File No: LTD/1359

19 June 2008

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

MHD-70

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:

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
NICNAS

TABLE OF CONTENTS

FULL PUBLIC REPORT

MHD-70

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Sony Australia Limited (ABN 59 001 215 354) of 33-39 Talavera Rd, 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 and structural formula, Molecular weight, Spectral data, Degree of purity, Non-hazardous impurities, Introduction volume and 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 (2000), US EPA (2000), Switzerland (2000)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
MHD-70 (at a concentration of <1% in imported ink ribbon products)

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 and UV spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
>95%

ADDITIVES/ADJUVANTS
None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Brown powder with lumps

Property	Value	Data Source/Justification
Melting Point/Boiling Point	Not determined	Decomposes at 90 °C Decomposition product melts at 140°C
Density	1340 kg/m^3 at 20°C	Measured
Vapour Pressure	<8.40 × 10^{-11} kPa at 20°C	Measured
Water Solubility	<0.001 g/L at 21°C	Measured
Hydrolysis as a Function of pH	Contains hydrolysable groups. These are not expected to hydrolyse under the environmental pH range of 4-9.	Not measured due to low solubility of the notified chemical
Partition Coefficient (n-octanol/water)	logP_{ow} = 6.38	Estimated using KOWWIN
Adsorption/Desorption	logK_{oc} >5.63	Measured
Dissociation Constant	pKa = 9.13	Measured
Particle Size	Inhalable fraction (<100 μm): 36.41% Respirable fraction (<10 μm): 11.10% MMAD* = 299.86 μm	Measured
Flash Point	Not determined	Not likely to have a low flash point, due to the low vapour pressure and high auto ignition temperature.
Autoignition Temperature	>400°C	Measured
Explosive Properties	Not explosive to heat, shock or friction	Measured
Oxidising Properties	Not oxidising	Estimated

* MMAD = Mass Median Aerodynamic Diameter

DISCUSSION OF PROPERTIES

The notified chemical is hydrophobic and non-volatile under ambient conditions. Powders of the notified chemical contain some proportion of respirable particles sizes; however, the notified chemical will not be imported in is pure, solid form (see below). For full details of tests on physical and chemical properties, please refer to Appendix A.

Reactivity

The notified chemical is stable at room temperature but decomposes at 90°C. Below 90°C, the notified chemical is non-oxidising and therefore not capable of causing fire or enhancing the risk of fire when in contact with combustible material. Expected thermal decomposition products would be oxides of carbon and oxides of nitrogen.

5. INTRODUCTION AND USE INFORMATION

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

The notified chemical will not be manufactured within Australia. The notified chemical will be imported into Australia as a component of ink ribbon products, which will contain <1% notified chemical 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

IDENTITY OF RECIPIENTS

The notified chemical will be sold to photo printing shops and the public throughout Australia.

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 is a component of colourant for use in colour dye sublimation printing (e.g. for the printing of 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%) contained in rigid plastic cassettes. Office workers will fit the ink ribbons directly into dye sublimation printers. 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*	*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 the transfer of dye during printing is highly localised in nature and should be contained within the printer.

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 fully cured upon exit from the printer (as it may take several hours or days to cure), but it is expected to prevent direct exposure to the notified chemical on printed paper.

6.1.2. Public exposure
The exposure of the public to the notified chemical is expected to be identical to that experienced by workers using the same products, or of a lesser extent 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*
Rat, acute oral toxicity	Low toxicity; LD_{50} >2000 mg/kg bw
Rabbit, skin irritation	Non-irritating
Rabbit, eye irritation	Slightly irritating
Guinea pig, skin sensitisation – adjuvant test	No evidence of sensitisation
Mutagenicity – bacterial reverse mutation	Non-mutagenic

Toxicokinetics, metabolism and distribution
There was no evidence from the toxicological investigations to suggest that the notified chemical was absorbed following oral or dermal administration. Given its low molecular weight, low water solubility (<1 mg/L) and relatively high estimated partition coefficient ($logP_{ow}$ = 6.38), some absorption from the gastrointestinal tract might be predicted, although absorption through the skin is expected to be slow and limited in extent (EC, 2003). Dermal absorption might be expected to be largely limited to uptake into the epidermis.

The particle size of the notified chemical indicates that a significant portion of the notified chemical will be inspirable with a small portion also respirable. If the notified chemical is inhaled at low levels, it is likely to be either absorbed or cleared from the respiratory tract through mucociliary action.

The azo linkage is the most labile portion of an azo dye molecule, and it is readily enzymatically metabolised in mammals, including man (SCCNFP, 2002). Liver azo reductase enzymes reductively cleave the molecule into component amines. Some metabolism may also occur in the cells of the bladder wall, and during percutaneous absorption. Anaerobic intestinal bacteria are also capable of catalysing reductive cleavage of the azo bond. In addition, bacterial skin microflora have been reported to be able to break down azo dyes into smaller amine species through azo reduction, and these may be readily absorbed (SCCNFP, 2002). The notified chemical contains structural substitutions that may make its azo bonds more susceptible to reduction than a similar but unsubstituted molecule.

Any assessment of the toxicity of azo dyes should consider their component amines.

General toxicity
The notified chemical was of low acute oral toxicity in rats (LD_{50} >2,000 mg/kg bw), and no treatment-related effects were observed. Acute dermal toxicity is not expected, given its expected lack of absorption by this route. Nothing is known about the acute inhalation toxicity of particles of the notified chemical, but extrapolation from the acute oral study might predict low acute inhalation toxicity.

The notified chemical was found to be non-irritating to the skin and only slightly irritating to the eyes. No irritant effects were severe enough to classify as a hazard (NOHSC, 2004).

It is noted that some of the component aromatic amines into which the notified chemical may be reductively cleaved are known to be toxic by a variety of routes (inhalation, skin contact, and if swallowed) and may cause cumulative effects.

Sensitisation
The notified chemical was negative in a maximisation test for skin sensitisation.

It, and its possible azo reduction products/metabolites, are either known sensitisers or contain structural moieties that are known to be alerts for sensitisation (Barratt *et al*, 1994). A number of azo dyes have been demonstrated to be skin sensitisers in animals and in humans using clinical patch tests; others have been associated with causing allergic contact dermatitis (Øllgaard *et al*, 1998). However, given the probable lack of absorption of the notified chemical through the epidermis, it is probably unlikely to induce skin sensitisation despite its structural alerts.

In conclusion, there is no direct evidence that the notified chemical is likely to induce skin sensitisation upon repeated exposure to humans.

Mutagenicity
Azo dyes as a class are a concern for their potential induction of mutagenicity and carcinogenicity. Reductive cleavage or degradation into component aromatic amines is thought to be one of the mechanisms involved (SCCNFP, 2002). It is perhaps because of this that the degree of correlation between mutagenicity study results and the *in vivo* carcinogenicity of azo dyes as a class is often poor (Brown and DeVito, 1993, referenced in Øllgaard, 1998).

While the notified chemical was tested to be not mutagenic in bacteria in an Ames test (performed according to OECD TG 471), the test guideline strongly recommends the use of alternative procedures for the detection of mutagenicity of azo dyes, as it is recognised that the standard procedure may not be sufficiently sensitive. Modified tests, such as that of Prival and Mitchell, utilise a reductive pre-incubation step (during which the azo dye may be reduced to amine species) before the test is carried out to yield a greater detection of mutagenic azo dyes (Prival and Mitchell, 1982). Given this deficiency in the study performed on the notified chemical, the test result is not considered to be strongly predictive of the notified chemical's mutagenicity *in vivo*. In addition, no data on the potential for the notified chemical to induce mutations and/or chromosomal damage in mammalian cells was available, from either *in vitro* or *in vivo* studies.

Each of the component amines of the notified chemical that might be formed upon reduction of azo bonds could potentially be mutagenic. Although the notified chemical is not expected to release any of the restricted aromatic amines specified in either the Appendix to EC Directive 76/769/EEC (EC, 2004) or the annexes of EU SCCNFP/0495/01 (SCCNFP, 2002), it can be reduced to form arylamine species that are either classified by the IARC as Category 3B carcinogens or closely resemble other known carcinogens (such as Category 2B carcinogens).

Overall, there is insufficient evidence on the notified chemical to override the potential for mutagenicity or carcinogenicity that is suggested from the analysis of its component amines, as reductive metabolism may be significant *in vivo*. One approach for classification is to classify azo dyes for carcinogenicity in the same categories as the corresponding carcinogenic or suspected carcinogenic amines (DFG, 2005). If such an approach were to be adopted, the notified chemical might be classified as a Category 2B carcinogen.

Health hazard classification
Based on the available data the notified chemical cannot be classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety
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, and given the predicted lack of epidermal penetration, the notified chemical is not expected to pose a risk of irritant or sensitisation effects resulting from dermal exposure.

Considering that the notified chemical may possess some propensity to be mutagenic, some consideration of the likely exposure scenario is required. In its use within dye sublimation printers, 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. Should dermal exposure occur, only limited absorption is expected beyond the epidermis. Reductive metabolism of the notified chemical into arylamines by skin microflora is possible, and these species may be expected to be more readily absorbed than the notified chemical. However, the extent of dermal exposure is likely to be small, and the extent to which these species may be formed is unknown. Also, despite that the rate of azo reduction by microflora is unknown, any dermal exposure to the notified chemical in the proposed use is likely to be only occasional and transient at low concentrations.

In conclusion, the risk to the health of workers associated with the notified chemical is not considered to be unacceptable, assuming that any exposure is of limited in concentration, frequency and duration. It is also noted that if the use changes in a way that results in higher exposure, or if the import volume of the notified chemical exceeds one tonne per annum, NICNAS will require additional testing of its potential for mutagenicity.

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 not expected to be unacceptable. 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 plastic 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. Thus, it will not be mobile in either aquatic or terrestrial ecosystems. It is not readily biodegradable, as indicated by appropriate an study (see Appendix C for details). However, it is fairly to moderately hydrolysable in the environmental pH range, and so it will be rapidly degraded in the environment, especially under acidic conditions.

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	LC50 >100 mg/L	Not toxic to fish
Daphnia Toxicity	LC50 >100 mg/L	Not toxic to *Daphnia magna*
Ready Biodegradability	Biodegradation after 28 days: 1%	Not readily biodegradable

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 >100 μg/L (= 100/1000 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 cannot be classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

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***
Environment	Chronic 4	May cause long lasting harmful effects to aquatic life

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

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

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

Recommendations

CONTROL MEASURES
Occupational Health and Safety

- 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 recommended by the notifier on any packaging for products that will be sold to the public, and which contain the notified chemical:
  - Avoid skin contact with ink
  - Wear suitable gloves

Disposal

- The notified chemical should be disposed of by landfill.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by disposal to landfill if the cassette is damaged.

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 for dye sublimation printing;
- additional information related to the mutagenicity and/or 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.

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/Freezing Point Decomposes at 90 °C
Decomposition product melts at 140°C

Method	OECD TG 102 Melting Point/Melting Range.
Remarks	The capillary method was used. No significant protocol deviations. GLP compliant.
Test Facility	ChemService (2000b)

Boiling Point The notified chemical decomposed prior to boiling.

Method	OECD TG 103 Boiling Point.
Remarks	Two melting transitions at 94.0 and 141.6 °C were observed by differential scanning calorimetry. The test substance underwent oxidative decomposition from 190 °C. No significant protocol deviations. GLP compliant.
Test Facility	ChemService (2000c)

Density 1340 kg/m^3 at 20°C

Method	OECD TG 109 Density of Liquids and Solids. EC Directive 92/69/EEC A.3 Relative Density.
Remarks	The density and relative density of the test substance was determined using a gas comparison stereopycnometer. No significant protocol deviations. GLP compliant.
Test Facility	NOTOX (2007)

Vapour Pressure $< 8.40 \times 10^{-10}$ kPa at 20°C

Method	OECD TG 104 Vapour Pressure. EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks	The vapour pressure of the test substance at 20°C was determined using the isothermal thermogravimetric effusion method. No significant protocol deviations. GLP compliant.
Test Facility	NOTOX (2007)

Water Solubility < 0.001 g/L at 21°C

Method	EC Directive 92/69/EEC A.6 Water Solubility.
Remarks	Flask Method. GLP compliant. The preliminary test varied from the guideline due to the notified chemical forming a microdispersion in water. No saturation equilibrium was achieved for the notified chemical at any concentration tested.
Test Facility	RBM (2000)

Adsorption/Desorption – screening test $\log K_{oc} > 5.63$

Method	OECD TG 121 Estimation of the Adsorption Coefficient on soil Using HPLC. EC directive 2001/59 EEC, EC.
Remarks	The notified chemical eluted from the column after the reference substances.
Test Facility	NOTOX (2007)

Dissociation Constant pKa = 9.13

Method	OECD TG 112 Dissociation Constants in Water.
Remarks	The pKa value corresponds to dissociation of an acidic group in the molecule.
Test Facility	NOTOX (2007)

Particle Size Inhalable fraction (<100 μm): 36.41%
Respirable fraction (<10 μm): 11.10%
Mass Median Aerodynamic Diameter = 299.86 μm

Method	OECD TG 110 Particle Size Distribution/Fibre Length and Diameter Distributions.
Remarks	Laser diffraction particle size analysis was used. No significant protocol deviations. GLP compliant.
Test Facility	Chilworth Technology (2007)

Autoignition Temperature > 400ºC

Method	EC Directive 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Remarks	No autoignition was observed up to a maximum of 400ºC. An additional test was performed to investigate whether it was possible to inject liquefied material in to the vessel of the auto-ignition apparatus by means of a variable volumetric pipette. This proved not possible due to the notified chemical crystallising in the tip of the pipette. No significant protocol deviations. GLP compliant.
Test Facility	NOTOX (2007)

Explosive Properties Not explosive to heat, shock or friction.

Method	EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks	The notified chemical was determined to not be explosive using the steel cartridge, drop-weight and friction mill test. No significant protocol deviations. GLP compliant.
Test Facility	NOTOX (2007)

Oxidizing Properties Not oxidising

Method	EC Directive 92/69/EEC A.17 Oxidizing Properties (Solids).
Remarks	The notified chemical does not contain any functional groups that might act as an oxidising agent. No significant protocol deviations.
Test Facility	NOTOX (2007)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 401 Acute Oral Toxicity – Limit Test. EC Directive 92/69/EEC B.1 Acute Toxicity (Oral) – Limit Test.
Species/Strain	Rat/Sprague Dawley Crl: CD (SD) BR
Vehicle	Deionised water
Remarks - Method	No significant protocol deviations.
RESULTS	
LD_{50}	>2000 mg/kg bw
Remarks - Results	No mortality or signs of toxicity were observed at 2000 mg/kg bw.
CONCLUSION	The notified chemical of low toxicity via the oral route.
TEST FACILITY	RBM (2000b)

B.2. 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
Number of Animals	3 males
Vehicle	None
Observation Period	72 hours
Type of Dressing	Occlusive
Remarks - Method	No significant protocol deviations
RESULTS	
Remarks - Results	No irritant effects were observed in any of the test animals.
CONCLUSION	The notified chemical is non-irritating to the skin.
TEST FACILITY	RBM (2000c)

B.3. 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
Number of Animals	3 males
Observation Period	72 hr
Remarks - Method	No significant protocol deviations.
RESULTS	
Remarks - Results	Slight conjunctival redness was observed in all rabbits one hour after treatment, but this was not present at subsequent observations. In one animal, the fluorescein staining that was performed 24 hours after application revealed a focal area of corneal opacity. However, this was not sufficiently severe to warrant a grade 1 score. All rabbits were normal at the 48-hour and 72-hour observations.
CONCLUSION	The notified chemical is slightly irritating to the eye.

TEST FACILITY	RBM (2000d)

B.4. Skin sensitisation

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 406 Skin Sensitisation - Maximisation Test. EC Directive 96/54/EC B.6 Skin Sensitisation - Maximisation Test.
Species/Strain	Guinea pig/Dunkin-Hartley
PRELIMINARY STUDY	Maximum Non-irritating Concentration: intradermal: 0.1% topical: 60%
MAIN STUDY	
Number of Animals	Test Group: 20 Control Group: 10
INDUCTION PHASE	Induction Concentration: intradermal: 1% topical: 60%
CHALLENGE PHASE	
1st challenge	topical: 5%
Remarks - Method	No significant protocol deviations. Topical concentrations of ≥20% gave a strong yellow or yellow-brown colouration of the treated areas that prevented the scoring of erythema – thus, the evaluations were scored on oedema only. At 5%, the staining was able to be removed using lukewarm water after 24 hours.
RESULTS	
Remarks - Results	No animals displayed skin reactions following challenge.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	RBM (2000e)

B.5. Genotoxicity – bacteria

TEST SUBSTANCE	Notified chemical
METHOD	Similar to OECD TG 471 Bacterial Reverse Mutation Test and EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria.
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2*uvr*A
Metabolic Activation System	S9 fraction of rat liver induced with phenobarbital and 5,6-benzoflavone
Concentration Range in Main Test	a) With metabolic activation: 313 - 5000 µg/plate b) Without metabolic activation: 313 - 5000 µg/plate
Vehicle	Dimethyl sulfoxide
Remarks - Method	Pre incubation procedure. No significant protocol deviations.
RESULTS	
Remarks - Results	The notified chemical did not induce any increases in revertant colonies in either the absence or presence of metabolic activation. Precipitation was observed at all dose levels. Valid and appropriate controls were included.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Genetic Laboratory, JBC, Inc. (1999)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 C Ready Biodegradability: Modified MITI Test (I).
Inoculum	Activated sludge
Exposure Period	28 days
Analytical Monitoring	Dissolved Organic content (DOC)
Remarks - Method	The notified chemical was exposed to activated sludge in a closed system oxygen consumption measuring apparatus. The biochemical oxygen demand (BOD) was measured over period of 28 days. The concentration of the dissolved organic carbon (DOC) was measured.

RESULTS

Notified chemical		*Aniline*	
Day	*% Degradation*	*Day*	*% Degradation*
7	-1	7	48.1
14	0	14	58.3
21	1	21	61
28	1	28	61

Remarks - Results	Little or no degradation of the notified chemical was observed during the study.
CONCLUSION	The notified chemical is not readily biodegradable.
TEST FACILITY	MSI (2000)

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 test renewed after 24 hours.
Species	*Brachydanio rerio*
Exposure Period	96 hours
Water Hardness	240 mg $CaCO_3$/L
Analytical Monitoring	Spectrophotometric analysis
Remarks – Method	A 100 mg/L test solution of notified chemical was prepared in deionised water with ultrasonication for 30 minutes. Undissolved test material was observed in the test media, which settled rapidly at the start of the test. Mean measured concentration was 30.74 mg/L. The values of dissolved oxygen, pH and temperature remained within the acceptable limits.

RESULTS

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

LC50	>100 mg/L at 96 hours.
NOEC	100 mg/L at 96 hours.
Remarks – Results	No animals in the control or treated group died. However, after 96 hours the treated fish were slightly yellow in colour.
CONCLUSION	The notified chemical is not toxic to *Brachydanio rerio.*
TEST FACILITY	RBM (2000f)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test - static EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia – Static test.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	Reconstituted water
Water Hardness	<250 mg $CaCO_3$/L
Analytical Monitoring	Spectrophotometric analysis at 506 nm.
Remarks - Method	Weighed amount of notified chemical (5.1 mg) was made up to 50 mL with reconstituted water. This solution was ultrasonicated for 30 minutes. Undissolved test material was observed in the test media. This material settled rapidly at the start of the test. Mean measured concentration was 9.01 mg/L. The values of dissolved oxygen, pH and temperature remained within the acceptable limits.

RESULTS

Nominal Concentration (mg/L)	*Number of D. magna*	*Number Immobilised*	
		24 h	*48 h*
100	20	0	0

LC50	>100 mg/L at 48 hours
NOEC	100 mg/L at 48 hours
Remarks - Results	No immobilisation observed.
CONCLUSION	The notified chemical is not toxic to *Daphnia magna.*
TEST FACILITY	RBM (2000g)

BIBLIOGRAPHY

Barratt MD, Basketter DA, Chamberlain M, Admans GD and Langowski JJ (1994) An Expert System Rulebase For Identifying Contact Allergens. *Toxic. in vitro.* 8(5):1053-1060.

Brown MA and DeVito SC (1993). Predicting Azo Dye Toxicity. *Critical Reviews in Environmental Science and Technology*. 23(3):249-324.

ChemService (2000a) UV/Vis, IR, NMR Spectra (Study No., CH-116/99, 28 January 2000), Milan, Italy, ChemService S.p.A (unpublished report submitted by Sony Australia Limited).

ChemService (2000b) Determination of the melting point (Study No., CH-117/99, 20 January 2000), Milan, Italy, ChemService S.p.A (unpublished report submitted by Sony Australia Limited).

ChemService (2000c) Determination of the boiling point (Study No., CH-118/99, 03 February 2000), Milan, Italy, ChemService S.p.A (unpublished report submitted by Sony Australia Limited).

Chilworth Technology (2007) Particle Size Analysis (Study No., GLP100652R1V1/07, 24 October 2007), Southampton, England (unpublished report submitted by Sony Australia Limited).

DFG (1988) *Occupational Toxicants and MAK values: Annual Thresholds and Classifications for the Workplace, Part A: Groups of substances requiring special consideration. Section III: Carcinogenic Substances.* Deutsche Forschungsgemeinschaft (DFG) Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area, Greim H (Chairman). ©2005 Wiley-VCH Verlag GmbH & Co. KGaA, Weinheim.

EC (2003) Technical Guidance Document on Risk Assessment, Part II. Institute for Health and Consumer Protection, European Chemicals Bureau, Joint Research Centre, European Commission.

EC (2004) EC Directive 76/769/EEC, Office for Official Publications of the European Communities (http://europa.eu.int/comm/enterprise/chemicals/legislation/markrestr/consolid_1976L0769_en.pdf)

Genetic Laboratory, JBC, Inc. (1999) Reverse Mutation Test using Microorganisms, Test Number: 3717. Genetic Laboratory, JBC, Inc., Osato-gun, Saitama, Japan. (unpublished report submitted by Sony Australia Limited).

MSI (2000) Ready Biodegradability Test, Report No 9B599G. Mitsubishi Chemical Safety Institute Ltd., 1-30 Shiba 2-chome, Minato-ku, Tokyo 105, Japan. (unpublished report submitted by Sony Australia Limited).

NOHSC (1994) 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 (2003) National Code of Practice for the Preparation of Material Safety Data Sheets, 2nd edition [NOHSC:2011(2003)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (2004) Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

NOTOX (2007) Determination of the physico-chemical properties (Study No., 485802, 05 November 2007), Hertogenbosch, Netherlands, NOTOX B.V. (unpublished report submitted by Sony Australia Limited).

Øllgaard H, Frost L, Galster J and Hansen OC (1998). Survey of Azo-Colorants in Denmark: Consumption, Use, Health and Environmental Aspects. Danish Technological Institute, Environment, Danish Environmental Protection Agency.

Prival MJ and Mitchell VD (1982) Analysis of a Method for Testing Azo Dyes for Mutagenic Activity in *Salmonella Typhimurium* in the Presence of Flavin Mononucleotide and Hamster Liver S9. *Mutat Res*. 97(2): 103-16.

RBM (2000a) Water Solubility Test, Report No 990828. Istituto di Recerche Biomediche "A.Mirxer" RBM S.p.A. Via Ribes 1, 10010 Colleretto Giacosa (Torino), Italy. (unpublished report submitted by Sony Australia Limited).

RBM (2000b) Acute Oral Toxicity Study in Rats, Report No 990831. Istituto di Recerche Biomediche "A.Mirxer" RBM S.p.A. Via Ribes 1, 10010 Colleretto Giacosa (Torino), Italy. (unpublished report submitted by Sony Australia Limited).

RBM (2000c) Acute Dermal Irritation Study in Rabbits, Report No 990832. Istituto di Recerche Biomediche “A.Mirxer” RBM S.p.A. Via Ribes 1, 10010 Colleretto Giacosa (Torino), Italy. (unpublished report submitted by Sony Australia Limited).

RBM (2000d) Acute Eye Irritation Study in Rabbits, Report No 990833. Istituto di Recerche Biomediche “A.Mirxer” RBM S.p.A. Via Ribes 1, 10010 Colleretto Giacosa (Torino), Italy. (unpublished report submitted by Sony Australia Limited).

RBM (2000e) Skin Sensitization Test in Guinea-Pigs Treated with the Test Article, Report No 990834. Istituto di Recerche Biomediche “A.Mirxer” RBM S.p.A. Via Ribes 1, 10010 Colleretto Giacosa (Torino), Italy. (unpublished report submitted by Sony Australia Limited).

RBM (2000f) Acute Toxicity study in Fish Test, Report No 990844 Istituto di Recerche Biomediche “A.Mirxer” RBM S.p.A. Via Ribes 1, 10010 Colleretto Giacosa (Torino), Italy. (unpublished report submitted by Sony Australia Limited).

RBM (2000g) Acute Immobilization Study, Report No 990845 Istituto di Recerche Biomediche “A.Mirxer” RBM S.p.A. Via Ribes 1, 10010 Colleretto Giacosa (Torino), Italy. (unpublished report submitted by Sony Australia Limited).

SCCNFP (2002) The Safety Review Of The Use Of Certain Azo-Dyes In Cosmetic Products: Opinion Of The Scientific Committee On Cosmetic Products And Non-Food Products Intended For Consumers. SCCNFP/0495/01 (prepared in the context of Directive 76/768/EEC).

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.