File No: LTD/1421

October 2009

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

No. 408 Yellow

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)
Toyo Ink Australia Pty Ltd (ABN 29 006 294 837)
29 Garden Street
KILSYTH VIC 3137

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, Purity, Impurities, Use details and Identity of manufacturer.

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)
No. 408 Yellow
Lionogen Yellow 0380 (imported product containing < 12% notified chemical)

MOLECULAR WEIGHT
> 500 Da

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

3. COMPOSITION

DEGREE OF PURITY > 98%

ADDITIVES/ADJUVANTS None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Yellow powder

Property	Value	Data Source/Justification
Melting Point	198.2°C	Measured
Boiling Point	Decomposes on melting.	Measured
Density	1390 kg/m^3 at 20°C	Measured
Vapour Pressure	Not determined	Expected to be low based on structure.
Water Solubility	2 x 10^{-5} g/L at 20°C	Measured
Hydrolysis as a Function of pH	Stable (half-life > 1 year) at pH 4 and pH 7.	Measured
Partition Coefficient (n-octanol/water)	log P_{ow} = 2.9 (neutral pH), 4.3 (pH 10.35) at 22°C	Measured
Adsorption/Desorption	log K_{oc} > 5.63 at 35°C	Measured
Dissociation Constant	pKa = 9.35	Calculated
Particle Size	Inhalable fraction (< 100 μm): ~99% Respirable fraction (< 10 μm): 60.4% MMAD = 8.9 μm	Measured
Flash Point	Not determined	Not conducted as does not autoignite.
Flammability	Not highly flammable	Measured
Autoignition Temperature	> 400°C	Measured
Explosive Properties	Not explosive	Measured

* MMAD = Mass Median Aerodynamic Diameter

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

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

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported as a component of a pigment mix at < 12%.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	0.125	0.125	0.125	0.125	0.125

PORT OF ENTRY
Melbourne

TRANSPORTATION AND PACKAGING
The notified chemical will be imported by sea or air as a component of a pigment mix at < 12% in 10 kg polyethylene lined cardboard boxes or bags. After reformulation, the ink products containing the notified chemical at < 3% will be packaged in 4 L and 20 L plastic containers and transported by road to customers.

USE
Component of printing inks at < 3%.

OPERATION DESCRIPTION
At the plant site, the imported pigment mix containing the notified at < 12% will be moved by forklift from the warehouse to the plant blending production area where it will be manually weighed and added to a mixer. After blending with other ingredients, the reformulated ink product containing the notified chemical at < 3% will be packaged by an automated process into 4 L and 20 L plastic containers for distribution to customers.

At the printer sites, the ink containing the notified chemical (at up to 3%) will be drawn automatically into the printing machine from the containers. The printing operation will be completely automated and largely enclosed. Colour matching tests that will involve manual handling of the ink products will also be conducted.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

Category of Worker	*Number*	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and storage	2	2-3	1-2
Manufacture			
Manual weighing	2	0.5-6	25
Blending	2	0.5-6	25
Packing	2	1	25
Quality control	2	1	25
Maintenance	2	3	25
End-use (printing process)	2	2.5	5-150

EXPOSURE DETAILS
Given the expected low vapour pressure of the notified chemical, inhalation exposure is only expected where aerosols or dusts may be formed.

Transport and storage
Transport and storage workers will only be exposed to the notified chemical (at up to 12%) in the unlikely event of an accident or spill. Should this occur, workers are expected to wear impervious gloves, coveralls, safety goggles and dust mask, when sweeping up spills for incineration to minimise exposure.

Manufacture
Dermal, ocular and inhalation exposure to the notified chemical (at up to 12%) may occur during weighing of the powdered pigment mix and addition to the mixer, blending and packing. Workers are expected to wear impervious gloves, coveralls and safety goggles to minimise dermal and ocular exposure. Inhalation exposure is expected to be reduced by use of enclosed systems (blending and packing) and local exhaust ventilation. Dust masks are also expected to be worn during manual handling procedures. If these masks are capable of filtering out respirable particles and are fitted and used correctly, the exposure to the airborne particles will be minimised.

QC testing
Dermal and ocular exposure to the notified chemical (at < 3%) may occur when taking samples for quality control testing. QC workers are expected to wear impervious gloves, coveralls and safety goggles to minimise exposure.

Maintenance
Dermal, ocular and inhalation exposure to the notified chemical (at up to 12%) may occur during cleaning of equipment. Maintenance workers are expected to wear impervious gloves, coveralls, safety goggles and respirator/dust masks to minimise exposure.

End-use (printing process)
The printing process is automated and potential worker exposure is expected to be minimal. However, dermal and ocular exposure to the notified chemical (at < 3%) may occur for short durations during the colour

matching process where ink handling is required. Workers are expected to wear impervious gloves, coveralls and safety goggles to minimise exposure.

6.1.2. Public exposure

The public may make dermal contact when handling products printed with the printing inks containing the notified chemical at < 3%. Once dried, the notified chemical will be trapped within an inert matrix and is not expected to be bioavailable.

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	LD50 > 5000 mg/kg bw; low toxicity
Rat, acute dermal toxicity	LD50 > 5000 mg/kg bw; low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	moderately irritating
Mouse, skin sensitisation – Local lymph node assay	no evidence of sensitisation
Mutagenicity – bacterial reverse mutation	mutagenic
Genotoxicity – in vitro chromosome aberration	genotoxic
Genotoxicity – in vivo micronuleus	equivocal

Toxicokinetics.

Given the molecular weight of the notified chemical and its poor water solubility, absorption across biological membranes is not expected. This is supported by the acute oral and dermal toxicity studies that showed no evidence to suggest that the notified chemical was absorbed. In oral toxicity studies the presence of an orange discolouration of the faeces suggests that a main route of excretion is via the faeces.

Azo compounds, such as the notified chemical, 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.

Airborne dusts of the notified chemical will be easily inhaled given that 99% of particles are within the inhalable size range and a significant proportion (60.4%) are respirable. However significant absorption from the lung is not expected given the molecular weight and low water solubility of the notified chemical. Particles of inhalable size will deposit in the nose, throat and upper respiratory tract, and a large proportion is likely to be cleared by muco-ciliary action and orally ingested. Respirable particles that deposit in the lower respiratory tract cannot be cleared by mucous and ciliary mechanisms and may be retained deep in the lungs, with long-term inhalation possibly leading to particle accumulation.

Acute toxicity.

The notified chemical was found to be of low acute oral and dermal toxicity based on studies conducted on rats (LD50 > 5000 mg/kg bw). No data was available on inhalation toxicity for the notified chemical. However, as described previously, the notified chemical contains a high proportion of inhalable particles, therefore it may present as an inhalation hazard.

Irritation and Sensitisation.

In a study conducted on rabbits, the notified chemical was found to be moderately irritating to the eye. Severe conjunctival irritation was observed up to one hour post treatment which moderated after 72 hours and iridial inflammation was noted in all animals that lasted up to 72 hours. Corneal opacity was noted in only 2 animals. All irritations effects were resolved completely by Day 8. Based on the iridial inflammation observed, the notified chemical is classifiable as an irritant under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004). However, the notified chemical was found to be non-irritating to the skin.

The notified chemical did not present as a skin sensitiser when tested up to a concentration of 2.5% (dose based

on the maximum solubility that could be obtained in the recommended vehicles under the OECD guideline) in a mouse local lymph node assay. Therefore, the notified chemical is unlikely to cause skin sensitisation in exposed humans.

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.

These aromatic amines that arise from the azo reduction of azo dyes are thought to be activated through their *N*-oxidation by cytochrome P450 isozymes (SCCNFP, 2002). These *N*-hydroxylarylamines may be further glucuronated (activated) or acetylated (inactivated), which may influence their mutagenicity (Bartsch, 1981). Under acidic pH, they form reactive nitrenium ions that can alkylate bases in DNA, particularly the nucleophilic centres in guanine. This mechanism is thought to contribute to the carcinogenicity of many azo compounds.

The notified chemical can not be reductively cleaved to release any of the restricted aromatic amines specified in either the Appendix to EC Directive 76/769/EEC or the annexes of EU SCCNFP/0495/01 (SCCNFP, 2002). However, the notified chemical can be broken by azo reduction into an arylamine species that may have mutagenic potential. This arylamine is structurally similar to a chemical on the EU restricted list and has been shown to be mutagenic in a number of Ames assays and produced chromosomal aberrations in Chinese hamster lung cells.

In addition, azo colourants are renowned for their content of impurities, particularly for the presence of component arylamines (SCCNFP, 2002; Øllgaard *et al* 1998). Such impurities are thought to contribute to their carcinogenicity, as these species may be more readily absorbed, and activated as carcinogens. The notified chemical contains two unknown impurities each at < 1% that may be aromatic amines.

The notifier supplied test results showing that the notified chemical was found to be mutagenic in bacteria (under the conditions of the Ames test used) with and without metabolic activation, and induced numerical chromosomal aberrations in mammalian cells *in vitro*. In an *in vivo* micronucleus assay conducted on the notified chemical there was no evidence of genotoxicity. However, there was no indication that the notified chemical reached the target organ bone marrow. This is supported by the lack of systemic effects in the acute oral toxicity study as well as the physical-chemical properties of the notified chemical, which predict limited absorption.

Therefore, given the positive in vitro results, the equivocal in vivo results, and the concern for this class of chemicals, the potential for the notified chemical to induce mutagenicity or carcinogenicity cannot be ruled out. However, given the expected low bioavailability this potential in vivo may be very low.

Health hazard classification
Based on the results of the eye irritation study, the notified chemical is classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

R36: Irritating to eyes

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

The notified chemical is classified as an eye irritant, therefore there is a risk to workers from ocular exposure to fine dust particles that could land on the mucous membranes of the eyes. Given workers will only handle the notified chemical at up to 12%, which is below the cut-off level (20%), and are expected to wear safety goggles to limit exposure, the risk of eye irritancy is expected to be low.

The notified chemical contains a high proportion of inhalable and respirable particles that have the potential to cause adverse respiratory effects after inhalation exposure. The risk of respiratory effects is most likely to occur during manual weighing and transfer of the powdered pigment mix (containing the notified chemical at < 12%) to the mixing vessels. 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.

The risk from dermal exposure is expected to be minimal, given its low acute dermal toxicity, expected low dermal absorption and lack of skin sensitising ability.

Some potential for mutagenicity/carcinogenicity cannot be ruled out. Given the high proportion of inhalable particles a significant proportion of the notified chemical to which workers are exposed is expected to enter the gastrointestinal tract after clearance by the mucociliary mechanism. 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. Therefore, systemic exposure is not expected but cannot be ruled out. In addition, although the dermal absorption is expected to be low, the potential for absorption across the skin cannot be ruled out completely. Therefore in order for the risk of mutagenicity/carcinogenicity to be reduced to a low level both respiratory and skin protection measures must be in place.

Overall, provided that all workers wear the proposed personal protective equipment (safety glasses, protective gloves, coveralls and appropriate dust masks when handling the powdered pigment mix) to limit exposure and engineering controls are in place to limit dust generation (local exhaust ventilation), the risk to workers presented by the notified chemical is not considered to be unacceptable.

6.3.2. Public health

Exposure to the notified chemical by the public in a form that it is bioavailable is not expected. Therefore, the notified chemical is not considered to pose an unacceptable risk to public health.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical will not be manufactured in Australia. Sources of release to the environment are during transport (accidental spillage from breach of the packaging) and during reformulation (manufacturing). From a 50 kg daily starting batch (containing 5 kg of notified chemical), an estimated 16 g of notified chemical will end up as waste from the blending process. Of this, an estimated 15 g will end up in landfill (mostly from waste cleaning cloths) with the balance (< 1 g) destroyed by thermal decomposition. Residual chemicals from the reformulation process will be treated (solvent cleaning) at a solvent recovery facility.

RELEASE OF CHEMICAL FROM USE

The formulated ink product will not be released directly to the environment. Inks containing the notified chemical will be bound in an inert matrix of printed materials. Ink containing the notified chemical may be released to sewer from the de-inking process during paper recycling.

RELEASE OF CHEMICAL FROM DISPOSAL

Residues in product containers and wastes from reformulation will be thermally decomposed or disposed

of to landfill in accordance with local and national regulations.

Printed paper products containing the notified chemical will be recycled (50%), landfilled or thermally decomposed at the end of their useful life.

7.1.2 Environmental fate

The notified chemical is expected to be stable under landfill and sewer conditions, as it resists hydrolysis and did not biodegrade under aerobic conditions. It is not expected to be released from landfill in significant quantities because of its very low water solubility. Similarly, the notified chemical is not expected to be discharged in significant quantities from sewage treatment works as it will tend to associate with sludge. While the notified chemical appears from its partition coefficient to have the potential to bioconcentrate in fish, such outcomes are not expected because of the limited aquatic exposure. 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 a PEC as aquatic exposure is expected to remain very low when the notified chemical is used as proposed, and when printed paper is recycled.

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 > 0.20 mg/L	Not toxic to limit of water solubility.
Daphnia Toxicity	EC50 > 0.17 mg/L	Not toxic to limit of water solubility.
Algal Toxicity	E_rC50 > 0.0088 mg/L	Not toxic to limit of water solubility.

Aquatic toxicity testing was complicated by the very low aqueous solubility of the notified chemical. Test organisms were exposed to serial dilutions of filtered solutions prepared at a nominal 100 mg/L. Measured concentrations were much less than nominal, and declined through the exposure period. The concentrations tabulated above are time weighted averages. No effects were seen in fish at these concentrations, while 20% of tested daphnids were immobilised. Algal growth was inhibited at very low concentrations, but the test did not distinguish between toxic effects and light reduction by the coloured test substance.

7.2.1 Predicted No-Effect Concentration

The PNEC cannot be determined, as measurement of toxic effects in fish, daphnids and algae was confounded by the very low water solubility. Median effect concentrations in aquatic organisms exceed the water solubility of the notified chemical.

7.3. Environmental risk assessment

The risk quotients (Q = PEC/PNEC) cannot be determined as measurement of toxic effects in fish, daphnids and algae was confounded by the very low water solubility. The notified chemical is not toxic 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 is classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)]. The classification and labelling details are:

- R36 Irritating to eyes

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*
Health		
Eye irritation	2B	Causes eye irritation
Environment		
Aquatic toxicity	Chronic 4	May cause long lasting effects to aquatic life.

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
Hazard Classification and Labelling

- The Office of the ASCC, Department of Employment and Workplace Relations (DEWR), should consider the following health hazard classification for the notified chemical:
  - R36 Irritating to eyes

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - R36 Irritating to eyes
    Xi; R36
    Conc ≥ 20%: Xi; R36

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical during manual weighing and powder transfer:
  - Local exhaust ventilation and/or appropriate dust extraction systems

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical:

- Avoid eye contact
- Avoid dust formation
- Avoid inhalation of dust

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical:
  - Eye protection
  - Gloves
  - Respiratory protection sufficient for respirable particulates during processes where exposure to dust is likely.

  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 component of printing inks, or is likely to change significantly;
  - the amount of chemical being introduced has increased from 125 kg 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 imported product 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 198.2°C

Method OECD TG 102 Melting Point/Melting Range.
EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks Measured by Differential Scanning Calorimetry (DSC)
Test Facility Covance Laboratories (2009a)

Boiling Point Decomposes upon melting at 198.2°C

Method OECD TG 103 Boiling Point.
EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks Measured by Differential Scanning Calorimetry (DSC). After melting a broad exotherm between 200 and 280 °C was observed due to decomposition.
Test Facility Covance Laboratories (2009a)

Density 1390 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 Pycnometer method
Test Facility Covance Laboratories (2009a)

Water Solubility 0.00002 g/L at 20°C

Method OECD TG 105 Water Solubility.
EC Directive 92/69/EEC A.6 Water Solubility.
Remarks Column Elution Method. Two flow rates (12 and 24 mL/hour) were used. Respective mean concentrations from ten measurements, after correction for procedural recovery, were 0.0192 and 0.0204 mg/L, with respective coefficients of variation of 12% and 15%.
Test Facility Notox (2009a)

Hydrolysis as a Function of pH

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

pH	*T (°C)*	*t½*
4	25	> 1 year
7	25	> 1 year
9	25	Not determined

Remarks The test was conducted at 50°C at a nominal concentration of 9 µg/L. Mean recoveries from the buffer solutions were 45-49%. Concentrations remained constant between 24 and 144 hours at pH 4 and pH 7, at respective concentrations of 3.3-3.8 µg/L and 2.4-3.2 µg/L, but declined below the limit of quantitation (1 µg/L) after 2.4 hours at pH 9, presumably reflecting the lower solubility of the free base.
Test Facility Notox (2009b)

Partition Coefficient (n-octanol/water) log P_{ow} = 2.9 (neutral pH), 4.3 (pH 10.35) at 22°C

Method OECD TG 117 Partition Coefficient (n-octanol/water).
EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks HPLC Method. It was decided to measure the partition coefficient at higher pH to meet the test requirement that < 10% of the test substance be ionised.
Test Facility Notox (2009c)

Adsorption/Desorption log K_{oc} > 5.63 at 35°C (neutral pH)

Method OECD TG 121 Estimation of the Adsorption Coefficient (K_{oc}) on Soil and on Sewage Sludge using HPLC.
Remarks The test substance eluted from the column much more slowly than the reference substance DDT.
Test Facility Notox (2009d)

Dissociation Constant pKa 9.35

Remarks The pKa of the amine was calculated using the Perrin calculation method.
Test Facility Notox (2009c)

Particle Size MMAD = 8.9 µm

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

Range (µm)	*Mass (%)*
< 10 µm	60.4%
< 100 µm	~ 99%

Remarks Particle size determined using a Malvern Instruments Mastersizer 2000, fitted with a Hydro S dispersion cell, which utilises laser diffraction in conjunction with Mie theory. The particle size range was measured as approximately 0.4-140 µm.
Test Facility Covance Laboratories (2009)

Flammability Not highly flammable

Method EC Directive 92/69/EEC A.10 Flammability (Solids).
Remarks Moisture content was determined to be 27% much higher than the anticipated < 1%. However the high moisture content was not considered to have affected the integrity of the flammability test.
Test Facility Covance Laboratories (2009a)

Autoignition Temperature > 400°C

Method EC Directive 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Remarks No relative self-ignition was observed up to 400 °C.
Test Facility Covance Laboratories (2009a)

Explosive Properties Not explosive

Method EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks The notified chemical was considered potentially explosive based on structural considerations (i.e. presence of explosophore and oxygen balance) and enthalpy of decomposition exotherms by DSC. Hence the notified chemical was subjected to the definitive heat sensitivity (flame), mechanical sensitivity (shock) and mechanical sensitivity tests. From these test results the notified chemical was determined not to have explosive properties.
Test Facility Covance Laboratories (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.
Species/Strain Rat/HsdRccHan:WIST
Vehicle 1% aqueous methyl cellulose
Remarks - Method No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5F	2000	0/6
2	5F	5000	0/3

LD50 > 5000 mg/kg bw
Signs of Toxicity There were no clinical signs of toxicity at a dose level of 2000 mg/kg bw except for piloerection, which was noted in three animals on the day of dosing only.

Piloerection was noted in all animals dosed at 5000 mg/kg bw, developing from one hour after dosing and lasting up to Day 8. Hunched posture was noted in one of these animals from Days 2 to 4, with orange coloured faeces noted in two animals from Days 4 to 7.

All the animals gained weight except for one animal dosed at 2000 mg/kg bw that showed a slight body weight loss during the second week of the test.
Effects in Organs Dark or pale foci on the lungs in two animals of the 2000 mg/kg bw dose group. One animal also had a red and distended bladder with a prominent vascular structure.

No abnormalities were noted at necropsy in the 5000 mg/kg bw dose group.
Remarks - Results No deaths occurred during the 14-day observation period.

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

TEST FACILITY Covance Laboratories (2009b)

B.2. Acute toxicity – dermal

TEST SUBSTANCE Notified chemical

METHOD OECD TG 402 Acute Dermal Toxicity – Limit Test.
Species/Strain Rat/HsdBrlHan:WIST
Vehicle Moistened with water.
Type of dressing Semi-occlusive.
Remarks - Method No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5M/5F	5000	0/10

LD50	> 5000 mg/kg bw
Signs of Toxicity - Local	Very slight to well-defined erythema was noted in four males and one female on Day 2, with very slight erythema noted in one male and one female on Day 3.
Signs of Toxicity - Systemic	All animals received body weight gains over the study period. There were no clinical signs of toxicity.
Effects in Organs	Pale, red or dark foci on the lungs and pale kidneys were noted in 3/10 animals upon necropsy.
Remarks - Results	No deaths occurred during the 14-day observation period.
CONCLUSION	The notified chemical is of low toxicity via the dermal route.
TEST FACILITY	Covance Laboratories (2009c)

B.3. Irritation – skin

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	Moistened with water.
Observation Period	72 hours
Type of Dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations.

RESULTS

Remarks - Results	No dermal response was reported in any animal throughout the observation period. It was noted that yellow staining of the test site throughout the study did not preclude evaluation of the dermal reactions.
CONCLUSION	The notified chemical is non-irritating to the skin.
TEST FACILITY	Covance Laboratories (2009d)

B.4. Irritation – eye

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Observation Period	8 Days
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	1.7	1.3	2.7	3.0	< 8 days	0
Conjunctiva: chemosis	1.3	1.3	2.0	4.0 (1 hr)	< 8 days	0
Conjunctiva: discharge	1.0	0	1.3	3.0	< 72 hrs	0
Corneal opacity	1.0	0	1.3	2.0	< 8 days	0
Iridial inflammation	0.7	1.0	1.0	1.0	< 8 days	0

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

Remarks - Results: All animals exhibited severe conjunctival irritation up to 1 hr post treatment which moderated to minimal to moderate irritation after 72 hours. Iridial inflammation was noted in all treated eyes from 30 minutes after instillation and lasted up to 72 hours after instillation. Corneal opacity was noted in only 2 animals from 24 to 72 hours after instillation. All irritant effects were resolved completely by Day 8.

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

TEST FACILITY: Covance Laboratories (2009e)

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
Vehicle: Dimethylformamide
Remarks - Method: No significant protocol deviations. The doses were selected on the basis of the maximum solubility that could be obtained in the recommended vehicles under the OECD guideline.

RESULTS

Concentration (% w/w)	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance		
0 (vehicle control)	217 (± 60.1)	-
0.5%	338 (± 149.8)	1.55
1.0%	238 (± 133.1)	1.10
2.5%	168 (± 42.1)	0.77
*Positive Control**		
25%	2084	9.60

* α-Hexylcinnamaldehyde in acetone/olive oil (4:1 v/v)

Remarks - Results: No evidence of irritation and clinical signs of toxicity were noted. Positive control demonstrated adequate performance of study.

CONCLUSION: There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical.

TEST FACILITY: Covance Laboratories (2009f)

B.6. Genotoxicity – bacteria

TEST SUBSTANCE

METHOD	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria. Plate incorporation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100, TA102.
Metabolic Activation System	Liver fraction from SD rats pre-treated with Aroclor 1254.
Concentration Range in Main Test	Test 1: a) With metabolic activation: 1 - 5000 µg/plate b) Without metabolic activation: 39 - 5000 µg/plate Test 2: a) With metabolic activation: 1 - 5000 µg/plate b) Without metabolic activation: 39 - 5000 µg/plate
Vehicle	0.5% aqueous methylcellulose
Remarks - Method	In Test 2 the concentration range varied depending on bacterial strain. TA98, TA1535, TA102 (with S9) 39 - 5000 µg/plate TA100, TA1537, TA102 (without S9) 39 - 5000 µg/plate

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent	> 5000			
Test 1		> 5000	5000	Positive
Test 2		> 5000	5000	Positive
Present	> 5000			
Test 1		5000 (TA102 only)	5000	Positive
Test 2		> 5000	5000	Positive

Remarks - Results	Positive controls confirmed the sensitivity of the test system and viability of S9 preparation. Slight reduction in background lawn was seen at 5000 µg/plate for TA102 with metabolic activation in Test 1 only. No evidence of cytotoxicity was seen for any other strain at any concentration in Tests 1 or 2. Statistically significant increases in revertant numbers were seen in TA98, TA100 and TA1537 with and/or without activation. These increases were dose related and above criteria increases (ie 2-fold increase for strains TA98 and TA 100, and 3-fold increase for TA 1537) for revertants per plate (test substance v controls) in both tests 1 and 2 for TA98 and TA 1537 and were within historical positive control values for the relevant tester strains.
CONCLUSION	The notified chemical was mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Covance Laboratories (2009g)

B.7. 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	CHL/IU
Metabolic Activation System	Liver fraction (S9) from SD rats pre-treated with phenobarbital and 5,6-benzoflavone.
Vehicle	1% CMC-Na (sodium carboxymethylcellulose) solution
Remarks - Method	No significant protocol deviations. Positive and negative control groups and treatment: Negative control: 1% sodium carboxymethylcellulose solution (and untreated control). Positive control without S9: mytomycin C. Positive control with S9: benzo[a]pyrene. Test chemical doses for CA test were selected from results of growth inhibition test.

Metabolic Activation	*Test Substance Concentration (μg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	1.5*, 3.0*, 6.0*, 12.0*	6 hr	24 hr
Present			
Test 1	3.0*, 6.0*, 12.0*, 24.0*	6 hr	24 hr
Test 2	4.0*, 5.0*, 6.0*, 7.0*	24 hr	24 hr
Test 3	2.0*, 3.0*, 4.0*, 5.0*	48 hr	48 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	6.9*	≥ 6.0	> 12.0	Positive
Present				
Test 1	12.0*	≥ 24.0	> 24.0	Positive
Test 2	6.2*	≥ 6.0	> 7.0	Positive
Test 3	4.6*	≥ 5.0	> 5.0	Positive

*Estimated value of 50% cell growth inhibition dose using interpolator.

Remarks - Results	Positive controls caused a marked increase in the total numbers of aberrant cells and the activity of the S9 mix was found to be satisfactory. In the presence and absence of S9 and at 6 hr exposure period, the notified chemical caused significant dose related increases of polyploidy at and above 12.0 and 3.0 μg/mL, respectivley. Similar increases were seen at and above 6.0 and 20.0 μg/mL in 24 hr and 48 hr tests respectivley (tests 2 and 3), indicating that the test substance was capable of inducing a moderate increase in numerical aberrations. No increase in polyploidy incidence was seen with positive controls. No significant increase was seen in structural aberrations in any test. Study authors concluded that notified chemical induced chromosomal aberrations, based on polyploidy, in CHL/IU cells under conditions of the study.
CONCLUSION	The notified chemical was clastogenic under the conditions of this in vitro mammalian chromosome aberration test.
TEST FACILITY	BMI Inc. (2009)

B.8. Genotoxicity – in vivo

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 474 Mammalian Erythrocyte Micronucleus Test.
Species/Strain	Mouse/CD-1 (ICR)
Route of Administration	Oral – gavage
Vehicle	Distilled water
Remarks - Method	

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
I (vehicle control)	5M	0	48 hr
II (low dose)	5M	500	48 hr
III (mid dose)	5M	1000	48 hr
IV (high dose)	5M	2000	48 hr
V (positive control, M)	5M	2*	24 hr

CP=cyclophosphamide. M=mitomycin C.
* Intraperitoneally administered

RESULTS	
Doses Producing Toxicity	No sign of overt marrow toxicity (measured by a significant decrease in the ratio of polychromatic erythrocytes to normal chromatic erythrocytes) was observed.
Genotoxic Effects	Negative. There were no statistically significant increases in the frequency of micronuclei observed in any dose group, except for positive response in positive control group.
Remarks - Results	There were no remarkable body weight changes or clinical signs seen in the study. Study regarded as valid as MNPCE / PCE ratios in negative and positive controls were within historical (for test lab) test background levels.
CONCLUSION	No clastogenicity was observed under the conditions of this in vivo bone marrow micronucleus test., however as there was no indication that the notified chemical reached the target organ the result is considered equivocal.
TEST FACILITY	CERI (2009)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test.
Inoculum	Activated sludge
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Acid titration of residual barium hydroxide.
Remarks - Method	

RESULTS

Test substance		*<Reference Substance>*	
Day	*% Degradation*	*Day*	*% Degradation*
14	0	14	75
28	0	28	89

Remarks - Results	Evolution of carbon dioxide from the toxicity control was about 10% less than from the reference substance alone, suggesting a possible inhibitory effect from the notified chemical.
CONCLUSION	The notified chemical cannot be classed as readily biodegradable.
TEST FACILITY	Covance Laboratories (2009h)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test - static. EC Directive 92/69/EEC C.1 Acute Toxicity for Fish - static.
Species	Carp (*Cyprinus carpio*)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	180 mg $CaCO_3$/L
Analytical Monitoring	UPLC/MS
Remarks – Method	Fish were exposed to serial dilutions of the water accommodated fraction (WAF) obtained by filtering (0.45 µm membrane) a 100 mg/L suspension that had been sonicated for 15 minutes and stirred for 45 hours.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
0		7	0	0	0	0	0
1		3	0	0	0	0	0
10		3	0	0	0	0	0
100	0.20	7	0	0	0	0	0

LC50	> 0.20 mg/L at 96 hours.
NOEC	0.20 mg/L at 96 hours.

Remarks – Results	The measured concentration declined from 0.29 mg/L at test initiation through 0.22 mg/L at 24 hours to 0.15 mg/L at test termination.
CONCLUSION	The notified chemical showed no toxicity to fish at concentrations up to the solubility limit.
TEST FACILITY	Notox (2009e)

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.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	180 mg $CaCO_3$/L
Analytical Monitoring	UPLC/MS
Remarks - Method	Daphnids were exposed to serial dilutions of the WAF obtained as in the fish test.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0		20	0	0
1		10	0	0
10		10	0	0
100	0.17	20	0	4

LC50	> 0.17 mg/L at 48 hours
NOEC	0.17 mg/L at 48 hours
Remarks – Results	The measured concentration declined from 0.256 mg/L at test initiation to 0.113 mg/L at test termination.
CONCLUSION	The notified chemical showed limited toxicity to daphnids at concentrations up to the solubility limit, with the median effect concentration exceeding this limit.
TEST FACILITY	Notox (2009f)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 201 Alga, Growth Inhibition Test. EC Directive 92/69/EEC C.3 Algal Inhibition Test.
Species	*Pseudokirchneriella subcapitata*
Exposure Period	72 hours
Concentration Range	Nominal: 10, 18, 32, 56 and 100% of WAF (nominally 100 mg/L) Actual: 1.3, 1.6, 2.2, 4.6, 8.8 µg/L
Auxiliary Solvent	None
Water Hardness	Typical algal culture medium (soft water)
Analytical Monitoring	UPLC/MS
Remarks - Method	The WAF was obtained as in the fish test.

RESULTS

Yield		*Growth*	
E_yC50 *µg/L at 72 h*	*NOEC* *µg/L*	*E_rC50* *µg/L at 72 h*	*NOEC* *µg/L*
8.5	1.3	> 8.8	2.2

Remarks - Results

Measured concentrations declined sharply (70-90%) in the first 24 hours but remained fairly stable for the remainder of the test period. The average concentrations reported above are time weighted. Algal growth was inhibited by the test substance, but the median effect concentration was higher than the solubility limit. The inhibition could reflect attenuation of light by the coloured test substance.

CONCLUSION

The notified chemical inhibited the growth rate of green algae, but the median effect concentration was higher than the solubility limit.

TEST FACILITY

Notox (2009g)

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