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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

MHD-31

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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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Sony Australia Ltd (ABN: 59 001 215 354)
33-39 Talavera Road
North Ryde NSW 2113

NOTIFICATION CATEGORY
Limited-small volume: Chemical other than polymer (1 tonne or less per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical Name, Other Names, CAS Number, Molecular Formula, Structural Formula, Molecular Weight, Purity, Non-Hazardous Impurities, Import Volume, Identity of Recipients.

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

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
EU (1998), TSCA, Switzerland (1998)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
MHD-31 (concentration of <1% in imported product)
Marketing names of the imported ink ribbon products include:
2UPC-R154(H,H/1,PC,HF,PF), 2UPC-R155(H,H/1), 2UPC-R156(H,H/1,HF,PF), 2UPC-R46A, 2UPC-R57A, 2UPC-R68A, 2UPC-C14, 2UPC-C15, UPC-21L, UPC-21S, 10UPC-X34/0, 10UPC-X46/0

MOLECULAR WEIGHT
< 500 Da

ANALYTICAL DATA
Reference NMR, IR, UV spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 97%

HAZARDOUS IMPURITIES
None

ADDITIVES/ADJUVANTS
None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Iridescent blue powder

Property	Value	Data Source/Justification
Melting Point	139.8 – 140.4°C	Measured
Boiling Point	The notified chemical did not boil during the test.	Measured
Density	1202 kg/m^3 at 22.2°C	Measured
Vapour Pressure	< 1.6 × 10^{-7} kPa at 25°C	Estimated
Water Solubility	0.69 (± 0.13) × 10^{-3} g/L at 20°C	Measured
Fat (or n-octanol) Solubility	1.31 (± 0.01) × 10^3 mg/100 g standard fat at 37.0°C	Measured
Hydrolysis as a Function of pH	$t_{1/2}$ = 87.3 hours at 25°C and pH 4.0	Measured
Partition Coefficient (n-octanol/water)	log P_{ow} = 5.0 (± 0.3) at 20°C	Measured
Adsorption/Desorption	log K_{oc} > 5.63 at 20°C	Estimated
Dissociation Constant	pK_a = 6.70 ± 0.03	Measured
Particle Size	Inhalable fraction (<100 μm): ~0.8% Respirable fraction (<10 μm): 0% MMAD* = 701.4μm	Measured
Flash Point**	Not determined	Low vapour pressure solid (see below discussion)
Flammability	Not highly flammable	Measured
Autoignition Temperature	Not observed up to 400°C	Measured
Explosive Properties	Not expected to be explosive	Estimated
Oxidising Properties	Not expected to be oxidising	Estimated

* MMAD = Mass Median Aerodynamic Diameter

DISCUSSION OF PROPERTIES

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

**Note: Following completion of the autoignition test, there was no test substance remaining, suggesting that it may have evaporated during the test. However, the notified chemical is not expected to flash under normal conditions of use, as indicated by the low vapour pressures observed during testing at temperatures up to 125°C.

Reactivity

The notified chemical is expected to be stable and not to react with air or water under normal conditions.

5. INTRODUCTION AND USE INFORMATION

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

The notified chemical will be imported into Australia as a component of an ink ribbon product at inclusion levels of <1% in the ink.

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

TRANSPORTATION AND PACKAGING

Printer ink ribbons will either be contained within a polypropylene bag inside a cardboard box or within rigid plastic cassettes. It will be transported in Australia mainly by truck.

USE

The notified chemical will be a component of dye for use in colour dye sublimation printing (eg. photographs). These printers will be used by both office workers, such as those in digital photo printing shops, and members

of the public.

OPERATION DESCRIPTION
The notified chemical will be supplied as a component of printer ink ribbons (inclusion levels of <1%). The ink ribbons will be fitted directly into dye sublimation printers by office workers. The printer ink ribbon consists of a polyester sheet with the notified chemical coated on one side. The dye will be transferred onto the substrate sheets by heat (approximately 200°C). Finally a clear film overlay will be applied to the receiving sheet from the printer ribbon, prior to the printed product being automatically expelled from the printer.

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)*
Operator in digital photo printing shop	1	Minimal	26

EXPOSURE DETAILS
Dermal exposure of workers to the notified chemical may occur infrequently by direct contact with the ink ribbon that is coated with the notified chemical (inclusion levels of <1%) during fitting or replacement of the ribbon into the printer. Such exposure is expected to be negligible, as the ribbon is likely to be contained within rigid plastic cassettes and the notified chemical only coats one side. In addition, the wearing of gloves is recommended during handling of the ink ribbon, further reducing the possibility for exposure.

Exposure to the notified chemical during printing processes, including inhalation exposure, is unlikely to occur as it is contained within the printer and is localised in nature.

Dermal exposure to the notified chemical from handling of printed sheets is unlikely to occur as the notified chemical will be covered with a clear film overlay (this film may not be cured upon exit from the printer, taking several hours or days, but is expected to prevent direct exposure to the notified chemical).

6.1.2. Public exposure
The exposure of the public to the notified chemical is expected to be identical or of a lesser extent than that experienced by workers using the same products, due to the likely lower frequency of use.

6.2. Human health effects assessment

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

Endpoint	*Result and Assessment Conclusion*
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – adjuvant test	evidence of sensitisation
Mutagenicity – bacterial reverse mutation	mutagenic

No information is available on the acute toxicity, toxicokinetics, metabolism, distribution, or effects following repeated exposure to the notified chemical. It may be absorbed from the gastrointestinal tract, as its partition coefficient and low water solubility are favourable for uptake by micellular solubilisation, and it is of relatively low molecular weight (EC 2003). In addition, its high partition coefficient also suggests possible bioaccumulation after prolonged exposure.

The notified chemical was found to be non-irritating to the skin and slightly irritating to the eyes.

A guinea pig maximisation test indicated the skin sensitisation of the notified chemical, with the majority of animals displaying skin reactions indicative of skin sensitisation following rechallenge application of the notified

chemical. The results of this test suggest that at least some dermal uptake occurs upon skin contact, although it may only be small on the basis of the low water solubility of the notified chemical and its relatively high partition coefficient.

The notified chemical was found to be mutagenic in the TA100 strain in a bacterial reverse mutation study in the presence of metabolic activation. This result was also confirmed by the outcomes of testing on a chemical of similar structure. In addition, the notified chemical also contains a structural alert for possible mutagenic activity. However, in the absence of *in vivo* testing on the notified chemical, classification on the basis of potential mutagenic effects is not possible in accordance with the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004). Further testing would be required to confirm whether the notified chemical is mutagenic and/or carcinogenic.

Classification
Based on the potential to induce skin sensitisation, the notified chemical is classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004).

The following risk phrase should be applied:
R43: May cause sensitisation by skin contact.

6.3. Human health risk characterisation

6.3.1. Occupational health and safety
Under normal circumstances, workers are unlikely to make deliberate contact with the notified chemical during handling of printer ink ribbons or printed sheets. Accidental exposure is likely to involve only occasional contact with inks on the fingertips at concentrations of <1% for relatively short periods of time. As such, the risk of irritancy effects resulting from dermal exposure to the notified chemical are unlikely. In addition, given the limited scope for direct exposure to the notified chemical under normal circumstances, the risk of skin sensitisation is also unlikely.

It is not certain whether the notified chemical is considered to be mutagenic. However, the notified chemical will be either enclosed within the printer or within a clear overlay film when printed onto paper and as such direct skin contact under normal conditions is not expected. It is recommended that workers wear gloves when handling printer ribbons to further minimise any potential exposure. It is also noted that if the import volume of the notified chemical exceeds one tonne per annum, NICNAS will require additional testing of its mutagenicity potential.

In conclusion, the occupational health and safety risk associated with the notified polymer is considered to be low, assuming that exposure is of low frequency and short duration.

6.3.2. Public health
The risk to the health of the public during the use of dye sublimation printers containing the notified chemical are expected to be identical or similar to that experienced by office workers, and therefore is expected to be low. It is recommended that members of the public wear gloves when handling printer ribbons.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE
The importation of the notified chemical as a minor component of printer ribbons contained within rigid plastic cassettes will limit any potential environmental releases to those arising from accidental breakages of the cassettes. It is expected that cassettes broken during importation, transport, or storage will be sent either to recyclers of plastic printing components or to landfill.

RELEASE OF CHEMICAL FROM USE
The notified chemical will be used exclusively in the production of photographic images on paper. In the production of these digital photographic prints, the transfer of the notified chemical from the printer ribbon to

the receiving paper occurs within the printer. This thermally activated process takes place in close proximity to the receiving paper and no fugitive releases of the notified chemical are expected from this application method. The clear plastic film that is overlaid on the image formed on the receiving sheet will prevent release of the notified chemical from the final photographic sheet until the photograph degrades.

A small fraction of the initial quantity of notified chemical may remain on spent printer ribbons. The used cassettes containing the spent ribbons (and hence the residual notified chemical) will be sent either to recyclers of plastic printing components or to landfill. This small residual quantity of notified chemical may slowly leach from spent printer ribbons in landfill, but it will adsorb strongly to soil and will not be mobile.

RELEASE OF CHEMICAL FROM DISPOSAL

The majority of the imported quantity of notified chemical will be disposed of in the form of discarded photographs. As photographs are unsuitable for paper recycling, it is expected that most photographs and hence the major proportion of imported notified chemical will be disposed of in landfill sites. The notified chemical may be slowly released by decomposing photographic prints, but it will adsorb strongly to soil and will not be mobile. A small proportion of photographs maybe incinerated in domestic situations. The incineration of photographs with residues of the notified chemical will release oxides of carbon and nitrogen, and water.

7.1.2 Environmental fate

The notified chemical is a very slightly water soluble substance with a very strong tendency to partition onto soil and sludge. The notified chemical will therefore not be mobile in either aquatic or terrestrial ecosystems. The notified chemical is not readily biodegradable, as indicated in Appendix C. However, the notified chemical is fairly to moderately hydrolysable in the environmental pH range and will therefore be degraded in the environment relatively quickly, especially under acidic conditions.

7.1.3 Predicted Environmental Concentration (PEC)

The notified chemical is not expected to be released to aquatic ecosystems in significant quantities. Hence, no PEC was calculated.

7.2. Environmental effects assessment

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

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity (96 hours)	LC50 0.22 mg/L	Very toxic
Daphnia Toxicity (48 hours)	EC50 0.69 mg/L	Very toxic

The notified chemical is very toxic to at least two of the three trophic levels of aquatic ecosystems.

7.2.1 Predicted No-Effect Concentration

The notified chemical is not likely to be released into aquatic ecosystems in ecotoxicologically significant concentrations. It is therefore not necessary or meaningful to calculate the environmental risk quotient for potential releases of the notified chemical. However, the PNEC for the notified chemical has been calculated. In this calculation, an assessment factor of 1000 was used because acute toxicity end-points for only two trophic levels of aquatic ecosystems have been provided. Hence, the PNEC for the notified chemical based on the most sensitive trophic level (fish) is 0.22 μg/L (= 0.22/1000 mg/L).

7.3. Environmental risk assessment

The notified chemical is used exclusively for a specific low volume application in photographic printers. There are no pathways for significant releases of the notified chemical into aquatic ecosystems based on the intended use. The limited releases that may occur within landfills will be widely distributed across Australia and are not expected to result in significant environmental exposure because the notified chemical will be immobilised on soil and ultimately degraded. The low quantities of notified chemical introduced, the distributed disposal pattern, and the very limited possibility for environmental release indicates that there will be no significant exposure of aquatic and terrestrial biota to this chemical. Therefore, the risk of an adverse effect on the

environment from the intended use of the notified chemical is acceptably low.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

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

R43: May cause sensitisation by skin contact.

and

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***
Skin sensitiser	1	May cause allergic skin reaction
Acute hazards to the aquatic environment	1	Very toxic to aquatic life
Chronic hazards to the aquatic environment	1	Very toxic 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 proposed use pattern and the low potential for environmental exposure, the notified chemical is not considered to pose a risk to the environment.

Recommendations

REGULATORY CONTROLS
Hazard Classification and Labelling

- The Office of the ASCC, Department of Employment and Workplace Relations (DEWR), should consider the following health hazard classification for the notified chemical:
  - R43: May cause sensitisation by skin contact.

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - Concentration ≥ 1%: R43 May cause sensitisation by skin contact.

- Products containing more than 1% notified chemical and available to the public must carry the following safety directions on the label:
  - Avoid contact with skin
  - Wear suitable gloves

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical:
  - Avoid contact with eyes and skin.

- Service personnel should wear cotton or disposable gloves when removing spent printer cartridges containing the notified chemical and during routine maintenance and repairs.

- 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.

Public Health

- The following measures should be taken to minimise public exposure to the notified chemical:
  - Avoid skin contact with ink.
  - Wear suitable gloves.

Environment

- The notified chemical should be disposed of by landfill.

Emergency procedures

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

Regulatory Obligations

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

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

(1) Under Section 64(1) of the Act; if

- the importation volume exceeds one tonne per annum notified chemical, in which case additional toxicological data on the mutagenic potential of the notified chemical will be required;
- the notified chemical is imported in any form other than on printer ribbons;
- additional information related to the mutagenicity/carcinogenicity of the notified chemical becomes available.

or

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

- the function or use of the chemical has changed from being a component of dye for use in colour dye sublimation printing, or is likely to change significantly;
- the amount of chemical being introduced has increased from 1 tonne per annum, or is likely to increase, significantly;
- if the chemical has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

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

No additional secondary notification conditions are stipulated.

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

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point 139.8 – 140.4ºC

Method	OECD TG 102 Melting Point/Melting Range. EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks	Decomposition was observed to occur
Test Facility	Covance (1998a)

Boiling Point

Method	OECD TG 103 Boiling Point. EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks	The notified chemical did not boil during the test.
Test Facility	Covance (1998a)

Density 1202 kg/m^3 at 22.2ºC

Method	OECD TG 109 Density of Liquids and Solids. EC Directive 92/69/EEC A.3 Relative Density. Gas comparison pycnometer
Test Facility	Covance (1998a)

Vapour Pressure < 1.6×10^{-7}kPa at 25ºC

Method	EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks	The vapour pressure at 25ºC was extrapolated from measurements taken with a vapour pressure balance.
Test Facility	SafePharm (1998)

Water Solubility 0.69 (± 0.13) × 10^{-3} g/L at 20ºC and pH 6.0–8.4

Method	OECD TG 105 Water Solubility. EC Directive 92/69/EEC A.6 Water Solubility.
Remarks	The water solubility was estimated as < 10 mg/L in a preliminary test based on a qualitative shake-flask method. The definitive test was carried out by a column elution method with quantification of the notified chemical in solution by means of HPLC-UV.
Test Facility	Covance (1998a)

Fat (or n-octanol) Solubility 1.31 (± 0.01) × 10^3 mg/100 g standard fat at 37.0°C

Method	OECD TG 116 Fat Solubility of Solid and Liquid Substances.
Remarks	The concentration of notified chemical in standard fat was quantified by means of reverse-phase HPLC-UV.
Test Facility	Covance (1998a)

Hydrolysis as a Function of pH Hydrolysable in the environmental pH range

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

pH	*T (°C)*	*$t_{½}$ (hours)*
4	25	87.3
7	25	656
9	25	642

Remarks	The concentration of notified chemical in aqueous solution was monitored by a validated analytical method based on reverse-phase HPLC-(UV-vis). The half-life for the notified chemical at 25°C and each pH level was extrapolated from the respective Arrhenius plots

of the rate constant for hydrolysis determined at 50°C and at 30°C (pH 4) or 40°C (pH 7 and 9).

Test Facility Covance (1997a)

Partition Coefficient (n-octanol/water) $\log P_{ow} = 5.0 (\pm 0.3)$ at 20°C (pH 8.0)

Method OECD TG 117 Partition Coefficient (n-octanol/water).
EC Directive 92/69/EEC A.8 Partition Coefficient.

Remarks The partition coefficient of the notified chemical in its unionised form was determined by HPLC elution of this substance (and the reference compounds) with a mobile phase comprising 25% water buffered to pH 8 in methanol.

Test Facility Covance (1998a)

Adsorption/Desorption – screening test $\log K_{oc} > 5.63$ at 20°C

Method OECD TG 121 Estimation of the Adsorption Coefficient (K_{oc}) on Soil and Sewage Sludge using High Performance Liquid Chromatography (HPLC)

Remarks The adsorption coefficient for the notified chemical is a lower limit that is based on the longer retention time of this substance as compared with a single reference compound (2,4-DDT, $\log K_{oc} = 5.63$) determined under standard chromatographic conditions and at neutral pH.

Test Facility NOTOX (2007)

Dissociation Constant $pK_a = 6.70 \pm 0.03$

Method OECD TG 112 Dissociation Constants in Water.

Remarks The acid-base properties of the notified chemical were determined by a titration method in water-methanol. The pK_a in water was extrapolated from the measurements in water-methanol by the Yasuda-Shedlovsky procedure. Based on the weak basicity of the notified chemical, it is expected to be ionized in the acidic to neutral range of environmentally accessible pHs (4–7).

Test Facility Sirius Analytical Instruments (1997)

Particle Size

Method OECD TG 110 Particle Size Distribution/Fibre Length and Diameter Distributions.
Laser diffraction (BS ISO 13320-1 : 1999)

Results

Range (μm)	*Mass (%)*
<365.976	10
<639.781	50
<1095.749	90

Mass Median Aerodynamic Diameter = 701.4 μm

Remarks Some sample agglomerations, which could not be dispersed, were observed during the laser diffraction analysis. These were believed to be responsible for the larger than expected particle distribution (preliminary optical microscope analysis indicated a particle size range of approximately 37 – 267μm).

Test Facility Chilworth (2007)

Flammability Not highly flammable

Method EC Directive 92/69/EEC A.10 Flammability (Solids).

Remarks During a preliminary test the notified chemical ignited and started to burn with a small orange flame, emitting black sooty smoke, however, the flame extinguished without propagating combustion.

Test Facility SafePharm (1994)

Autoignition Temperature No ignition observed at temperatures up to 400°C

Method	EC Directive 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Remarks	After the experiment there was no test substance remaining and it was concluded that it had evaporated during the test.
Test Facility	NOTOX (2007)

Explosive Properties Not expected to have explosive properties

Method	EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks	An expert statement was provided, indicating that the notified chemical is not expected to have explosive properties, given the lack of known explosophores within its structure, and its oxygen balance of –238.
Test Facility	Bootman (2007)

Oxidizing Properties Not expected to have oxidising properties

Method	EC Directive 92/69/EEC A.17 Oxidizing Properties (Solids).
Remarks	An expert statement was provided outlining several structural considerations for the expected lack of oxidising properties of the notified chemical.
Test Facility	Bootman (2007)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Irritation – skin

TEST SUBSTANCE	Notified chemical
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 (Crl:NZW/Kbl.BR strain)
Number of Animals	3F
Vehicle	Distilled water
Observation Period	72 hr
Type of Dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations.
RESULTS	
Remarks - Results	No dermal response to treatment was observed in any animal throughout the observation period
CONCLUSION	The notified chemical is non-irritating to the skin.
TEST FACILITY	Covance (1998b)

B.2. Irritation – eye

TEST SUBSTANCE	Notified chemical
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 (Crl:NZW/Kbl.BR strain)
Number of Animals	2M, 1F
Observation Period	9 days
Remarks - Method	No significant protocol deviations.
RESULTS	
Remarks - Results	In two of the rabbits, some conjunctival reddening was observed up to four hours after instillation and both eyes were discharging at the 4 hour observation. All eyes were normal at the end of the observation period.
CONCLUSION	The notified chemical is slightly irritating to the eye.
TEST FACILITY	Covance (1998c)

B.3. Skin sensitisation

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 406 Skin Sensitisation - Magnusson and Kligman Maximisation Test. EC Directive 96/54/EC B.6 Skin Sensitisation - Magnusson and Kligman Maximisation Test.
Species/Strain	Guinea pig/ Dunkin-Hartley
PRELIMINARY STUDY	Maximum Non-irritating Concentration: intradermal: 10% topical: 40%

MAIN STUDY

Number of Animals	Test Group: 20 males	Control Group: 10 males
INDUCTION PHASE	Induction Concentration: intradermal: 10% topical: 55%	
Signs of Irritation	Intradermal injection of the adjuvant alone elicited slight erythema at one or both injection sites in all the control and test group animals. Intradermal injection of vehicle with adjuvant caused slight erythema in control animals, with some scab formation apparent at several injection sites. Injection of the test article in the adjuvant produced slight erythema in five of the test animals. Injection of the vehicle alone resulted in slight erythema in three of the control animals. Following topical application, blue staining obscured the dose sites of fifteen of the test animals, which precluded accurate assessment of erythema. All of the test animals displayed either extensive eschar or scab formation. Erythema, of severity up to 'well defined', was observed in animals for which such reactions could be assessed. One control animal displayed slight erythema upon topical application.	
CHALLENGE PHASE		
1st challenge	topical: 40%, 20%	
2nd challenge	topical: 10%, 5%	
Remarks - Method	No significant protocol deviations.	

RESULTS

Animal	*1st Challenge Concentration*	*2nd Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*			
			1st challenge		*2nd challenge*	
			24 h	*48 h*	*24 h*	*48 h*
Test Group	40%	10%	5/20	7/20	12/20	20/20
	20%	5%	7/20	8/20	14/20	20/20
Control	40%	10%	1/10	3/10	1/10	6/10
	20%	5%	0/10	2/10	1/10	7/10

Remarks - Results

Note: in the below discussion some animals exhibited more than a single effect at each site.

First challenge

All test and control animals displayed blue staining at the sites of test article application, but this did not prevent assessment of skin reactions.

Following the first challenge, a small number of control animals exhibited skin reactions that included slight erythema (2 animals) or desquamation (1 animal). Application of the vehicle to test animals resulted in reactions in a few animals, such as slight erythema (2 animals), desquamation (2 animals), and/or scab formation (3 animals).

At the 24 hour observation time following the first challenge application with 20% test material, observations in the test group animals included slight erythema in two animals, scab formation in four animals, induration in two animals, and desquamation in two animals. At the 48 hour observation four animals displayed slight erythema, three animals showed scabbing, and four animals desquamation.

At the 48 hour observation time following the first challenge application with 40% test material, observations in the test group animals included slight erythema in two animals, scab formation in three animals, and desquamation in two animals. At the 48 hour observation four animals showed slight erythema, two animals showed scabbing, and four animals

desquamation.

Second challenge
Following the rechallenge, there were no erythematous reactions observed in the control animals. However, one animal developed eschar, although this was considered to be the result of the repeated exposure of the control animals to the test substance. In addition, seven of the control animals displayed desquamation.

Following the second challenge application with 10% test material, the presence of eschar was observed at seven sites 24 and 48 hours after dosing, with a further six sites developing this change 48 hours after application. Eleven sites were indurated at either or both of the 24 and 48 hour assessment points and one site was clearly fissured at 24 hours following dosing. At the 24 hour observation, ten sites had areas of desquamation that were stained blue by the test article, which prevented assessment of erythema skin reactions; four of these sites could also not be scored at 48 hours.

Following the second challenge application with 5% test material, eight animals developed eschar, seven animals were indurated, and one was fissured. Slight erythema was observed in five animals, however, twelve animals displayed heavy staining by the test material which prevented assessment of erythema at one or both of the time points.

CONCLUSION — There was evidence indicative of skin sensitisation to the notified chemical under the conditions of the test.

TEST FACILITY — Covance (1998d)

B.4. 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
Metabolic Activation System	S9 mix from Sprague-Dawley rat liver induced with Aroclor 1254.
Concentration Range in Main Test	a) With metabolic activation: 125-5000 µg/plate b) Without metabolic activation: 125-5000 µg/plate
Vehicle	Dimethyl formamide
Remarks - Method	2-Aminoanthracene was used as the sole indicator of the efficacy of the metabolic activation system, which is not in accordance with the Test Guideline. The preliminary test was performed using TA100 only.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1*	>5000	5000	>1000	Equivocal (TA98 and TA100)
Test 2*	-	>5000	>1000	Negative
Present				
Test 1*	>5000	5000	>1000	Positive in TA100

Test 2**	-	≥500	>500	Positive in TA100

* Plate incorporation method
** Pre-incubation method. For TA100, the plate incorporation method was also used.

Remarks - Results	Evidence of toxicity, as thinning of the background bacterial lawn, was observed at 1000, 2000 and 5000 µg/plate in the Salmonella strains in the presence of S9 mix when pre-incubation was employed. Statistically significant increases in revertant numbers were observed in TA100 in the preliminary test in the absence of S9 and in Test 2 in TA98 in the absence of S9. Treatment of TA100 with the test material in the presence of metabolic activation resulted in statistically significant increases in revertant colony numbers. These increases were indicative of weak mutagenic activity in the presence of metabolic activation only.
CONCLUSION	The notified chemical was mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Covance (1997b)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test
Inoculum	Activated sludge bacteria from the return lines of a municipal sewage treatment plant treating predominantly domestic sewage.
Exposure Period	28 days
Auxiliary Solvent	None. The required quantity of notified chemical was loaded onto PTFE disks and placed in the test vessels.
Analytical Monitoring	The quantity of evolved CO_2 was determined by acid-base titration.
Remarks - Method	The biodegradation of the notified chemical and the sodium benzoate reference substance were both evaluated at nominal test concentrations equivalent to 15 mg of organic carbon per litre.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
2	0	2	20
4	0	4	36
6	0	6	49
8	0	8	55
10	0	10	59
15	0	15	62
20	0	20	68
23	0	23	73
28	0	28	78

Remarks - Results	The biodegradation of the reference substance reached the 60% pass value within 14 days of passing the 10% threshold figure for degradation. The notified chemical did not inhibit the biodegradation of the reference substance in the toxicity control sample. The test is therefore valid. No biodegradation of the notified chemical was observed over the course of the 28 day test period. The notified chemical is therefore not readily biodegradable according to the test guidelines.
CONCLUSION	The notified chemical is not readily biodegradable
TEST FACILITY	Covance (1997c)

C.1.2. Bioaccumulation

The notified chemical has some potential to bioaccumulate based on its high log P_{ow}, its low water solubility and moderate fat solubility, and its relatively low molecular weight. However, in the environment, the potential for bioaccumulation will be limited by the relatively rapid hydrolysis of the notified chemical which, particularly at acidic pH, will compete with the tendency to partition into biological membranes. The risk of bioaccumulation is further reduced by the very limited exposure of aquatic organisms to this notified chemical arising from its use in photographic image production, and the strong tendency of the chemical to bind to soil and sludge.

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test – (Semi-Static). EC Directive 92/69/EEC C.1 Acute Toxicity for Fish – (Semi-Static).
Species	*Rainbow trout (Oncorhynchus mykiss)*
Exposure Period	96 hours
Auxiliary Solvent	Acetone
Water Hardness	65.3–66.3 mg $CaCO_3$/L
Analytical Monitoring	HPLC-(UV-vis)
Remarks – Method	The test medium was dechlorinated mains water of neutral pH and was replaced every 24 hours. The notified chemical, dissolved in acetone, was diluted with dechlorinated mains water to give clear blue test solutions. The clear blue appearance of the test solutions was unchanged at the end of the exposure period. A probit analysis was used to calculate the acute toxicity end points at each major time point. These analyses are based on the mean measured concentration of notified chemical in the test medium and the observed lethality. The confidence intervals for these end points were not reported.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control		7	0	0	0	0	0
Solvent		7	0	0	0	0	0
0.045	0.03	7	0	0	0	0	0
0.09	0.06	7	0	0	0	0	0
0.18	0.11	7	0	0	0[c]	0[e]	0[g]
0.35	0.24	7	0	0[a]	0[d]	3[f]	5[h]
0.70	0.56	7	0	0[b]	7	7	7

MT = fish displayed signs of mild toxic effects (e.g., increased cough frequency or swimming position in test vessels different from controls); ST = fish displayed signs of severe toxic effects (e.g., swimming abnormally or lying on bottom of tank). [a] 7 × MT. [b] 7 × ST. [c] 2 × MT. [d] 3 × MT and 4 × ST. [e] 3 × MT. [f] 4 × ST. [g] 3 × MT. [h] 2 × ST.

LC50	> 0.56 mg/L at 24 hours. 0.36 mg/L at 48 hours. 0.25 mg/L at 72 hours. 0.22 mg/L at 96 hours.
NOEC	0.06 mg/L at 96 hours.
Remarks – Results	There were no mortalities in the control and solvent samples, and the environmental test parameters remained within the specified limits. The test is therefore valid. The measured concentration of notified chemical in test solutions declined by approximately 50% over the 24-hour exposure period. The actual concentration listed in the dose-response table is the average of the concentrations in fresh test solutions measured at the 0- and 48-hour time points, and of the concentrations in spent exposure solutions measured at the 24- and 72-hour time points. The notified chemical has non-lethal toxic effects on fish at a concentration of 0.11 mg/L after 48 hours exposure under these test conditions. At concentrations ≥ 0.24 mg/L, the non-lethal toxic effects are more pronounced over the same exposure period with fish observed to swim abnormally or to lie on the bottom of the tank. At the highest test

concentration, all fish were severely affected after 24 hours and complete mortality was observed after 48 hours.

CONCLUSION — The notified chemical is very toxic to fish.

TEST FACILITY — Covance (1998e)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE — Notified chemical

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

Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	Acetone
Water Hardness	193–244 mg $CaCO_3$/L
Analytical Monitoring	HPLC-(UV-vis)
Remarks - Method	The test medium was standard hard water with a pH of 7.0–7.6 and was replaced after 24 hours. The test solutions of the notified chemical were prepared by the same procedure as that used for the fish test. As for the fish test, these test solutions remained clear blue at the end of the exposure period. The acute toxicity end-point for 48 hours exposure was calculated by means of a probit analysis. This analysis was based on the mean measured concentration of notified chemical in the test medium and the observed immobility of the daphnia.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
Control		20	0	0
Solvent		20	0	0
0.045	0.05	20	0	0
0.09	0.11	20	0	0
0.18	0.21	20	0	0
0.35	0.41	20	1	1
0.70	0.66	20	0	9

EC50	0.69 mg/L at 48 hours (95% CI: 0.59–1.09 mg/L)
NOEC	0.21 mg/L at 48 hours
Remarks - Results	There were no mortalities in the control and solvent test samples, and the environmental parameters remained within the specified limits. The test is therefore valid. The actual concentration listed in the dose-response table is the average of the concentrations in fresh test solutions measured at the 0- and 24-hour time points, and of the concentrations in spent exposure solutions measured at the 24- and 48-hour time points. There was no indication in the test report that non-lethal effects of the notified chemical had been monitored. Hence, the NOEC is based solely on the observed immobility of the notified chemical. Based on this criterion, the 48-hour LOEC for daphnia is 0.41 mg/L. The low 48-hour acute toxicity end-point for the notified chemical

	indicates that it is very toxic to daphnia.
CONCLUSION	The notified chemical is very toxic to daphnia.
TEST FACILITY	Covance (1998f)

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