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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Chemical in Kodak Versamark 6911 Red 193 Ink

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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Director
NICNAS

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Chemical in Kodak Versamark 6911 Red 193 Ink

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Kodak Australia Pty Ltd (ABN 49 004 057 621)
181 Victoria Parade
COLLINGWOOD VIC 3066

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, molecular and structural formulae, molecular weight, impurities, degree of purity, spectral data, use details, import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: Dissociation Constant, Particle Size, Flammability Limits.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
EU, US , Canada

2. IDENTITY OF CHEMICAL

CAS NUMBER
Not assigned

MARKETING NAME(S)
Kodak Versamark 6911 Red 193 Ink (containing the notified chemical at <6% concentration)

MOLECULAR WEIGHT
Mn >500 Da.

ANALYTICAL DATA
Reference NMR, IR, HPLC, LCMS, NIMS, UV/VIS spectra were provided.

3. COMPOSITION

DEGREE OF PURITY >80%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None

ADDITIVES/ADJUVANTS
None

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
None

DEGRADATION PRODUCTS

The ageing of the notified chemical was tested by storing at temperatures of 54 ± 2°C for 2 weeks (Intertek ASG, 2005). No changes to the mass or appearance of the notified chemical were observed during the test.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: dark brown powder

Property	Value	Data Source/Justification
Melting Point	>300°C	Measured
Boiling Point	Decomposes without boiling	Measured
Density	1640 kg/m^3 at 20°C	Measured
Surface Tension	71.9 mNm^{-1} at 25°C	Measured
Vapour Pressure	<3 x 10^{-6} kPa at 20°C	Measured
Water Solubility	>412 g/L	Measured
Hydrolysis as a Function of pH	$t_{½}$ >1 year at 25°C, pH 4–9	Measured
Partition Coefficient (n-octanol/water)	log Pow = -2.5 to -4.3	Measured
Adsorption/Desorption	log K_{oc} <1.5 at 20.9–22.3°C, pH 3 and pH 10	Measured
Dissociation Constant	Not determined	The notified chemical is a salt and is expected to be ionised under environmental conditions
Particle Size	Not determined	The notified chemical will only be introduced as a component of ink formulations.
Flash Point	≥300°C	Measured
Flammability (solid)	Not flammable	Measured
Autoignition Temperature	265°C	Measured
Explosive Properties	Not explosive	Measured

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

Reactivity
The notified chemical is predicted to be stable under normal environmental conditions.

Dangerous Goods classification
Based on the submitted physical-chemical data in the above table the notified chemical is not classified according to the Australian Dangerous Goods Code (NTC, 2007). However the data above does not address all Dangerous Goods endpoints. Therefore consideration of all endpoints should be undertaken before a final decision on the Dangerous Goods classification is made by the introducer of the chemical.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will not be manufactured or reformulated in Australia. It will be imported by sea and air as a component of ink formulations.

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 RECIPIENTS
Kodak Australia Pty Ltd

TRANSPORTATION AND PACKAGING
The notified chemical will be imported as a component of ink formulations in 20 L cubitainers (plastic cubes surrounded by a fibreboard box) or 208 L drums and transported to commercial customers by road.

USE
The notified chemical will be used as a component of ink formulations at <6% concentration for use in commercial inkjet printers.

OPERATION DESCRIPTION
Ready to use ink formulations containing the notified chemical at <6% concentration will be imported and transported to commercial customer sites. Once ready for use, a pipe or hose will be connected to the containers holding ink formulations containing the notified chemical and the ink will be transferred to inkjet printing machines via an automated and enclosed process. The inkjet printer will transfer the ink containing the notified chemical onto the paper substrate, which will be dispensed with the ink bound to the surface in a cured, inert matrix. Once the ink has been consumed, the empty ink container will be disconnected from the printer and will be replaced with a new container of ink.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

Category of Worker	*Number*	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and storage	6-8	2-3	10-15
Printing operators	6-10	2-4	260

EXPOSURE DETAILS
Transport and storage workers will not be exposed to the notified chemical, except in the case of an accident involving damage to the packaging.

Printing operators may also experience dermal and ocular exposure to the notified chemical at <6% concentration in ink formulations during connecting and disconnecting pipes from the ink containers to the printing machines, cleaning and maintenance. However, exposure is expected to be minimised during these activities by the use of personal protective equipment (PPE), such as gloves, goggles, coveralls or aprons.

Dermal, ocular and inhalation exposure is also expected to be minimal during the printing process as printing is expected to be carried out within a closed and automated system. Any aerosols generated in the printing process that are not contained within the enclosed casing of the machine are expected to be captured by the catcher vacuum.

Printing operators may experience dermal exposure to printed paper containing the notified chemical at <6%. However, the notified chemical is expected to be bound within an inert print matrix and is not expected to be bioavailable. Therefore, exposure to the notified chemical from contact with printed paper is not considered likely.

6.1.2. Public exposure
Ink formulations containing the notified chemical at <6% will not be sold to the public. Therefore, the public will not be exposed to the notified chemical in ink. Members of the public may experience dermal exposure to printed paper containing the notified chemical at <6%. However, the notified chemical is expected to be bound within an inert print matrix and is not expected to be bioavailable. Therefore, public exposure to the notified chemical is not expected.

6.2. Human health effects assessment

The results from toxicological investigations conducted on the notified chemical are summarised in the table below. Details of some 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
Skin sensitisation, mouse local lymph node assay (LLNA)*	not a skin sensitiser at 10% concentration
Mutagenicity – bacterial reverse mutation*	non mutagenic
Genotoxicity – *in vitro* chromosome aberration*	non genotoxic

* See Appendix B for details

Toxicokinetics
The notified chemical has a high molecular weight (>500 Da.), high water solubility (412 g/L) and a low log PoW (-2.5 to -4.3) which would indicate limited potential for absorption. However, the red-stained urine in the acute oral toxicity study in rats would indicate that oral absorption of the notified chemical has occurred to some extent. Absorption via the dermal and inhalation routes is not expected to be significant based on the high molecular weight and low log PoW.

Acute toxicity
The notified chemical was found to be of low acute oral toxicity in female rats at 2000 mg/kg bw/day. No mortalities or adverse effects were reported. Red-staining of the urine was observed but in the absence of any other signs of systemic toxicity this was not considered to be an adverse effect. All animals showed expected body weight gains during the study period. The LD50 was established as >2000 mg/kg bw (Safepharm Laboratories, 2005a).

The notified chemical was found to be of low acute dermal toxicity in rats treated with 2000 mg/kg bw (5 females and 5 males). No mortalities or adverse effects were reported. All animals showed expected body weight gains during the study period. However, red staining of the application site prevented evaluation of erythema. The LD50 was established as >2000 mg/kg bw (Safepharm Laboratories, 2005b).

Irritation and Sensitisation
The notified chemical was tested for the potential to illicit skin irritation in 3 albino rabbits using a semi-occluded patch (Safepharm Laboratories, 2005c). The notified chemical was reported to stain the skin of the rabbits, however, no signs of skin irritation were observed.

The notified chemical was found to be slightly irritating to the eye of rabbits (see Appendix B for details).

The notified chemical was found not to be a skin sensitiser in a mouse local lymph node assay (LLNA) at the maximum tested concentration of 10% (see Appendix B for details). The potential for skin sensitisation at higher concentrations is not considered likely as it does not contain any known structural alerts for skin sensitisation (Barratt et al. 1994) and is therefore not expected to be a skin sensitiser.

Repeated Dose Toxicity
No data were provided to assess the potential for repeat dose or chronic toxicity.

Mutagenicity
The notified chemical was found to be not mutagenic in bacteria (under the conditions of the Ames test used), and did not induce chromosomal aberrations in mammalian cells *in vitro* (see Appendix B for details).

Health hazard classification
Based on the data provided the notified chemical is not classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

The main acute risk from the use of the notified chemical is the potential for slight eye irritation. Dermal, ocular and to a lesser extent, inhalation exposure of workers to the notified chemical in ink formulations at <6% concentration may occur during connecting and disconnecting hoses from printing machines to bottles containing the ink formulation as well as during cleaning and maintenance of the printing machines. However, PPE (gloves, goggles, coveralls or aprons) and engineering controls such as catcher vacuums are anticipated to be in use to reduce the level of exposure.

Based on the expected low exposure and the use of PPE, the risk presented by the notified chemical to the health and safety of workers is not expected to be unacceptable.

6.3.2. Public health

Inks containing the notified chemical will not be sold to the public. However, members of the public may experience dermal contact with substrates containing the notified chemical cured in an ink matrix. The notified chemical in this case is expected to be bound within an inert print matrix and is not expected to be bioavailable. Therefore, the risk to public health is not expected to be unacceptable, based on the low potential for exposure.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical will be imported into Australia as a component of ready to use commercial ink formulations for inkjet printers. No manufacturing, reformulation or repackaging of the notified chemical will take place in Australia. Environmental release of the notified chemical is unlikely to occur during importation, storage and transportation as containers are designed to minimise release. In the event of an accidental spill the ink containing the notified chemical will be adsorbed with inert material and disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

The ink containers containing the notified chemical will be connected to the printing machines by transfer piping, and it is expected that <1% of the annual import volume of the notified chemical may be spilt. If leakage or spillage does occur, the ink will be physically contained with absorbent material and disposed of to landfill. The ink containers will be contained within the printer until the contents are consumed. The empty containers, estimated to contain <1% of the annual import volume of the notified chemical, will be removed and disposed of to landfill or sent for recycling.

RELEASE OF CHEMICAL FROM DISPOSAL

Most of the notified chemical will be bound to printed paper and, once the ink has dried, will be contained in an inert matrix. It is assumed that 50% of the waste paper will end up in landfill and the rest will undergo paper recycling processes. During recycling processes, waste paper is repulped using a variety of chemical agents which, amongst other things, enhance detachment of ink from the fibres. The notified chemical may partition to the supernatant water, due to its high water solubility, which is released to the sewer. Notified chemical in the sludge generated during the recycling process will be sent to landfill for disposal.

7.1.2 Environmental fate

The majority of the notified polymer will be bound to paper, of which half is assumed to be recycled. During the paper recycling process, waste paper is repulped using a variety of alkaline, dispersing and wetting agents, water emulsifiable organic solvents and bleaches. Trade sources estimate the washing process will recover 30-60% of the total amount of ink and, therefore, at least 30% of the notified chemical in the recycled paper will be disposed of with sludge in landfill. However, due to the high water solubility of the notified chemical, a greater proportion can be expected to remain in the aqueous phase released to the sewer. The notified chemical is not readily biodegradable, however, due to its estimated low BCF value, low log Pow and its high water solubility, its potential for bioaccumulation is low in exposed aquatic organisms.

In landfill, notified chemical in sludge may leach, due to its high water solubility, although notified chemical bound to paper is likely to remain in the ink matrix. The notified chemical is expected to slowly degrade through biotic and abiotic processes to form water, oxides of carbon, nitrogen and sulphur, and inorganic salts.

For the details of the environmental fate studies, refer to Appendix C.

7.1.3 Predicted Environmental Concentration (PEC)

A predicted environmental concentration (PEC) for the worst case scenario has been calculated on the assumptions that 50% of the annual import of the notified chemical is released to the sewer as de-inking aqueous wastes from paper recycling over 260 days/year, with no removal of the notified chemical by sewage treatment plant (STP) processes.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	<1,000	kg/year
Proportion expected to be released to sewer	50 %	
Annual quantity of chemical released to sewer	<500	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	1.92	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:	<0.45	µg/L
PEC - Ocean:	<0.05	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m^2/year (10 ML/ha/year). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m^3). Using these assumptions, irrigation with a concentration of 0.454 µg/L may potentially result in a soil concentration of approximately 3.029 µg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 15.15 µg /kg and 30.29 µg /kg, respectively.

7.2. Environmental effects assessment

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

Endpoint	*Result*	*Assessment Conclusion*
Daphnia Toxicity	EC50 (48 h) >120 mg/L	Not harmful to aquatic invertebrates
Algal Toxicity	E_rC50 (72 h) > 76.8 mg/L	Not toxic to algae
Inhibition of Bacterial Respiration	IC50 (3 h) >100 mg/L	Not harmful to microbial respiration

Under the Globally Harmonised System of Classification and Labelling of Chemicals (United Nations, 2009) the notified chemical is formally classified as not harmful to aquatic invertebrates but can only be classified as not toxic to algae. The results obtained for algal growth inhibition are concluded to be very likely influenced by the light absorbing properties of the notified chemical, but it cannot be concluded that algal growth has been inhibited solely as a result of a reduction in light intensity (EC 2006, and references therein). The E_rC50 for algae is therefore classified as not toxic to algae. As the algal toxicity results do not exclude the possibility that the notified chemical is harmful to aquatic organisms and as it is not readily biodegradable, the notified chemical has been classified as 'Acute Category 3; Harmful to aquatic life' and 'Chronic Category 3; Harmful to aquatic life with long lasting effects'.

7.2.1 Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) was calculated using the minimum algal toxicity E_rC50 (72 h) value and an assessment factor of 1000, as the endpoints for only two trophic levels are available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
E_rC50 (Alga).	>76.8	mg/L
Assessment Factor	1,000	
PNEC:	>76.8	µg/L

7.3. Environmental risk assessment

The risk quotients (Q = PEC/PNEC) are calculated below:

Risk Assessment	*PEC µg/L*	*PNEC µg/L*	*Q*
Q - River:	<0.45	>76.8	<0.006
Q - Ocean:	<0.05	>76.8	<0.001

The concentration of the notified chemical in surface waters is expected to be very low based on the reported use pattern and the maximum import volume. It is not expected to bioaccumulate, based on its estimated low BCF value, high water solubility and low partition coefficient. As the risk quotients are well below 1, the notified chemical is not expected to pose a risk to the aquatic environment.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the data provided, the notified chemical is not classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

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

	Hazard category	*Hazard statement*
Aquatic environment	Acute Category 3 Chronic Category 3	Harmful to aquatic life Harmful to aquatic life with long lasting effects

Human health risk assessment

Under the conditions of the occupational settings described, the notified chemical is not considered to pose an 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 expected to pose a risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer as introduced at <6% concentration, in the product Kodak Versamark 6911 Red 193 Ink:
  - Avoid contact with eyes

- No specific engineering controls, work practices or personal protective equipment are required for the safe use of the notified chemical as a component of ink formulations at <6% concentration for use in commercial inkjet printers.

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

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

Disposal

- The notified chemical should be disposed of to landfill. Emergency procedures

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

Regulatory Obligations

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

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

(1) Under Section 64(1) of the Act; if
  - the importation volume exceeds one tonne per annum notified chemical;
  - the notified chemical is intended for use in products available to the public;

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the chemical has changed from component of ink at <6% for use in inkjet printers, or is likely to change significantly;
  - the chemical has begun to be manufactured in Australia;
  - additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

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

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

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point/Freezing Point >300ºC

Method EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks Decomposes before melting
Test Facility Intertek ASG (2005)

Boiling Point Decomposes without boiling

Method EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks Differential Scanning Calorimetry
Test Facility Syngenta (2005)

Density 1640 kg/m^3 at 20ºC ± 0.5ºC

Method OECD TG 109 Density of Liquids and Solids.
EC Directive 92/69/EEC A.3 Relative Density.
Remarks Measured using a Micromeritics Pycnometer 1330 TC.
Test Facility Intertek ASG (2005)

Vapour Pressure <3 x 10^{-3} kPa at 20ºC

Method OECD TG 104 Vapour Pressure.
EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks Measured by effusion manometry
Test Facility Syngenta (2005)

Water Solubility >412 g/L

Method In house flask method based on EC Directive 92/69/EEC A.6 Water Solubility. A series of solutions were prepared in deionised/distilled water (34.9 to 50.3% w/w). After vigorous manual stirring the flasks were left for up to 7 days at ambient temperature, with occasional stirring. Water solubility was determined by visual assessment.
Remarks No solid material was visually observed in any of the test vessels, however two test vessels, with concentrations >45% w/w, were reported to contain very thick immobile liquid. It was reportedly not possible to determine the solubility with any degree of confidence in the thick liquids. The notified chemical is very soluble as the highest test concentration that retained mobility with no solid material present was 41.2% w/w.
Test Facility Intertek ASG (2005)

Hydrolysis as a Function of pH $t_{½}$ >1 year at 25°C, pH 4–9

Method EC Directive 92/69/EEC C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH. Test concentrations (1 g/L) at pH 4, 7, and 9 were maintained at 50°C. After 5 days, the concentrations were determined by HPLC.

pH	*T (°C)*	$t_{½}$
4	25	>1 year
7	25	>1 year
9	25	>1 year

Remarks Less than 10% hydrolysis was observed after 5 days at 50°C at pH 4, 7, and 9. Therefore, the test material is considered stable with a half life greater than 1 year at 25°C.
The test material was found to precipitate on storage at pH 4 with no apparent degradation.
Test Facility Intertek ASG (2005)

Partition Coefficient (n-octanol/water) log Kow = -2.5 to -4.3

Method EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks Shake flask method. Concentrations of the test material were determined spectrophotometrically by comparison of absorbance to a calibrated curve. The tests were conducted at pH ~7.4 and the notified chemical exists in an ionised form at this pH. Therefore, the results should be treated with caution. However, the low log Kow is consistent with the high water solubility indicating a low affinity for the organic phase and organic component of soils, sediment and sludge.
Test Facility Intertek ASG (2005)

Adsorption/Desorption – screening test log K_{oc} <1.5 at 20.9–22.3°C, pH 3 and pH 10

Method OECD TG 121 Estimation of the Adsorption Coefficient (K_{oc}) on Soil and on Sewage Sludge using High Performance Liquid Chromatography (HPLC). The log K_{oc} for the notified chemical was determined by comparison of its retention time to a calibration curve.
Remarks The test was carried out at pH 3 and pH 10 measuring the adsorption coefficient in the notified chemical's various ionised forms. The low log K_{oc} is consistent with the high water solubility and low log Kow. The notified chemical is highly mobile in soil and is not expected to sorb to organic matter in soil.
Test Facility Brixham Environmental Laboratory (2005a)

Flash Point ≥300°C at 101.3 kPa

Method EC Directive 92/69/EEC A.9 Flash Point.
Remarks The flash point was not detected below 300°C, the upper limit of the test. The test substance is not classified as flammable in terms of its flash point.
Test Facility Syngenta (2005)

Flammability (Solids) Not flammable

Method EC Directive 92/69/EEC A.10 Flammability (Solids).
Remarks The test substance did not propagate combustion.
Test Facility Syngenta (2005)

Autoignition Temperature 265°C ± 5°C

Method EC Directive 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Remarks The notified chemical reached a temperature of 400°C when heated to 265 °C
Test Facility Syngenta (2005)

Explosive Properties Not explosive

Method EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks The notified chemical is not classified as explosive in terms of mechanical sensitivity with respect to shock, friction or heating under confinement.
Test Facility Syngenta (2005)

Surface Tension 71.9 mNm^{-1} at 25°C ± 1°C

Method EC Directive 92/69/EEC A.5 Surface Tension.
Remarks Concentration: $1.454x10^{-3}$M. The results indicate that the notified chemical was not considered to be surface active.
Test Facility Intertek ASG (2005)

Oxidizing Properties Not oxidizing

Method EC Directive 92/69/EEC A.17 Oxidizing Properties (Solids).

Remarks	Determined not to be oxidizing based on structural analysis and by analogy to results for a similar chemical.
Test Facility	Avecia (2005)

Stability Testing Stable under normal environmental conditions

Method	OECD TG 113 Screening Test for Thermal Stability and Stability in Air.
Remarks	The notified chemical was stored at 54°C ± 2°C for two weeks. No change to the appearance or mass of the notified chemical was observed
Test Facility	Intertek ASG (2005)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Irritation – eye

TEST SUBSTANCE: Notified chemical

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	72 hours
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	0.67	0.33	0.33	1	48 hrs	0
Conjunctiva: chemosis	0.33	0	0	1	24 hrs	0
Conjunctiva: discharge	0.33	0.33	0.33	1	24 hrs	0
Corneal opacity	0	0	0	0	-	0
Iridial inflammation	0.33	0	0	1	24 hrs	0

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

Remarks - Results: Minimal to moderate conjunctival irritation was observed in all treated eyes 1 hr following application, clearing within 48 hrs in 2 animals and 72 hrs in 1 animal. Minimal iridial inflammation was observed in 1 animal at the 1 and 24 hr observations. Purple-coloured staining of the fur was noted around the treated eye of the rabbits throughout the observation period.

CONCLUSION: The notified chemical is slightly irritating to the eye.

TEST FACILITY: Safepharm Laboratories (2005d)

B.2. Genotoxicity – bacteria

TEST SUBSTANCE: Notified chemical

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

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA (pKM101)
Metabolic Activation System	Rat S9 fraction from Aroclor 1254-induced rat liver
Concentration Range in Main Test	a) With metabolic activation: 100-5910 µg/plate b) Without metabolic activation: 100-5910 µg/plate
Vehicle	Dimethyl sulfoxide (DMSO)
Remarks - Method	The plate incorporation method was used in the first experiment and the pre-incubation method used in the second. The OECD test guideline recommends the use of the pre-incubation method for this type of chemical. The test guideline also recommends the use of alternative procedures such as a reductive metabolic activation system for this type of chemical.

RESULTS

Remarks - Results	Decreased numbers of revertants per plate was observed at the highest dose level of 5910 µg/plate in the TA100 and WP2*uvrA* (pKM101) strains without metabolic activation in the 2nd experiment and in the WP2*uvrA* (pKM101) strain with metabolic activation in the 2nd experiment. No precipitation was observed in any of the bacterial strains treated with the notified chemical in the plate incorporation procedure or the pre-incubation procedure in the presence or absence of metabolic activation. In the first experiment using the plate incorporation procedure, a statistically significant increase (100% or more) in the mean number of revertants per plate compared to the solvent control was reported in the TA1535 strain treated with the notified chemical at 500 µg/plate and the TA1537 strain treated with the notified chemical at 100 and 200 µg/plate. However, these values were comparable to historical control data for the TA1535 and TA1537 strains and no dose-response could be established and thus, were not considered to be toxicologically significant. All the positive control chemicals used in the test induced marked increases in the frequency of revertant colonies thus confirming the activity of the S9-mix and the sensitivity of the bacterial strains. There were no toxicologically significant increases in the number of revertant colonies in any of the strains tested using the plate incorporation method (in the absence and presence of metabolic activation) or the pre-incubation method (in the presence of metabolic activation).
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Central Toxicology Laboratory (2005a)

B.3. Genotoxicity – in vitro

TEST SUBSTANCE	Notified chemical
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	Human peripheral blood lymphocytes
Metabolic Activation System	Rat S9 fraction from Aroclor 1254-induced rat liver
Vehicle	Physiological saline
Remarks - Method	No significant protocol deviations

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	31, 63, 125, 250, 500, 1000*, 2000*, 5000*	3 hrs	20 hrs
Test 2	31, 63, 125, 250, 500*, 1000*, 2500*, 5000	20 hrs	20 hrs
Present			
Test 1	31, 63, 125, 250, 500, 1000*, 2000*, 5000*	3 hrs	20 hrs
Test 2	250, 500*, 2500*, 5000*	3 hrs	20 hrs

*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	-	-	-	Negative
Test 2	-	>2500*	-	Negative
Present				
Test 1	-	-	-	Negative
Test 2	-	-	-	Negative

* 20 hr treatment

Remarks - Results

Cytotoxicity (a 54% reduction in mitosis) was observed following continuous treatment for 20 hrs with the notified chemical at 2500 µg/mL in the absence of metabolic activation. No other cytotoxicity and no precipitation was observed in any of the treated cultures.

No statistically or biologically significant increases in the percentage of aberrant cells above the solvent control values were reported in any of the treated cultures.

The positive control substances, mitomycin C and cyclophosphamide induced statistically and biologically significant increases in the percentage of aberrant cells compared to solvent control values, thus confirming the sensitivity of the test system.

CONCLUSION

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

TEST FACILITY

Central Toxicology Laboratory (2005b)

B.4. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE

Notified chemical

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/Ca

Vehicle: Ethanol/Distilled water (7:3 v/v)

Remarks - Method

The notified chemical was tested for solubility in a number of different solvents and found to have the highest solubility in Ethanol/Distilled water (7:3 v/v). A test to confirm the reliability of the positive control substance (Alpha-Hexylcinnamaldehyde (HCA)) to predict the skin sensitisation potential using the LLNA test was conducted within the 6 months prior to the test using the notified chemical. No other significant protocol deviations.

RESULTS

Concentration (% w/w)	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance		
0 (vehicle control)	820.21	-
2.5	855.94	1.04
5	832.20	1.01
10	811.59	0.99
Positive Control - HCA		
5	Not provided	2.64
10	Not provided	8.36
25	Not provided	12.94

Remarks – Results	Purple-staining of the fur and ears were noted in all animals. However, a stimulation index of ≥3.0 was not reached in the lymph nodes in any of the treated animals up to the highest concentration tested (10%). Therefore, under the conditions of the test, the notified chemical was found not to be skin sensitising. The positive control test found HCA to induce a Stimulation Index (SI) of 8.36 at 10% concentration and a SI of 12.94 at 25% concentration, thus confirming the acceptability of HCA as a reliable positive control substance.
CONCLUSION	The notified chemical may have skin sensitising ability at the highest test concentration but the test conditions only allowed for evaluation up to 10% concentration. Therefore, on the basis of the results of this test, the notified chemical is not a skin sensitiser up to a concentration of 10%.
TEST FACILITY	Safepharm Laboratories (2005e)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 F Ready Biodegradability: Manometric Respirometery.
Inoculum	Activated sludge from a domestic sewage treatment works
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	The measurement of oxygen uptake was conducted by the Hach manometric Biochemical Oxygen Demand (BOD) apparatus. The concentration of the test substance was determined by HPLC.
Remarks - Method	Innoculated medium containing the test substance (100 mg/L) was stirred in a closed flask, and the consumption of oxygen was mesaured in accordance with the test guidelines above. A blank and reference control (sodium benzoate) were run in parallel. A toxicity control was not used. Evolved carbon dioxide was absorbed by potassium hydroxide solution. The biodegradability is expressed as the oxygen uptake by the microorganisms in the test substance (corrected for the blank) as a percentage of the chemical oxygen demand (COD). Test conditions were: 22 ± 2°C, pH 7.2 – 7.5.

RESULTS

Notified chemical		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
7	<5	7	58
14	<5	14	61
21	<5	21	61
28	<5	28	61

Remarks - Results	The percentage degradation of the reference substance (sodium benzoate) surpassed the pass level by day 14, thereby confirming that the activated sludge contained viable organisms. The pass level (60% of ThOD) was not reached by the test substance within a ten day window, or over the test period, thus it is not considered to be readily biodegradable. The COD of the test substance was determined to be 1.04 g O_2/g and its BOD was found to be <0.05 g O_2/g at Day 7 and 28. The concentration of the test substance was analysed by a validated HPLC method at the start and end of the study. The results indicated that a mean of 110% of nominal was present at the end of the test, and that the test substance had not structurally changed over the course of the study.
CONCLUSION	The notified chemical is not readily biodegradable
TEST FACILITY	Brixham Environmental Laboratory (2005b)

C.1.2. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 D Ready Biodegradability: Closed Bottle Test.
Inoculum	Secondary effluent of Shanghai Longhua sewage plant
Exposure Period	28 days
Auxiliary Solvent	None

Analytical Monitoring	Not reported
Remarks - Method	Study summary provided only. The test was conducted according to the guidelines above with no deviations from protocol reported. Test conditions were: 20 ± 1°C, pH 7.33.

RESULTS

Test substance		*Aniline*	
Day	*% Degradation*	*Day*	*% Degradation*
7	0.55	7	Not reported
14	0.82	14	69.3
21	1.10	21	Not reported
28	1.37	28	Not reported

Remarks - Results	The pass level (60% of ThOD) was not reached by the test substance within a ten day window, or over the test period, thus it is not considered to be readily biodegradable. Whilst nitrification was not reported, this is not expected to affect the outcome of the test. The percentage degradation of the reference substance (aniline) surpassed the pass level by day 14, thereby validating the test.
CONCLUSION	The notified chemical is not readily biodegradable
TEST FACILITY	Shanghai Academy of Environmental Sciences Environmental Testing Laboratory (2005)

C.1.3. Bioaccumulation

TEST SUBSTANCE	Notified chemical
METHOD	BCFWIN (v2.14), EPIsuite (v3.10)
Remarks - Method	The notified chemical was assessed as an ionic structure by BCFWIN (v2.14).
RESULTS	
Bioconcentration Factor	3.162 (log BCF = 0.5)
Remarks - Results	A BCF value of <500 indicates that a substance is unlikely to bioaccumulate. This result is supported by the high water solubility of the notified chemical (412 g/L) and its preference to partition from octanol to the water phase (log Kow -2.5 to -4.3).
CONCLUSION	The notified chemical is not expected to bioaccumulate
TEST FACILITY	Avecia Inkjet Limited (2005b)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 202 *Daphnia* sp. Acute Immobilisation - static.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	231 mg $CaCO_3$/L
Analytical Monitoring	Test concentrations were determined by HPLC (UV/visible detector): limit of quantification (LOQ) was 0.026 mg/L.
Remarks - Method	A single nominal concentration (120 mg/L; coloured solution) and a

blank were run in parallel, according to the test guidelines above. Four replicates per concentration each had 5 daphnia added. The daphnia were observed for immobilisation over the course of the test. Test conditions were: 20 ± 1°C, 16 h/8 h light dark cycle, 9.2-9.4 mg O_2/L, pH 7.9-8.1.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0	<LOQ	4 × 5	0	0
120	120	4 × 5	0	0

EC50 >120 mg/L at 48 hours
NOEC (or LOEC) 120 mg/L at 48 hours
Remarks - Results There were no immobilised daphnids observed, thus validating the test. It was not reported as to whether the colour of the solutions made it difficult to detect abnormal daphnid behaviour.

CONCLUSION The notified chemical is not harmful to aquatic invertebrates.

TEST FACILITY Brixham Environmental Laboratory (2005b)

C.2.2. Algal growth inhibition test

TEST SUBSTANCE Notified chemical

METHOD OECD TG 201 Alga, Growth Inhibition Test.
Species *Pseudokirchneriella subcapitata* (formerly known as *Selenastrum capricornutum*)
Exposure Period 72 hours
Concentration Range Nominal: 0, 1.0, 2.3, 5.0, 11, 25, 55 and 120 mg/L
Actual: <LOQ, 1.0, 2.3, 5.7, 11, 25, 54 and 120 mg/L
Auxiliary Solvent None
Water Hardness 0.15 mmol Ca^{2+} and Mg^{2+}
Analytical Monitoring Test concentrations were determined by HPLC (UV/visible detector): limit of quantification (LOQ) was 0.026 mg/L.
Remarks - Method The guidelines above were modified to differentiate the indirect effect of light absorption by the coloured test substance from any direct toxicity. Four replicate cultures of the control and each test concentration were employed. For each test substance concentration there were two replicates of each of the exposure and shaded test vessels. Exposure vessels incubated algae in test substance solutions, shaded by control culture medium; shaded vessels incubated algae in control culture medium shaded by the test substance medium. Test conditions were: 24 ± 2°C, continuous illumination, pH 7.5-7.8. One way analysis of variance and dunnetts procedure were used for statistical analysis.

RESULTS

	Biomass		*Growth*	
	E_bC_{50} mg/L at 72 h	*NOEC mg/L*	*E_rC_{50} mg/L at 72 h*	*NOEC mg/L*
Exposed	5.19	<1.0	76.8	1.0
Shaded	6.42	1.0	62.8	2.3

Remarks - Results The biomass in the control culture increased by a factor of 16, thereby validating the test.
The inhibition curves were found to be similar for both shaded and

	exposed solutions. However, this method is too simplistic to allow evaluation of both toxic and light absorption effects of coloured substances (EC, 2006a). Therefore, as it cannot be concluded that algal growth has been inhibited solely as a result of a reduction in light intensity (EC, 2006b) the endpoint cannot be classified. It is likely that the coloured solution did contribute to the observed growth inhibition to a large extent if not completely.
CONCLUSION	The notified chemical is not toxic to algae
TEST FACILITY	Brixham Environmental Laboratory (2005c)

C.2.3. Inhibition of microbial activity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test.
Inoculum	Activated sludge from Buckland Sewage Treatment Works
Exposure Period	3 hours
Concentration Range	Nominal: 0, 1.0, 3.2, 10, 32, and 100 mg/L
Remarks – Method	Conducted according to the guidelines above. A series of test cultures containing activated sludge, excess synthetic sewage and notified chemical (1.0-100 mg/L), and two control cultures containing sludge and synthetic sewage, were prepared. The inhibition of respiration at 3 hours was determined by comparing the respiration rate of the test cultures to the respiration rate of the controls. Test conditions were: 20 ± 2°C, pH 7.0-8.0.
RESULTS	
IC50	>100 mg/L
NOEC	100 mg/L
Remarks – Results	The percentage inhibition of the test concentrations containing the notified chemical was found to be ≤10%. However as this was reportedly due to the variability of the test and not to be an effect of the notified chemical, the NOEC is 100 mg/L. The 3 h IC50 of 5.6 mg/L for the reference substance (3,5-dichlorophenol) was found to be within the expected normal range of 5 to 30 mg/L. The respiration rates in to two control flasks were within 15% of each other, thereby validating the test.
CONCLUSION	The notified chemical is not harmful to microbial respiration.
TEST FACILITY	Brixham Environmental Laboratory (2005d)

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