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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Y-513

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)
DIC Australia Pty Ltd (ABN 12 000 079 550)
42 Sunmore Close, Heatherton VIC 3202

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical name, Other names, CAS number, Molecular formula, Structural formula, Molecular weight, Spectral data, Method of detection and determination, Purity, Additives, 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
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Y-513
Symuler Fast Yellow 4407NF (containing 3-8% notified chemical)

MOLECULAR WEIGHT
>500 Da

ANALYTICAL DATA
Reference NMR, IR, HPLC, MS(ESI), ICP-AES, UV spectra were provided.

3. COMPOSITION

The notified chemical is a reaction mixture consisting of several structurally related azo components derived from 3,3'-dichlorobenzidine.

DEGREE OF PURITY >95%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None. The notifier has indicated that they expect that the notified chemical does not contain impurities of 3,3'-dichlorobenzidine at levels greater than 10ppm.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Yellow powder

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Decomposes at approx. 300°C	Measured
Boiling Point	Decomposes at approx. 300°C	Measured
Density	1450 kg/m^3 at 20°C	Measured
Vapour Pressure	< 1.33 x 10^{-11} kPa at 20°C	Measured
Water Solubility	< 0.36 mg/L at 20°C	Measured
Hydrolysis as a Function of pH	Not measured, because of very low water solubility.	Expected to be stable to hydrolysis.
Partition Coefficient (n-octanol/water)	log P_{ow} > 6.5 at 20°C	Measured
Adsorption/Desorption	log K_{oc} > 5.63 at 35°C	Measured
Dissociation Constant	Not measured, because of very low water solubility.	Not expected to dissociate in the environment.
Particle Size	Inhalable fraction (<100 μm): 90.69 % Respirable fraction (<10 μm): 24.86 % MMAD = 30.615 μm	Measured
Flash Point	Not determined	Test not conducted as notified chemical is a solid
Flammability	Not flammable	Measured
Autoignition Temperature	Not self-ignitable	Measured
Explosive Properties	Not explosive	Measured
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.

Reactivity
The notified chemical is expected to be stable under normal conditions of use. The notified chemical does not contain any structural indications of oxidising properties or other particular reactivity.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported in yellow pigment at concentrations of 3-8% and in printing inks at concentrations of 0.5%.

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, Melbourne

TRANSPORTATION AND PACKAGING
The imported notified chemical will be transported by truck in Kraft paper bags with a laminated liner (10kg) and in flexible containers (300kg).

Printing inks will be transported in cans (18L) and drums (200L), by truck.

USE
The notified chemical will be used as a pigment in printing inks. The products that it will be used to print paper or film substrates including magazines, catalogues, food packaging (not direct food contact), etc.

OPERATION DESCRIPTION

Formulation
The notified chemical (3-8% concentration) will be weighed either by counting the number of paper bags (known to contain 10kg per bag) or by manual weighing under local ventilation for quantities smaller than 10kg. It will then be transferred by manual emptying of the paper bags into a hopper that is fitted with a dust extractor (local ventilation equipment) together with a few other ingredients. Alternatively, for larger volumes of pigment (3-8% notified chemical) that are imported in flexible 300kg containers, the contents will be transferred into the hopper using automated procedures involving little direct handling by workers. From the hopper the material will then be pumped into an enclosed mixing tank. It will be mixed in a closed tank with other ingredients. At the completion of the mixing, the concentration of the notified chemical will be 0.5%. It will then be transferred to a kneader or beads mill for processing in a closed system. This transfer will be performed using a pump and hosing. During milling, quality control sampling will involve removing samples using a sampling valve. After milling, the processed ink containing the notified chemical (0.5%) will be transferred to packaging containers through a filter using a pump and hosing. Filters will be changed after this transfer and washed with organic solvents. Equipment will be cleaned by circulating organic solvent.

End use
Printing using inks containing the notified chemical (0.5%) will be performed mainly using gravure printing and also some using conventional offset printing processes (that may also include heat-set drying). Generally, the ink containing the notified chemical (0.5%) will be transferred to the printing machine with a pump and through a filter (if necessary). Filters will be removed and washed with organic solvents. The printing process itself will be automated. For heat-set inks, the printed material will be briefly placed in a heatset oven that will typically be at temperatures of 120^{o}C (range of 100 - 130 ^{o}C). Any ink remaining on the printing machine will be wiped off with a waste cloth soaked in organic solvents.

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)*
Printing ink formulators			
Mixing	2	30 minutes/day	80 times/year
Milling and packaging	2	2 hours/day	80 times/year
Printing ink users			
Charging	8	10 minutes/day	80 times/year

EXPOSURE DETAILS
Formulation
Inhalation exposure of workers to the notified chemical in powder form at concentrations of 3-8% may occur when weighing and transferring pigments to the mixing tank during ink formulation processes. The use of dust extractors and local ventilation systems is expected to collect most pigments containing the notified chemical that may be scattered during these processes. EASE modelling predicts dust exposure of 0.16-0.4 mg/m^3 (for powders consisting of 8% of the notified chemical), assuming that effective local exhaust ventilation is utilised. For a 70 kg worker, assuming an inhalation rate of 1.3 m^3/h, 4 hour exposure and that the notified chemical was all either absorbed or ingested via the mucociliary clearance mechanism, systemic exposure after inhalation is estimated to be 0.01-0.03 mg/kg bw/day. This estimate assumes that no respiratory protection is worn. However, the notifier has indicated that dust protective masks are expected to be worn during such procedures.

The process of weighing and transferring pigments to the mixing tank may also result in dermal and ocular exposure of workers to the notified chemical (3-8%). EASE modelling predicts 'very low' dermal exposure during such processes. Workers are also expected to wear personal protective equipment such as gloves, safety glasses, overalls, etc, that should further lower the potential for exposure.

Dermal and accidental ocular exposure of workers to the notified chemical at concentrations of 0.5% may

occur during the occasional connecting and disconnecting of hoses from the mixing tank to the beads mill or from the beads mill to packaging. EASE modelling of the pipe disconnection, cleaning and quality control operations was performed to estimate dermal exposure of workers to the notified chemical. The following assumptions were used for these estimates: direct handling, non-dispersive use (only used by workers with knowledge of the processes and use of controls), and incidental contact level (assumed to be one event per day). The predicted dermal exposure to the notified chemical is up to 0.0005 mg/cm^2/day. This is equivalent to up to 0.0003 mg/kg bw/day, based on dermal absorption of 10%, a surface area of 420 cm^2 (equivalent to the area of one hand or two half hands), and 70kg worker, and that the notified chemical is present at 0.5% concentration (EC, 2003). Such exposure is expected to be lowered by the use of personal protective equipment such as gloves, safety glasses and perhaps also protective masks.

Dermal and accidental ocular exposure of workers to the notified chemical at concentrations of 0.5% may also occur during quality control sampling, cleaning of removed filters and other equipment. Such exposure is expected to be lowered by the use of personal protective equipment such as gloves, safety glasses and perhaps also protective masks.

The total systemic exposure after both inhalation and dermal exposure is estimated to be 0.0103 - 0.0303 mg/kg bw/day. The lower end of this range is considered to be a more appropriate estimate of exposure when local exhaust ventilation is present and dermal protection is worn.

End use
Dermal and ocular exposure of workers to the notified chemical at concentrations of 0.5% may occur during transfer of inks to the printing machine, cleaning of filters and printing equipment, and contact with printed materials. Such exposure is expected to be lowered by the use of personal protective equipment such as gloves, safety glasses and, where necessary, protective masks. Also, during contact with the printed material, the ink will often be dry and thus the notified chemical should be trapped within a dried matrix and be unavailable for exposure. The notifier has also stated that for some end use applications the notified chemical will be covered by resin following its printing onto the substrate, which would minimise exposure.

6.1.2. Public exposure
The general public may make dermal contact with articles printed with the ink containing the notified chemical. However, once the ink has dried, the notified chemical will be trapped within the dried matrix and is not expected to be bioavailable. Whilst the potential for blooming and bleeding of the notified chemical from the substrate may exist, it is expected that the inks containing the notified chemical will be appropriately formulated with other ingredients and processed such as to minimise the tendency to bleed.

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 oral toxicity LD50 >2000 mg/kg bw
Rat, acute dermal toxicity	low dermal toxicity LD50 >2000 mg/kg bw
Rat, acute inhalation toxicity	Not determined
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating
Mouse, skin sensitisation – Local lymph node assay	no evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days.	NOAEL 1000 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro mammalian chromosome aberration test	non genotoxic

Note: there is a significant amount of toxicological information available on a chemical that is structurally related to the two major components of the notified chemical (an azo pigment derived from 3,3'-dichlorobenzidine). Where relevant, such data will be detailed in the below discussion, together with that on the notified chemical itself.

Toxicokinetics
The notified chemical has relatively high molecular weight (>500 Da), low water solubility (<0.36 mg/L) and high partition coefficient (log P >6.5).

Based on its chemical properties (relatively high molecular weight, low water solubility and high partition coefficient), absorption of the notified chemical through the skin is not expected to be significant (European Commission 2003, NOTOX 2009b).

Systemic exposure following oral administration of the notified chemical is not expected to be significant as its absorption from the gastrointestinal tract is likely to be limited by its water solubility and molecular weight. Any uptake is likely to occur via micellular solubilisation, given its highly lipophilic nature and low water solubility. Yellow stool in the acute and repeated dose oral studies suggests that the main route of excretion is through the faeces, and therefore indicate that the majority of the notified chemical is not absorbed from the gastrointestinal tract.

Studies on a chemical that is structurally related to the notified chemical have shown that it was not absorbed following oral ingestion or dermal administration in rats, with the majority of the dose being excreted in the faeces following oral administration, or remaining at the application site following dermal application (Exempt reference 2,6).

The vast majority of the notified chemical (~91%) is of inhalable (< 100 μm) particle size and could be inhaled into the upper respiratory tract. A significant portion (~25%) is also of small enough particle size (<10 μm) to reach the lower respiratory tract (tracheobronchial and pulmonary regions). Larger particles of inhalable size are expected to deposit in the nasopharyngeal region and be cleared by coughing/sneezing or be swallowed. Due to the low water solubility of the notified chemical smaller particles lodging in the tracheobronchial region are likely to be cleared by the mucociliary mechanism and swallowed. However, inhaled respirable particulates of the notified chemical lodging in the pulmonary region may not be readily cleared due to its low water solubility. There may be some potential for absorption across the respiratory tract epithelium due to its lipophilic nature. In summary, higher concentrations of exposure may be expected to result in increased impairment of clearance mechanisms (European Commission 2003, NOTOX 2009b).

Azo compounds may also break down to their component amines. The azo linkage is the most labile portion of an azo colourant molecule, and it is readily enzymatically metabolised in mammals, including man (SCCNFP, 2002). Liver azo reductase enzymes reductively cleave the molecules into component amines. Some metabolism of azo colourants may also occur in the cells of the bladder wall, and during percutaneous absorption. Intestinal bacteria are also capable of catalysing reductive cleavage of the azo bond. Any cleavage of the notified chemical that may occur in the gastrointestinal tract, though limited, will result in molecules with different physical and chemical properties than the notified chemical and are expected to be absorbed to a greater extent. The metabolites of the notified chemical are expected to be excreted via the bile or the urine (NOTOX 2009b).

Several studies on structurally related chemicals have suggested that the degree of breakdown is low. Following oral administration to test animals these studies did not detect significant amounts of 3,3'-dichlorobenzidine in the urine of the animals (Exempt references 1,3). A rat inhalation study revealed no detectable levels of 3,3'-dichlorobenzidine in the urine or blood, suggesting that the test substance was not metabolically cleaved following inhalation (Exempt reference 3). Levels of 3,3'-dichlorobenzidine and monoacetyl-3,3'-dichlorobenzidine were below the detection limit in all urine samples obtained from textile workers who had been exposed to dichlorobenzidine based pigments (Exempt reference 3).

Acute toxicity
The notified chemical was found to be of low acute oral and dermal toxicity in studies conducted on rats (LD50 > 2,000 mg/kg bw).

The acute inhalation toxicity of the notified chemical has not been determined. Based on the acute inhalation toxicity of a structurally related chemical, the notified chemical may be at least harmful via inhalation.

Irritation and Sensitisation.
The notified chemical was found to be non-irritating to the skin of rabbits. It was found to be slightly irritating to rabbit eyes, with irritation that was not sufficient to warrant hazard classification.

The notified chemical was not a skin sensitiser when tested up to a concentration of 25% in a mouse local lymph node assay (maximum concentration that could technically be applied). Therefore, the notified chemical is unlikely to cause skin sensitisation in exposed humans. This is further supported by human patch testing that was performed with the azo pigment that is structurally related to the notified chemical (Exempt reference 10). However, there are some reports of skin sensitisation of this structurally related chemical in humans (Exempt reference 1).

Repeat Dose Toxicity.
The NOAEL in a 28 day oral repeat dose study in rats was determined to be 1000 mg/kg bw/day (the highest tested dose). There were no toxicologically significant effects observed during the study.

Mutagenicity and Carcinogenicity.
Azo colourants are a concern for their potential induction of mutagenicity and carcinogenicity mainly through the aromatic amines that are present as impurities in the colourants, or that arise from their azo reduction in or outside of the body.

The notified chemical may be reductively cleaved to release one of the restricted aromatic amines specified in the Appendix to EC Directive 76/769/EEC (EC, 2004), that is, 3,3'-dichlorobenzidine, CAS number 91-94-1, which is a category 2 carcinogen.

The notified chemical did not appear to contain impurities of component arylamines based on the HPLC information provided. The notifier has also indicated that they expect that the notified chemical does not contain impurities of 3,3'-dichlorobenzidine at levels greater than 10ppm. As such, impurity levels are unlikely to contribute to carcinogenicity of the notified chemical.

The extent of azo reduction through metabolism is not known, however it is thought that this is likely to be lesser in pigments than in dyes due to reduced bioavailablity. It is noted that the EU and IARC lists benzidine-based azo dyes as being category 2 carcinogens (IARC 1987). However, this is not the case for 3,3'-dichlorobenzidine based azo pigments (Exempt reference 3).

However, the German Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area (DFG, 1988) states that "*all azo colourants whose metabolism can liberate a carcinogenic aryl amine are suspected of having carcinogenic potential*." It is also mentioned that if there are indications that the colourant or its carcinogenic break down products are not bioavailable, the absence of risk needs to be proven either experimentally, substantiated by biomonitoring, or suitable animal experiments performed to rule out carcinogenic potential.

Amines may also be released during storage or processing. The USEPA considers dichlorobenzidine-based pigments to be of concern for their potential release of 3,3'-dichlorobenzidine when used at temperatures in excess of 200^{o}C (when release of 3,3'-dichlorobenzidine may occur) (USEPA 2002).

The notified chemical was not mutagenic in bacteria, nor did it induce chromosomal aberrations in mammalian cells *in vitro*. In both studies, precipitation of the test substance was observed at several of the concentrations tested. An *in vivo* genotoxicity study was not provided.

The Ames test provided was performed in accordance with the modified procedure suggested for azo compounds (Prival and Mitchell, 1982). The study utilised a reductive pre-incubation step (during which it is expected that the azo colourant may be reduced to amine species) before the test is carried out to potentially yield a greater detection of mutagenic azo species.

A structurally related chemical has been extensively tested for its genotoxicity. It was negative in several Ames tests (including some studies that involved prior reduction of the azo pigment) (Exempt references 4,9) and at least one chromosome aberration test (Exempt reference 8). However, one sister chromatid exchange test gave equivocal results (Exempt reference 8) and it was genotoxic in hepatocytes in a comet assay (Exempt reference 7). One study tested metabolites of the azo colourant and found them to be strongly mutagenic (Exempt reference 5). The lack of mutagenicity generally observed for the structurally related chemical has sometimes been attributed to its lack of solubility in the test medium (Exempt references 1,3,9).

Several in vivo tests have also been performed on the carcinogenicity of a structurally related chemical. All such

studies gave negative results (Exempt reference 4).

In summary, although the notified chemical may potentially be metabolised to a known carcinogen *in vivo*, studies on the notified chemical itself, as well as a structurally related chemical, indicate that it is not likely to be significantly bioavailable. In addition, in vivo carcinogenicity studies on this structurally related chemical indicated that it was not an in vivo carcinogen. Overall, the data suggests that the notified chemical is not expected to be mutagenic or carcinogenic, however as very low exposures can cause these effects, the potential cannot be ruled out.

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
Respiratory effects
The acute and chronic effects after inhalation exposure to the notified chemical were not investigated, and therefore an inhalation NOAEL can not be determined. Based on respiratory effects seen in the acute inhalation studies of structurally related azo pigments of similar particle size distribution, the notified chemical may pose both an acute and a chronic respiratory hazard. Repeated inhalation of airborne dusts of the notified chemical, or inhalation of high airborne concentrations, may present some risk of lung overloading effects.

Inhalation exposure of workers to the notified chemical (concentrations up to 8%) may occur when handling the notified chemical in solid form during formulation of the inks. Some of this airborne powder is expected to be of respirable size. Since an inhalation NOAEL could not be determined the safety of the EASE estimated atmospheric concentration after repeated exposure could not be established. Based on the potential for respiratory effects after acute or chronic exposure the inhalation risk to workers handling the powder may be significant.

The notifier has not specified the types of masks that will be worn by workers when formulating the notified chemical into inks. If particle filter masks capable of filtering out particles of respirable size are worn by formulation workers and cleaners and are used and fitted correctly, the exposure to the airborne notified chemical, and therefore the risk to formulation and cleaning workers, will be significantly reduced.

Systemic effects
Dermal and inhalation exposure are the main routes by which workers may be exposed to the notified chemical (at concentrations up to 8%) during formulation processes. EASE modelling predicted 'very low' levels of dermal exposure assuming that effective local exhaust ventilation was in place.

Dermal exposure to the notified chemical at concentrations of 0.5% during pipe connection/disconnection, cleaning and quality control operations may occur and some of the notified chemical may be absorbed into the skin. It is noted that the use of PPE will act to further reduce exposure.

As the NOAEL value in a 28 day oral repeat dose toxicity study was determined to be greater than or equal to the highest tested dose (1000 mg/kg bw/day), significant systemic effects are not expected to occur as a result of dermal/inhalation exposure to the notified chemical.

In summary, the risk of systemic effects associated with dermal/inhalation exposure to the notified chemical during formulation and end use is not considered to be unacceptable.

Mutagenicity/Carcinogenicity
Some potential for mutagenicity/carcinogenicity related to the carcinogenic metabolite, 3,3'-dichlorobenzidine, cannot be ruled out.

Whilst breakdown of the pigment through metabolism in the body is possible it is believed that for insoluble azo pigments such as the notified chemical this would be limited by the low solubility and thus low bioavailability of the notified chemical (Exempt reference 3). This is also supported by substantial testing on a structurally related chemical, including a negative carcinogenicity test.

No component amines were identified as impurities in the notified chemical and the level of 3,3'-dichlorobenzidine is expected to be low.

The engineering controls in place and personal protective equipment expected to be used by workers during formulation and printing are expected to reduce exposure to a low level and consequently further minimise the risk of mutagenicity or carcinogenicity.

The use of heat may result in degradation of the notified chemical to 3,3'-dichlorobenzidine (a category 2 carcinogen), particularly at temperatures in excess of 200°C (USEPA 2002). It is expected that the temperatures of heatset ovens used for application of heat-set inks will not exceed 200°C and thus the notified chemical is unlikely to degrade to 3,3'-dichlorobenzidine during such processes. Thus the risk associated with end use of heat-set inks containing the notified chemical is unlikely to be significant.

Worker exposure to dried inks is likely to result in minimal exposure to the notified chemical, so the risk presented by the notified chemical in this scenario is not expected to be significant.

In summary, the risk of mutagenic/carcinogenic effects associated with worker exposure to the notified chemical is not considered to be unacceptable based on the use scenarios and controls in place to reduce exposure.

6.3.2. Public health

Potential for mutagenic or carcinogenic effects related to the carcinogenic metabolite of the notified chemical, 3,3´-dichlorobenzidine, cannot be ruled out.

The public will generally only have dermal exposure to dried inks containing the notified chemical, from which it is not expected to be significantly bioavailable. Therefore the risk to the public is not considered to be unacceptable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

Minor releases from formulation (estimated as < 4 kg/year) are possible from spillages, container residues and equipment cleaning.

RELEASE OF CHEMICAL FROM USE

Minor releases during use (estimated as < 6 kg/year) are possible from container residues and equipment cleaning. The main source of environmental exposure is expected to arise from paper recycling, during which the pigment will become detached from the fibres. The detached pigment would be expected to associate with sludge because of its very low water solubility, with very little potential for aquatic exposure.

RELEASE OF CHEMICAL FROM DISPOSAL

Wastes from formulation and use are expected to be disposed of to landfill or by thermal decomposition.

7.1.2 Environmental fate

The notified chemical is expected to slowly degrade *in situ* following landfill disposal, as it has very low water solubility and is resistant to biodegradation. It is not expected to bioconcentrate in fish, based on its structure and the known behaviour of analogue pigments. While no analogue test reports have been provided, the low bioconcentration factors (< 10) reported by the notifier are considered reliable based on the chemical structures of the notified chemical and the nominated analogue, and the properties of organic pigments. In particular, the notified chemical is expected to have a low potential for bioaccumulation because of its very limited affinity for the lipid phase of living organisms, as has been discussed in the screening assessment of Pigment Red 187 (Environment Canada and Health Canada, 2008). For the details of the environmental fate studies please refer to Appendix C.

7.1.3 Predicted Environmental Concentration (PEC)

It is neither necessary nor meaningful to determine the PEC as no aquatic exposure is expected when the notified chemical is used as proposed.

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	EC50 > 0.024 mg/L	Not toxic to limit of water solubility
Daphnia Toxicity	EC50 > 0.031 mg/L	Not toxic to limit of water solubility
Algal Toxicity	EC50 > 0.0043 mg/L	Not toxic to limit of water solubility
Inhibition of Bacterial Respiration	EC50 > 100 mg/L	Not harmful

Aquatic toxicity testing was conducted at a single nominal concentration of 100 mg/L, with actual exposure concentrations limited by the very low water solubility as tabulated above. No harmful effects were observed from exposure to concentrations up to the limit of water solubility.

7.2.1 Predicted No-Effect Concentration

It is not possible to determine the PNEC as the median effect concentrations cannot be determined. The notified chemical is not harmful to aquatic life at concentrations up to the solubility limit.

7.3. Environmental risk assessment

The notified chemical is not considered to pose a risk to the environment, as no aquatic exposure is expected when it is used as proposed, and testing has shown that it is not harmful to aquatic life at concentrations up to the solubility limit.

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)].

Human health risk assessment

Based on the proposed use scenarios and occupational controls in place to reduce exposure, 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 very low water solubility and the reported use pattern, the notified chemical is not considered to pose a risk to the environment.

Recommendations

REGULATORY CONTROLS

Health Surveillance

- As the notified chemical may be harmful by inhalation, employers should consider carrying out health surveillance of workers.

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical as introduced in the powdered pigment:
  - Local exhaust ventilation wherever weighing and addition to mixers occurs

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced in the powdered pigment:
  - Avoid the formation of airborne dusts
  - Avoid skin contact
  - Regularly clean up any spills of the powdered pigment
  - Minimisation of the use of heat during handling/processing/use of the notified chemical

- Employers should implement the following safe work practices to minimise occupational exposure to the notified chemical in end use inks:
  - Situations under which the notified chemical may be subject to temperatures in excess of 200^{o}C should be avoided, particularly when heat-setting inks containing the notified chemical.

- Measures should be taken to minimise the levels of 3,3'-dichlorobenzidine in the imported products containing the notified chemical.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced in powdered pigment:
  - Respiratory protection sufficient for respirable particulates during processes where exposure to dust is likely
  - Gloves
  - Coveralls
  - Safety glasses

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical in printing inks:
  - Gloves
  - Coveralls
  - Safety glasses

  Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

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

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *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 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;
- further information becomes available as to the mutagenic/carcinogenic potential of the notified chemical or its potential for breakdown;
- the notified chemical is proposed to be used in printing inks for use by consumers;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from a pigment used in printing inks, or is likely to change significantly;
- the amount of chemical being introduced has increased from 1 tonne per annum, or is likely to increase, significantly;
- 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 the notified chemical (and 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 Decomposes at approx. 300°C

Method	OECD TG 102 Melting Point/Melting Range. EC Directive 92/69/EEC A.1 Melting/Freezing Temperature. Differential scanning calorimetry (DSC).
Remarks	Reaction and/or decomposition of the test substance were observed above approximately 300°C. Melting was not observed below the temperature at which reaction and/or decomposition started.
Test Facility	NOTOX (2009a)

Boiling Point Decomposes at approx. 300°C

Method	OECD TG 103 Boiling Point. EC Directive 92/69/EEC A.2 Boiling Temperature. Differential scanning calorimeter (DSC).
Remarks	Reaction and/or decomposition of the test substance were observed above approximately 300°C. Boiling was not observed below the temperature at which reaction and/or decomposition started.
Test Facility	NOTOX (2009a)

Density 1450 kg/m^3 at 20°C (solid)

Method	OECD TG 109 Density of Liquids and Solids. EC Directive 92/69/EEC A.3 Relative Density. Gas comparison stereopycnometer.
Remarks	Average of two experiments.
Test Facility	NOTOX (2009a)

Vapour Pressure < 1.33 X 10^{-11} kPa at 20°C.

Method	OECD TG 104 Vapour Pressure. EC Directive 92/69/EEC A.4 Vapour Pressure. Isothermal thermogravimetric effusion method.
Remarks	The vapour pressure of the test substance was found to be below the vapour pressure of benzo(ghi)perylene.
Test Facility	NOTOX (2009a)

Water Solubility < 3.6 x 10^{-4} g/L at 20°C

Method	OECD TG 105 Water Solubility. EC Directive 92/69/EEC A.6 Water Solubility.
Remarks	Although the column elution method is recommended for determination of water solubility at such low concentrations, this was precluded by the low solubility of the notified chemical in volatile solvents. The test relied on a non-specific analytical method (TOC) because the low solubility in water and organic solvents precluded a specific method such as HPLC. The measured solubility may therefore be an overestimate.
Test Facility	NOTOX (2009a)

Hydrolysis as a Function of pH Not measured.

Remarks	Hydrolytic stability could not be measured because of the very low aqueous solubility and the lack of a sufficiently sensitive and specific analytical method. The absence of transformation in the biodegradation test indicates that the notified chemical can be expected to be hydrolytically stable, consistent with its structure.

Partition Coefficient (n-octanol/water) log P_{ow} > 6.5 at 20°C

Method OECD TG 117 Partition Coefficient (n-octanol/water), HPLC method.
EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks HPLC Method, using acidified tetrahydrofuran as mobile phase. The notified chemical eluted from the column after the reference substance DDT.
Test Facility NOTOX (2009a)

Adsorption/Desorption – screening test $\log K_{oc} > 5.63$ at 35°C

Method OECD 121 Estimation of the Adsorption Coefficient (Koc) on Soil and on Sewage Sludge using High Performance Liquid Chromatography
EC Directive 2001/59/EC C.19 Estimation of the Adsorption Coefficient (Koc) on Soil and on Sewage Sludge using High Performance Liquid Chromatography
Remarks No test substance peak was observed during isocratic elution, but one test substance related peak eluted at 14.3 minutes (twice the time for isocratic elution of DDT) under gradient elution.
Test Facility NOTOX (2009a)

Dissociation Constant Not measured

Remarks Measurement was precluded by the very low aqueous solubility and the lack of a sufficiently sensitive and specific analytical method. The notified chemical is not expected to dissociate under environmental conditions, based on the structure.

Particle Size

Method OECD TG 110 Particle Size Distribution/Fibre Length and Diameter Distributions.

Range (μm)	*Mass (%)*
< 2.785	10
< 10	24.86
< 25.424	50
< 95.275	90

Remarks Samples of the test substance were dispersed in kerosene and five runs performed to ensure repeatability of results.
Mass Median Aerodynamic Diameter (MMAD) = 30.615 μm
Test Facility Chilworth (2008)

Flammability Not highly flammable

Method EC Directive 92/69/EEC A.10 Flammability (Solids).
Remarks The flame of a gas burner ignited the test substance pile. In contact with the flame, the test substance glowed, burned with a yellow flame, produced grey smoke and turned into a charred residue. After removal of the ignition source, the flame extinguished after 10 seconds and no more glowing or propagation of combustion (e.g. by smouldering) was observed. Since the test substance did not burn with flame or smoulder over 200 mm within 4 minutes was not considered to be highly flammable.
Test Facility NOTOX (2009a)

Autoignition Temperature Not self-ignitable

Method 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Remarks An exothermic reaction was observed to occur during the experiment, though the temperature of the sample during this reaction did not reach 400°C (as required by the test guideline). After the experiment, a partially charred, white residue was observed in the cube. No test substance had been collected in the container placed below the cube. Hence it was concluded that most of the test substance sample had evaporated during the test.

Test Facility NOTOX (2009a)

Explosive Properties Not explosive

Method EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks The test substance is not explosive as it is not thermally sensitive, shock sensitive or friction sensitive.
Test Facility NOTOX (2009a)

Oxidizing Properties No oxidizing properties

Method Expert Statement
Remarks The molecular structure of the test substance suggests that it is unlikely to have oxidising properties.
Test Facility NOTOX (2009a)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
EC Directive 92/69/EEC B.1tris Acute Oral Toxicity – Acute Toxic Class Method.

Species/Strain: Rat/Wistar Crl:WI (Han) (outbred, SPF quality)
Vehicle: Propylene glycol
Remarks - Method: No significant protocol deviations.

RESULTS

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

LD50: >2000 mg/kg bw
Signs of Toxicity: Hunched posture, uncoordinated movements and/or piloerection were noted in all animals on Day 1. Yellow faeces were noted in all animals on Days 2 or 3.
Effects in Organs: None

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

TEST FACILITY: NOTOX (2008a)

B.2. Acute toxicity – dermal

TEST SUBSTANCE: Notified chemical

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

Species/Strain: Rat/Wistar Crl:WI (Han) (outbred, SPF quality)
Vehicle: Propylene glycol
Type of dressing: Occlusive
Remarks - Method: No significant protocol deviations.

RESULTS

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

LD50: >2000 mg/kg bw
Signs of Toxicity - Local: Scales and/or scabs were observed in the majority of the animals during the observation period.
Signs of Toxicity - Systemic: Chromodacryorrhoea was observed in two animals on Day 1. Given the short duration of this symptom and the absence of any associated signs, it was considered to be of no toxicological significance.
Effects in Organs: No toxicologically significant effects.
Remarks - Results: Yellow staining of the treated skin was noted in all animals during most

of the observation period. One female animal also showed yellow staining of other areas of the body on days 2 and 3. This was likely to be due to the staining properties of the test substance.

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

TEST FACILITY NOTOX (2008b)

B.3. 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	Water/ethanol (50% v/v)
Observation Period	72 hr
Type of Dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations.

RESULTS

Remarks - Results No skin irritation effects were observed in the animals during the observation period.
Yellow staining of the treated skin was observed in all animals throughout the observation period. This did not interfere with the scoring of the skin reactions.

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

TEST FACILITY NOTOX (2008c)

B.4. 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

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	0.3	1.0	0.3	2	<72hr	0
Conjunctiva: chemosis	0	0	0	1	<24hr	0
Conjunctiva: discharge	0.3	0	0	1	<48hr	0
Corneal opacity	0	0	0	0	-	0
Iridial inflammation	0	0	0	0	-	0

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

Remarks - Results	Remnants of the test substance were present in the eye and/or on the outside of the eyelids during the observation time. Yellow staining of fur on the head and paws, caused by the test substance was also noted.
CONCLUSION	The notified chemical is slightly irritating to the eye.
TEST FACILITY	NOTOX (2008d)

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

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 429 Skin Sensitisation: Local Lymph Node Assay.
Species/Strain	Mouse/CBA strain, inbred, SPF quality
Vehicle	Methyl ethyl ketone
Remarks - Method	No significant protocol deviations. In the preliminary irritation study the 50% material did not remain adhered to the ear, therefore 25% was chosen as the highest concentration for the main study.

RESULTS

Concentration (% w/w)	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance		
0 (vehicle control)	369 ± 85	1.0
5	419 ± 72	1.1
10	523 ± 72	1.4
25	496 ± 101	1.3
Positive Control (α-Hexylcinnamaldehyde)		
5	445 ± 127	1.0
10	930 ± 141	2.0
25	2649 ± 505	5.7

Remarks - Results	Yellow staining by the test substance or its remnants prevented scoring for erythema. No oedema was observed in any of the animals examined.
CONCLUSION	There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical.
TEST FACILITY	NOTOX (2008e)

B.6. Repeat dose toxicity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents. EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral).
Species/Strain	Rat/Crl:CD(SD)
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 7 days per week Post-exposure observation period: 14 days
Vehicle	Test substance was suspended in 5 %w/v gum arabic solution
Remarks - Method	No significant protocol deviations. Dose levels were chosen on the basis of a preliminary 14 day repeated oral dose toxicity study.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
control	5M; 5F	0	0/10
low dose	5M; 5F	50	0/10
mid dose	5M; 5F	250	0/10
high dose	5M; 5F	1000	0/10
control recovery	5M; 5F	0	0/10
high dose recovery	5M; 5F	1000	0/10

Mortality and Time to Death
No mortality occurred during the study.

Clinical Observations
Yellow stool was continuously observed in both sexes of the mid and high dose groups. In the high dose recovery group yellow stool was only observed up to three days after termination of the dosing period in both sexes. This was considered to be a treatment-related effect, though not of toxicological significance, as it reflected the colour of the test substance.

Remarks – Results
No other toxicologically significant changes were observed in animals during the study.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as 1000 mg/kg bw/day in this study, based on the absence of toxicologically significant effects.

TEST FACILITY CERI (2008a)

B.7. 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.
Pre incubation procedure

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA
Metabolic Activation System	S9-mix (uninduced male Golden Syrian Hamster liver S9-mix in modified co-factors)
Concentration Range in Main Test	a) With metabolic activation: 3 - 333 µg/plate b) Without metabolic activation: 3 - 333 µg/plate
Vehicle	Dimethyl sulfoxide
Remarks - Method	The method incorporated the Prival and Mitchell modification for azo compounds (Prival MJ and Mitchell VD 1982). The concentrations chosen for the main study were based on the observation of precipitation during the range finding study. The highest concentration used in the main study was that at which limited solubility was shown.

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

*Precipitation observed at the end of the incubation period. Note that precipitation was observed at the start of the incubation period at concentrations of >10 µg/plate.

Remarks - Results	The test substance caused no visible reduction in the growth of the bacterial background lawn or decrease in the number of revertants at any dose level in all tester strains in the presence and absence of S9-mix. No significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains, with any dose of the test material. The Prival-Mitchell modification positive control, Congo Red, used in the test induced marked increases in the frequency of the TA98 revertant colony with metabolic activation only. Thus, the sensitivity of the assay and the efficacy of the uninduced hamster liver S9-mix was validated.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	NOTOX (2008f)

B.8. Genotoxicity – in vitro

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 473 In vitro Mammalian Chromosome Aberration Test.
Species/Strain	Chinese hamster
Cell Type/Cell Line	Chinese hamster lung fibroblasts (CHL/IU cells)
Metabolic Activation System	Rat liver S9-mix induced by a combination of phenobarbital and 5,6-benzoflavone.
Vehicle	0.5 w/v% carboxymethyl cellulose sodium salt (CMC) solution
Remarks - Method	During the 24 hour continuous treatment test the medium was exchanged 2 hours before the end of the culture using the same procedure as that of the short term treatment (due to difficulties in analysis of the chromosomes caused by precipitation of the test substance). In each treatment, the highest dose for observation of chromosomal aberration was selected at the highest dose that the analysis of the chromosomal aberration was possible (at higher concentrations cells were condensed, spread of the chromosomes was poor, and the test substance was observed to precipitate on the chromosomes).

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	78.1, 156*, 313*, 625*, 1250, 2500, 5000	6 hr	24 hr
Test 2			
Present			
Test 1	78.1, 156*, 313*, 625*, 1250*, 2500, 5000	6 hr	24 hr
Test 2	19.5*, 39.1*, 78.1*, 156, 313, 625, 1250	24 hr	24 hr

*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	1300	1800	All doses	Negative
Test 2				
Present				
Test 1	2100	>5000	All doses	Negative
Test 2	320	250	All doses	Negative

*Precipitation observed at the start and end of treatment. At the end of the culture, precipitation was observed at ≥156 µg/mL in both short term treatment tests.

Remarks - Results The frequency of cells with structural or numerical aberrations was not significantly increased following treatment with the test substance.

CONCLUSION The notified chemical was not clastogenic to Chinese hamster lung fibroblasts treated in vitro under the conditions of the test.

TEST FACILITY CERI (2007)

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
- Auxiliary Solvent: None
- Analytical Monitoring: Oxygen consumption and HPLC

RESULTS

Test substance		*Aniline*	
Day	*% Degradation*	*Day*	*% Degradation*
7	0	7	52
28	0	28	76

CONCLUSION The notified chemical is not readily biodegradable.

TEST FACILITY CERI (2008b)

C.1.2. Bioaccumulation

Remarks A bioaccumulation test was not conducted because of the lack of a sufficiently sensitive analytical method, but the notifier argues that the notified chemical is not expected to have potential for bioaccumulation because bioconcentration factors for analogue pigments are < 10. While supporting test reports were not presented, the notified chemical is not expected to bioconcentrate in fish because of its very limited affinity for the lipid phase of living organisms, as has been discussed in the screening assessment of Pigment Red 187 (Environment Canada and Health Canada, 2008).

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE Notified chemical

METHOD OECD TG 203 Fish, Acute Toxicity Test – static..
- Species: *Oryzias latipes* (Medaka)
- Exposure Period: 96 hours
- Auxiliary Solvent: None
- Water Hardness: 28 mg $CaCO_3$/L
- Analytical Monitoring: HPLC of tetrahydrofuran extracts of filtered samples
- Remarks – Method: The solubility of the test substance in the test medium was 0.014 mg/L

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
0	0	8	0	0	0	0	0
100	0.024	8	0	0	0	0	0

LC50	> 0.024 mg/L at 96 hours.
NOEC (or LOEC)	0.024 mg/L at 96 hours.
Remarks – Results	No sublethal effects were observed.

CONCLUSION The notified chemical is not toxic to fish at concentrations up to the solubility limit.

TEST FACILITY CERI (2008c)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified chemical

METHOD OECD TG 202 Daphnia sp. Acute Immobilisation Test - static.

Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	28 mg $CaCO_3$/L
Analytical Monitoring	HPLC of tetrahydrofuran extracts of filtered samples
Remarks – Method	The solubility of the test substance in the test medium was 0.017 mg/L

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24*	*48 h*
0	0	20	0	0
100	0.031	20	0	0

LC50	> 0.031 mg/L at 48 hours
NOEC (or LOEC)	0.031 mg/L at 48 hours
Remarks - Results	No abnormal responses were observed.

CONCLUSION The notified chemical is not toxic to daphnids at concentrations up to the solubility limit.

TEST FACILITY CERI (2008d)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified chemical

METHOD OECD TG 201 Alga, Growth Inhibition Test..

Species	*Pseudokirchneriella subcapitata*
Exposure Period	72 hours
Concentration Range	Nominal: 0 and 100 mg/L Actual: 0 and 0.0043 mg/L
Auxiliary Solvent	None
Water Hardness	Soft water (OECD culture medium)
Analytical Monitoring	HPLC of tetrahydrofuran extracts of filtered samples.
Remarks - Method	The solubility of the test substance in the test medium was 0.029 mg/L

RESULTS

Biomass		*Growth*	
E_bC50 mg/L at 72 h	*NOEC mg/L*	*ErC50 mg/L at 72 h*	*NOEC mg/L*
> 0.0043	0.0043	>0.0043	0.0043

Remarks - Results Cell growth in controls met the validity criterion.

CONCLUSION The notified chemical is not toxic to freshwater green algae at concentrations up to the solubility limit.

TEST FACILITY CERI (2008e)

C.2.4. Inhibition of microbial activity

TEST SUBSTANCE Notified chemical

METHOD OECD TG 209 Activated Sludge, Respiration Inhibition Test.
EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test

Inoculum Activated sludge
Exposure Period 3 hours
Concentration Range Nominal: 100 mg/L
Remarks – Method Sonication was used to facilitatate dispersion of the poorly soluble test substance in the test medium. Contact was optimised by stirring and continuous aeration.

RESULTS

IC50 > 100 mg/L
NOEC 100 mg/L
Remarks – Results

CONCLUSION The test substance does not inhibit the respiration of activated sludge.

TEST FACILITY NOTOX (2008g)

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