive 92/69/EEC C.2 Acute Toxicity for *Daphnia* - static.
Species	*Daphnia magna* (1st instar neonates <24 h old).
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	Not stated
Analytical Monitoring	Ion chromatographic (IC/CON) analysis of test solutions at 0 and 48 h.
Remarks – Method	The test was carried out as a limit test with one test concentration. Exposure solution was prepared by weighing 7.0588 g of the test substance into separate 10 mL beakers and transferring the contents to 22 L glass test vessels containing 20 L of laboratory dilution water. Dissolved oxygen range: 8.6-9.1 mg/L. Test temp: 20°C. Test water pH 8.3-8.5. Photoperiod: 16 h light: 8 h dark.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
Control	0	20 (2 replicates of 10)	0	0
120	115.9	"	0	0

EC50	>115.9 mg notified chemical/L at 48 hours
NOEC	115.9 mg notified chemical/L at 48 h (highest concentration tested)
Remarks - Results	No immobility or adverse behavioural effects were observed in the daphnids in the control or test substance solutions during the study. No statistical analysis was required. No adverse effects were noted at the highest test concentration. Throughout the test, the test solutions appeared clear and colourless. Analysis of samples at 0 and 48 h indicated negligible (up to 4.6%) loss of the test substance.
CONCLUSION	The test formulation containing the notified chemical is practically acutely non-toxic to daphnids (L{E}C50 >100 mg/L, Mensink *et al*., 1995).
TEST FACILITY	Eastman Kodak (2003m)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	Formulation containing 34% notified chemical
METHOD	OECD TG 201 Alga, Growth Inhibition Test.
Species	Green alga *Selenastrum capricornutum*
Exposure Period	72 hours
Concentration Range	
Nominal (t_0)	6.25, 12.5, 25, 50 and 100 mg notified chemical/L
Actual (t_0)	6.08, 14.0, 26.4, 52.7, 113 (light/dark control) mg notified chemical/L
Auxiliary Solvent	None
Water Hardness	Not stated
Analytical Monitoring	Liquid chromatography/mass spectrometry (LC/MS) analysis of test solutions at 0, 24, 48 and 72 h.
Remarks - Method	Stock solution was prepared by dissolving 0.26 g test substance in 17.28 g sterile algal working media. The solution was then sterilised by filtration (0.45 μm) to give a concentration of 2220 mg/L (999.0 mg notified chemical/L). Test solutions were prepared by serial dilution of the stock solution, and solutions were incubated under constant mixing (100 rpm). Test solutions at the highest test concentration were also tested under light and dark conditions. Dissolved oxygen range: not stated. Test temp: 24°C. Test water pH 7.1-8.4. Photoperiod: continuous. Initial cell count: ~10^4 cells/mL. Statistical analyses wee performed using MINITAB by ANOVA and t-tests.

RESULTS

Biomass		*Growth*	
EbC50 mg notified chemical/L at 72 h	*NOEC mg/L*	*ErC50 mg notified chemical/L at 0-72 h*	*NOEC mg/L*
11.8	<6.25	34.1	<6.25

Remarks - Results	Control cell counts exhibited normal log growth (~10^6 cells/mL at 72 h) and increased by >95-fold within 3 days, meeting the OECD test criteria. Analytical monitoring indicates that the notified chemical was not stable during the test. No notified chemical was detected in the lowest four test solutions at 72 h, and % losses in the highest test concentration was ~68% of initial at 72 h. As a consequence of test material losses, test values are expressed based on nominal concentrations. Losses under light and dark conditions were ~52% and ~41%, respectively, of the initial test concentration. Loss of the notified chemical may be attributed to binding to growth media added to the test solution and subsequent unavailability to algae (ie. secondary effects due to a deficiency of essential elements required for algal growth).
CONCLUSION	The test substance is harmful to freshwater alga (EC50 10-100 mg/L) under the conditions of the test (United Nations, 2003).
TEST FACILITY	Eastman Kodak (2004f)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE	
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test and EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test
Inoculum	Washed activated sludge supernatant (centrifuged) from a domestic sewage treatment plant. pH 7.2.
Exposure Period	3 hours

Concentration Range	
Nominal	25, 50, 100, 500 and 1000 mg/L
Remarks – Method	Microbial respiration, expressed as the oxygen consumption (mg O_2/L/h) was measured under controlled conditions. Inhibition values were calculated by comparing test respiration rates to control respiration rates. A positive control (known toxicant, 3,5-dichlorophenol; 3.05, 9.77 and 31.25 mg/L) was prepared. Stock solution (5 g/L) was prepared by addition of test material (5.0 g/L) to deionised water. Serial dilutions were made to provide the required nominal test concentrations. After 3 h, at 12 minute intervals, aliquots of test solution were removed from consecutive test containers and the rate of respiration was monitored with a DO meter for 9 minutes or until the DO level reached 0.3 mg/L. The rate of respiration was monitored over the linear portion of the oxygen consumption trace for ~10 minutes (between 8.0 mg O_2/L and 1.2 mg O_2/L).

RESULTS

IC50	>1000 mg /L
NOEC	1000 mg/L (highest concentration tested)
Remarks – Results	The 3 h EC50 of the reference toxicant was not calculated; however, 50% inhibition occurred between 9.77 and 31.25 mg/L (within the acceptable range of 5-30 mg/L). The two negative control respiration rates were within 15% of each other (acceptable).

CONCLUSION	The test material did not inhibit the respiration of sewage sludge microbes up to a concentration of 1000 mg/L, which is well above the limit of water solubility.
TEST FACILITY	Eastman Kodak (2004g)

8.3E. Biochemical/chemical oxygen demand (BOD/COD)

TEST SUBSTANCE	Formulation containing 34% notified chemical
METHOD	BOD: EEC Annex V, Method C.5 Degradation, Biochemical Oxygen Demand. COD: EEC Annex V, Method C.6 Degradation, Chemical Oxygen Demand.
Inoculum	Not described.
Exposure Period	5 and 20 days
Auxiliary Solvent	None
Analytical Monitoring	Dissolved oxygen (initial and final).
Remarks – Method	BOD: Following a range finding test, a definitive test was performed using a test substance stock solution of ~50 g dissolved in 1.0 L of dilution water. COD: Test solution consisted of ~2 g test substance in 1.0 L of dilution water using for the BOD test. Aliquots of the test solution were incubated in COD vials for 2 h (150°C), cooled and analysed spectrophotometrically at 620 nm. Test solution contained a known quantity of dichromate. After exposure, the amount of Cr(III) generated was determined spectrophotometrically. The amount of Cr(VI) reduced to Cr(III) is proportional to the COD of the test substance.

RESULTS

BOD		*COD*			*BOD/COD*
Volume	BOD (5 days) g/g*	Volume	COD mg/L**	COD g/g*	
90 mL	$3.35x10^{-4}$	2 mL	652	0.9476	
120 mL	$3.20x10^{-4}$	"	639	0.9287	
180 mL	$3.41x10^{-4}$	"	649	0.9432	

270 mL	$3.83x10^{-4}$			
Mean±SD	$3.4x10^{-4}$ ±$0.3x10^{-4}$	647	0.94	$3.6X10^{-4}$

* Units of grams BOD/COD per gram of test substance, corrected for purity of the notified chemical.
** COD based on the formulation, and not corrected for purity of the notified chemical.

Remarks – Results

The BOD_5 of the reference standard (glucose-glutamic acid) was ~185 mg/L (acceptable). A potassium acid phthalate (KHP) standard and blank samples were also tested and validated the COD test conditions. Using a KHP spiked system, there was no interference of the test substance on the COD determination.

CONCLUSION

The mean of four BOD_5 measurements was $3.4x10^{-4}$ g/g of the test substance. The mean of four BOD_{20} measurements was $2.8x10^{-4}$ g/g of the test substance. The mean COD of the notified chemical was 0.94 g/g. The BOD_5:COD ratio is $3.6x10^{-4}$. The test results indicate a much greater potential for chemical than biochemical oxidation of the modified chemical. BOD values are relatively low, indicating low rate of biodegradation, which is supported by the chemical being not readily biodegradable according to OECD classification.

TEST FACILITY

Eastman Kodak (2004h,i)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified chemical is readily soluble in water and has a low affinity to organic carbon (log Koc of <1.25) but, based on chemical structure, is expected to bind to soils, sediments and suspended particulate matter. It is not readily biodegradable under 28 day OECD test conditions and test results indicate no appreciable hydrolysis at pH 4 and 7 with slow hydrolysis at pH 9 ($t_{½}$ ~80 days). However, biotic and abiotic degradation of the notified chemical is expected to occur over time.

The notifier estimates that the manufacturing process may potentially generate wastewaters containing the notified chemical and an estimate of 12 g per day (0.001% of annual import volume) may potentially be discharged in industrial wastewater to sewer from the notifier's facility. With a total effluent discharge from the notifier's facility of 0.4 ML/d, a wastewater concentration of ~30 µg/L is calculated. This effluent mixes with a further ~500 ML/d within the sewerage system, potentially with a predicted effluent concentration of ~0.024 µg/L assuming no attenuation other than dilution.

Not accounting for the quantity of finished products exported, use of the notified chemical throughout Australia may potentially result in a small but unspecified proportion of the notified chemical entering the sewerage system. Conservatively, if 10% of the notified chemical were to enter the sewerage system (120 kg/y), a sewage concentration of 0.08 µg/L may be calculated. This assumes an Australian population of 20.1 million people generates 200 L/person/day (ie. $1.467x10^{12}$ L/y) and no attenuation within the sewerage system. Assuming dilution factors for freshwater and marine environments of 1 and 10, respectively, $PEC_{freshwater}$ and PEC_{marine} of 0.08 µg/L and 0.0008 µg/L are calculated. Attenuation of the notified chemical within the sewerage system by partitioning to sludge is expected based on the chemical structure.

9.1.2. Environment – effects assessment

Aquatic toxicity data were available for the formulation containing 34% of the notified chemical for four taxonomic groups (freshwater); fish, invertebrates, algae and sewage sludge microbes. The notified chemical was practically not toxic to fish, invertebrates and sewage microbes, but was harmful to the algae (E_bC50 11.8 mg/L). A predicted no effect concentration (PNEC) of 118 µg/L has been derived by dividing this value by an assessment (safety) factor of 100. Although ecotoxicity data are only available for the formulation containing 34% of the notified chemical, the majority of the formulation is water with only a fraction of impurities and it has been assumed that the notified chemical is the principal source of the ecotoxicity of the formulation.

9.1.3. Environment – risk characterisation

A fraction of the notified chemical may enter the sewerage system during local manufacture of finished products. A risk quotient (RQ) approach where RQ = [PEC ÷ PNEC] has been used to estimate an RQ value for its freshwater receiving environment following sewage treatment. An RQ value of <0.001 (0.024 ÷ 118) indicates a very low risk to the environment from the notified chemical in this effluent. During use of the notified chemical formulation, a fraction of the notified chemical may potentially enter the Australian sewerage system. RQ values of <0.001 (0.08 ÷ 118) and <0.0001 (0.008 ÷ 118) have been derived. These very low estimates of environmental risk assume no sewerage system attenuation of the notified chemical; however, attenuation such as by chelation and precipitation in sludge is likely to occur during this process thereby reducing the environmental risk further.

A fraction of the notified chemical may also be disposed of to landfill with emptied container residues. Within a landfill environment, the notified chemical is unlikely to pose an unacceptable risk to the environment based on the relatively small import volume. Binding to soils and biodegradation processes are likely attenuation pathways in a landfill environment. Thermal treatment of recovered solutions containing the notified chemical following it use will likely destroy the notified chemical, resulting in the formation of oxides of carbon, nitrogen and phosphorus.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Formulation

Intermittent exposure to drips and splashes of the notified chemical at a concentration of 43-45% could occur during transfer of Budex 5103 to the mixing vessel.

The estimated dermal exposure during formulation is 0-0.045 mg/cm^2/day, based on EASE model (EASE) and assuming the notified chemical is present at concentration of 45%. Therefore, for a 70 kg worker with surface area for hands at 820 cm^2 and forearms at 1140 cm^2 and a worst case 100% dermal absorption factor, systemic exposure is estimated to be 0-1.26 mg/kg bw/day.

Exposure to the notified chemical would be reduced by the use of PPE.

Exposure during the filling operation is expected to be negligible due to the low concentration of the notified chemical (<5%) in photoprocessing solution and the use of automatic systems.

Minimal exposure will occur during the laboratory testing due to the small quantities involved and limited exposure time (a few minutes per batch).

End Use

Exposure to the notified chemical is more likely in the large processing laboratories than the min-lab customers due the manual transfer of the photoprocessing solution and the expected larger quantities involved. However, even in these large laboratories exposure is expected to be negligible due to expected limited contact and the low concentration (<5%) of the notified chemical.

9.2.2. Public health – exposure assessment

The photoprocessing solution is sold to professional customers only. Therefore, no exposure to the general public is expected.

9.2.3. Human health - effects assessment

As the notified chemical cannot be isolated out of water, toxicological data were submitted for the notified chemical in solution. A comparison of the composition of the test substance and the notified chemical as introduced is as follows:

	Tested sample	Budex 5103 as introduced
% notified chemical	34	43-45
% impurities	11	5-7
% water	55	48-52

The toxicity of the test substance is considered to be indicative of the toxicity of the notified chemical as introduced. In addition, in the dose dependent studies (acute toxicity, repeated dose toxicity and genotoxicity), the dose used corresponded to the amount of the notified chemical and therefore these studies are considered to be indicative of the toxicity of the notified chemical itself. In the following summary the word 'solution' refers to a 34% aqueous solution of the notified chemical.

Acute toxicity.

The notified chemical was of low oral and dermal toxicity in acute rat studies.

Irritation and Sensitisation.

In a skin irritation study with a solution of the notified chemical, no erythema, oedema or abnormal physical signs were noted. The solution, and therefore the notified chemical as

introduced, is considered to be non-irritating to skin. In the eye irritation study with the same solution, signs of irritation consisted of redness (grade 1) for all non-irrigated treated eyes and one irrigated eye. All eyes appeared normal from the 24-hour examination onwards. Immediate irrigation had a slight palliative effect on the minimal irritation caused by the test substance. The solution, and therefore the notified chemical as introduced, is considered to be very slightly irritating to eyes. The solution was negative in a skin sensitisation adjuvant test in guinea-pigs, and therefore the notified chemical as introduced is unlikely to be a skin sensitiser.

Repeated Dose Toxicity.
In a 29/30 day oral repeat study in rats with a solution of the notified chemical there were considered to be no toxicologically significant treated related effects. Although one high dose animal died during the study, this was considered to be due to gavage trauma and not the toxicity of the notified chemical. This was supported by the presence of pink fluid in the abdominal cavity and the fact that no mortality was observed in animals dosed up to 1349 mg/kg in the range finding study. The doses used corresponded to the amount of the notified chemical itself. The No Observed Adverse Effect Level (NOAEL) was established as 1000 mg/kg bw/day in this study.

Mutagenicity.
A solution of the notified chemical was negative in an Ames test and an in vitro chromosomal aberration study in Chinese Hamster Ovary Cells. As the doses used corresponded to the amount of the notified chemical itself, it is considered that the notified chemical has low potential for *in vitro* mutagenicity or clastogenicity.

Hazard classification for health effects.
In the absence of toxicological data, the notified chemical as introduced would be classified as hazardous based on the presence of the impurities phosphoric acid and phosphorus acid. The following risk phrases would apply: R36/38 Irritating to eyes and skin.

However, based on the results of the toxicological studies, the notified chemical is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2002).

9.2.4. Occupational health and safety – risk characterisation

The notified chemical is a very slight eye irritant. Therefore protective eye wear should be worn during the weighing and transfer of the notified chemical as introduced (Budex 5103).

Exposure to the notified chemical during formulation was estimated to be 0 – 1.26 mg/kg bw/day. The margin of exposure (MOE) is calculated as 794. The MOE was based on a NOAEL of 1000 mg/kg bw/day, derived from a 29/30-day rat oral study. MOE greater than or equal to 100 are considered acceptable to account for intra- and inter-species differences. Therefore, the risk of systemic effects using modelled worker data is acceptable for formulation workers.

Following formulation of the photoprocessing solution, exposure to the notified chemical is expected to be negligible. Therefore the risk to workers involved in the use or handling of the photoprocessing solution is also expected to be negligible.

9.2.5. Public health – risk characterisation

No exposure to the general public is expected and therefore the risk to public health from the proposed use is expected to be negligible.

10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

10.1. Hazard classification

In the absence of toxicological data, the notified chemical as introduced would be classified as hazardous based on the presence of the impurities phosphoric acid and phosphorus acid. The following risk phrases would apply: R36/38 Irritating to eyes and skin.

However, based on the results of the toxicological studies, the notified chemical is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

and

As a comparison only, the classification of notified chemical using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations, 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes. It is not classified as hazardous on the basis of human health effects.

	Hazard category	***Hazard statement***
Chronic hazards to the aquatic environment	3	Harmful to aquatic life with long lasting effects

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratios, the chemical is not considered to pose an unacceptable risk to the environment based on its reported use pattern.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

10.3.2. Public health

There is Negligible Concern to public health when used in the proposed manner.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of Budex 5103 provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994a). It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

The label for Budex 5103 provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994b). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

CONTROL MEASURES
Occupational Health and Safety

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced:
  - Protective eyewear

  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 NOHSC *Approved Criteria for Classifying Hazardous Substances*, 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/release of the notified chemical should be handled by containing the spill, absorbing with inert material and placing in a labelled sealable container for disposal. Avoid releases to waterways and stormwater.

12.1. Secondary notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under subsection 64(2) of the Act:
- if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

13. BIBLIOGRAPHY

Covance (2003a) *Salmonella-Escherichia coli*/Mammalian-Microsome Reverse Mutation Assay with a Confirmatory Assay with EK2003-0081 (Study no. 25383-0-409OECD, 21 October 2003). Virginia, USA, Covance Laboratories Inc. Sponsor: Eastman Kodak Company (Unpublished report submitted by notifier).

Covance (2003b) Chromosomal Aberrations in Chinese Hamster Ovary (CHO) Cells (Study no. 25383-0-437OECD, 31 December 2003). Virginia, USA, Covance Laboratories Inc. Sponsor: Eastman Kodak Company (Unpublished report submitted by notifier).

Estimation and Assessment of Substance Exposure (EASE). The EASE system was developed by the UK Health and Safety Executive in conjunction with the Artificial Intelligence Applications Institute. For a further description see: Marquart et al., Evaluation of Methods of Exposure Assessment for Premarket Notifications, TNO Report V 94.229 TNO Nutrition and Food Research (Zeist), 1994.

Eastman Kodak (2003a) Phosphonic acid, (4-morpholinylmethylene)bis-,Sodium salt in water: Structure confirmation using Mass Spectrometric Detection (Report no. 2370-SMS, 9 October 2003). New York, USA, Eastman Kodak Company (Unpublished report submitted by the notifier).

Eastman Kodak (2003b) Phosphonic acid, (4-morpholinylmethylene)bis-,Sodium salt in water: UV-vis Absorption Spectra (Report no. 2370-SUV, 1 October 2003). New York, USA, Eastman Kodak Company (Unpublished report submitted by the notifier).

Eastman Kodak (2003c) Phosphonic acid, (4-morpholinylmethylene)bis-,Sodium salt in water: Analysis by NMR Spectroscopy (Report no. 2370-NMR, 1 October 2003). New York, USA, Eastman Kodak Company, (Unpublished report submitted by the notifier).

Eastman Kodak (2003d) Phosphonic acid, (4-morpholinylmethylene)bis-,Sodium salt in water: Purity Determination (Report no. 2370-PKV, 2 October 2003). New York, USA, Eastman Kodak Company (Unpublished report submitted by the notifier).

Eastman Kodak (2003e). Phosphonic acid, (4-morpholinylmethylene)bis-,Sodium salt in water: Abiotic Degradation: Hydrolysis as Function of pH. (Report no. 2370-HYD, 26 November 2003). New York, USA, Eastman Kodak Company (Unpublished report submitted by the notifier).

Eastman Kodak (2003f). Phosphonic acid,(4-morpholinylmethylene)bis-,Sodium salt in water: Acute Oral Toxicity Study (Fixed Dose) in the Rat (Project ID. 2003081A0, 25 September 2003). New York, USA, Eastman Kodak Company (Unpublished report submitted by the notifier).

Eastman Kodak (2003g). Phosphonic acid, (4-morpholinylmethylene)bis-,Sodium salt in water: Acute Dermal Toxicity Study in the Rat (Project ID. 2003081A1, 24 September 2003). New York, USA, Eastman Kodak Company (Unpublished report submitted by the notifier).

Eastman Kodak (2003h). Phosphonic acid, (4-morpholinylmethylene)bis-,Sodium salt in water: Acute Dermal Irritation/corrosion Study in the Rabbit (Project ID. 2003081A2, 26 August 2003). New York, USA, Eastman Kodak Company (Unpublished report submitted by the notifier).

Eastman Kodak (2003i). Phosphonic acid, (4-morpholinylmethylene)bis-,Sodium salt in water: Acute Eye Irritation in the Rabbit (Project ID. 2003081A6, 30 September 2003). New York, USA, Eastman Kodak Company (Unpublished report submitted by the notifier).

Eastman Kodak (2003j). Phosphonic acid, (4-morpholinylmethylene)bis-,Sodium salt in water: Skin Sensitization Study (GPMT Method) in the Guinea Pig (Project ID. 2003081A3, 30 September 2003). New York, USA, Eastman Kodak Company (Unpublished report submitted by the notifier).

Eastman Kodak (2003k). Phosphonic acid, (4-morpholinylmethylene)bis-,Sodium salt in water: Determination of Ready Biodegradability (Biotic Degradation) using the CO_2 Evolution Test (Modified Sturm) (Study no. EN-105-10090886-A, 28 August 2003). New York, USA, Eastman Kodak Company (Unpublished report submitted by the notifier).

Eastman Kodak (2003l). Phosphonic acid, (4-morpholinylmethylene)bis-,Sodium salt in water: An Acute Aquatic Effects Limit Test with the Minnow, *Pimephales promelas*. (Study no. EN-401-10090886-A, 5 December 2003). New York, USA, Eastman Kodak Company (Unpublished report submitted by the notifier).

Eastman Kodak (2003m). Phosphonic acid,(4-morpholinylmethylene)bis-,Sodium salt in water: An Acute Aquatic Effects Limit Test with the Daphnid, *Daphnia magna* (Study no. EN-403-10090886-A, 5 december 2003) New York, USA, Eastman Kodak Company (Unpublished report submitted by the notifier).

Eastman Kodak (2004a) Phosphonic acid, (4-morpholinylmethylene)bis-,Sodium salt in water: Physico-Chemical Properties with respect to Boiling and Autoignition Temperatures (Report no. 2370-0081, 16 January 2004). New York, USA, Eastman Kodak Company (Unpublished report submitted by the notifier).

Eastman Kodak (2004b) Phosphonic acid, (4-morpholinylmethylene)bis-,Sodium salt in water: Pdensity Determination (Report no. 2370-DEN, 24 February 2004). New York, USA, Eastman Kodak Company (Unpublished report submitted by the notifier).

Eastman Kodak (2004c). Phosphonic acid, (4-morpholinylmethylene)bis-,Sodium salt in water: Estimation of the Adsorption Coefficient (Koc) on Soil and on Sewage Sludge using High Performance Liquid Chromatography (HPLC) (Report no. 2370-EAD, 31 March 2004). New York, USA, Eastman Kodak Company (Unpublished report submitted by the notifier).

Eastman Kodak (2004d). Phosphonic acid, (4-morpholinylmethylene)bis-,Sodium salt in water: pKa Determination (Report no. 2370-PKA, 4 May 2004). New York, USA, Eastman Kodak Company (Unpublished report submitted by the notifier).

Eastman Kodak (2004e). Phosphonic acid, (4-morpholinylmethylene)bis-,Sodium salt in water: A four-week oral toxicity study in the rat (Project ID 2003081G1, 3 May 2004). New York, USA, Eastman Kodak Company (Unpublished report submitted by the notifier).

Eastman Kodak (2004f). Phosphonic acid, (4-morpholinylmethylene)bis-,Sodium salt in water: A Growth Inhibition Test with the Alga, *Selenastrum capricornutum* (Study no. EN-512-10090886-A, 5 February 2004). New York, USA, Eastman Kodak Company (Unpublished report submitted by the notifier).

Eastman Kodak (2004g). Phosphonic acid, (4-morpholinylmethylene)bis-,Sodium salt in water: Activated Sludge Respiration Inhibition Test (study no. EN-620-10090886-B, 22 March 2004) New York, USA, Eastman Kodak Company (Unpublished report submitted by the notifier).

Eastman Kodak (2004h). Phosphonic acid, (4-morpholinylmethylene)bis-,Sodium salt in water: Biochemical Oxygen Demand (BOD) (Report no. 2370-BOD, 31 March 2004). New York, USA, Eastman Kodak Company (Unpublished report submitted by the notifier).

Eastman Kodak (2004i). Phosphonic acid, (4-morpholinylmethylene)bis-,Sodium salt in water: Chemical Oxygen Demand (COD) (Report no. 2370-BOD,31 March 2004). New York, USA, Eastman Kodak Company (Unpublished report submitted by the notifier).

McCall, P. H., Swann, R. L., Laskowski, D. A., Unger, S. M., Vrona, S. A. and Dishburger, H. J. (1980). Estimation of Chemical Mobility in Soil from Liquid Chromatographic Retention Times. *Bull. Environ. Contam. Toxicol*., 24: 190-195.

Mensink, B. J. W. G., Montforts, M., Wijkhuizen-Maslankiewicz, L., Tibosch, H. and Linders, J. B. H. J (1995). Manual for Summarising and Evaluating the Environmental Aspects of Pesticides. National Institute of Public Health and Environmental Protection, Bilthoven, The Netherlands. Report no. 679101022.

NOHSC (1994a) National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (1994b) National Code of Practice for the Labelling of Workplace Substances [NOHSC:2012(1994)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (2002) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(2002)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (2003) Draft List of Designated Hazardous Substances. National Occupational Health and Safety Commission, Canberra.

Safepharm Laboratories (2003) Determination of Physico-chemical Properties Phosphonic acid, (4-morpholinylmethylene)bis-,Sodium salt in water (Project ID 674/089, 31 October 2003). Shardlow, UK, Safepharm Laboratories, Sponsor: Eastman Kodak Company (Unpublished report submitted by the notifier).

United Nations (2003) Globally Harmonised System of Classification and Labelling of Chemicals (GHS). United Nations Economic Commission for Europe (UN/ECE), New York and Geneva.United Nations (2003)