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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME
(NICNAS)

FULL PUBLIC REPORT

Chemical in Red SA

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 Resources, 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

TABLE OF CONTENTS

FULL PUBLIC REPORT

Chemical in Red SA

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Digital Graphic Solutions Pty Ltd (ABN 81 003 982 947) of 9 First Avenue, Unanderra, NSW 2526
and
DIC Australia Pty Ltd (ABN 12 000 079 550) of 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, Structural and Molecular formulae, Molecular weight, Purity, Non-hazardous impurities, Manufacture/import volume, and Identity of sites

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)
NCE/176

NOTIFICATION IN OTHER COUNTRIES
EU, Japan, Korea, China, and USA

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Red SA

MOLECULAR WEIGHT
<1000 Da

ANALYTICAL DATA
Reference IR and UV spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
The pigment Red SA is >90% pure, and it is comprised of <50% notified chemical.

HAZARDOUS IMPURITIES
None

ADDITIVES/ADJUVANTS
None

4. PHYSICAL AND CHEMICAL PROPERTIES

All physicochemical test data provided by the notifier were for the substance Red SA, comprised of <50% notified chemical. The properties of Red SA are considered to reflect those of the notified chemical.

APPEARANCE AT 20ºC AND 101.3 kPa
Red powder

Property	Value	Data Source/Justification
Melting Point	Not determined (>241ºC)	Decomposes before melting
Density	1710 kg/m^3 at 25 ± 0.5ºC	Measured
Vapour Pressure	<1.1x10^{-7} kPa at 25ºC	Measured
Water Solubility	<2.01x10^{-5} g/L at 20.5 ± 0.5ºC	Measured
Hydrolysis as a Function of pH	Not determined	Complex mixture that is essentially insoluble in water
Partition Coefficient (n-octanol/water)	Not determined	Insoluble in both water and n-octanol
Adsorption/Desorption	Not determined	Insoluble in water
Dissociation Constant	pKa ≤1 (acidic) pKa -4.9 and -8.7 (basic)	Estimated and/or modelled
Particle Size	Inhalable fraction (<100 µm): 33.3% Respirable fraction (<10 µm): 3.87%	Measured
Flash Point	Not determined	Solid with a low vapour pressure
Flammability	Not highly flammable	Measured
Autoignition Temperature	400ºC	Measured
Explosive Properties	Not expected to be explosive	Estimated
Oxidising Properties	Not expected to be oxidising	Estimated

DISCUSSION OF PROPERTIES
Red SA, containng the notified chemical, is insoluble in water and is predicted to be insoluble in n-octanol. The notifier has also advised that Red SA is insoluble in several organic solvents, including methanol, acetonitrile and tetrahydrofuran. The only solvent that was found to successfully dissolve it was dimethylformamide. Despite the probable ionisation of the notified chemical at environmental or physiological pH, its salt nature and probable crystalline structure appears to limit its solubility.

A significant proportion (33%) of powdered Red SA (containing notified chemical) is inspirable and could be inhaled into the upper respiratory tract. However, only a small fraction (<4%) was of small enough particle sizes to reach the lower respiratory tract (<10 µm).

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

Reactivity
Based on the chemical structure and experience in use, the notified chemical is predicted to be stable under normal conditions. It is not expected to be flammable, explosive or oxidising.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported into Australia as:

1) A component of pigments (1-5% Red SA concentration);
2) A formulated ink or paint, containing the pigment (≤1% Red SA concentration, typically 0.25%); and
3) Formulated ink incorporated into printer cartridges.

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
Melbourne and Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
The recipients' sites will be located in NSW and Victoria.

TRANSPORTATION AND PACKAGING
1) Pigments will be transported in polyethylene-laminated bags (10 kg), by truck.
2) Inks/paints will be transported in cans and drums (18 L and 200 L, respectively), by truck.
3) Ink cartridges (440 mL) will be transported by truck.

USE
The notified chemical will be used as a component of ink or paint. Imported pigments containing the notified chemical will be used to formulate paints and inks. Imported paints containing Red SA will be used by industry for painting metals, primarily for OEM car exteriors and for fire extinguishers. Imported bulk inks will be used in industrial photogravure printing onto paper. Imported ink cartridges will be used in various industrial printing applications (mainly for sign graphics) onto a variety of substrates (e.g. plastics, films, metallic plates or glass).

OPERATION DESCRIPTION
Paint/ink formulation
A typical batch size for paint formulation will be 1 tonne, which will be processed over 0.6 days. The imported pigment containing the notified chemical will be weighed into a pre-mixing tank, along with varnishes and solvents. After the pre-mixing stage, the components are further combined through a bead-mill and may be filtered. Finished paints or inks will then be manually filled into 18 L cans and/or 200 L drums.

Imported inks and paints (containing the notified chemical) will be used without reformulation.

Use of paints and inks
At the manufacturing site of articles to which imported or finished paints will be applied, the paints containing the notified chemical will be transferred to a paint storage tank. Professional painters will then apply the paint to various items. Paints containing the notified chemical may be applied in different ways (e.g. spray, roller or brush), but the primary and recommended method of application will be by spray. Spray painting will be conducted in dedicated spray booths within the manufacturing site of the article to which it will be applied.

Bulk inks will be used in photogravure printing. This equipment is largely an enclosed system, in which the ink will be drawn automatically into the printing machine from the drum or can by a pipe. An ink pan will collect residual and waste ink automatically. Waste ink in the ink pan and residual ink on the printing plates will be washed off using a solvent; this is an automatic process in which the dissolved waste will be collected within the machine. Any residue remaining on the printing plates (only very small amounts expected) will be removed by wiping with a cloth.

Use of printer cartridges
Cartridges will be connected to the printer on an as needed basis (i.e. to replace spent cartridges). The design of the cartridges is expected to be such that changing them will be easy and only required occasionally.

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)*
Paint/ink formulation			
Weighting and pre-mixing	2	0.25	10
Filling of containers	2	0.5	10
Use of paints and inks			
Filling of paint tank	2	0.25	30
Painting and printing	2	0.5	30
Use of printer cartridges			
Printer operator	2	Momentary	Rare
Printer technician	2	0.1	<52

EXPOSURE DETAILS

Paint/ink formulation

The workers who may experience the greatest exposure are those involved with weighing and transfer of the imported pigments containing the notified chemical (1-5% Red SA) to the pre-mixing vessel. Shaking and pouring of powdered pigments may generate airborne dusts from import bags during weighing and addition to the mixer (the dustiness of these preparations is unknown). Therefore, the exposure of paint/ink manufacturing workers will primarily be via the dermal, ocular and inhalation routes. These operations are expected to be carried out under LEV, which will reduce the exposure of workers from airborne dusts.

As the mixing and blending of the paint components will take place in closed mixing vessels, the potential for worker exposure during these processes is expected to be low. The finished paint products (<1% notified chemical) are likely to be of high viscosity, and so aerosol generation is likely to be low if the vessels were opened for sampling or additions. Low-viscosity inks may result in greater inhalation exposure to aerosols containing the notified chemical.

Workers may experience dermal and/or accidental ocular exposure to paint formulations (<1% notified chemical) during the operation of the beads mill, performing filtration operations, or during manual filling of cans/drums. Where transfer of the finished paint/ink products to the packaging line takes place via a dedicated pipeline (automated filling of cans/drums), worker exposure to the paint containing the notified chemical is not anticipated.

All paint manufacturing workers are expected to wear personal protective equipment (PPE) such as overalls, safety glasses, gloves and safety boots, and reformulation plants are often equipped with LEV at most of not all workstations.

Use of paints and inks

Occupational exposure during the professional application of paints to metal surfaces by spray, roller or brush is likely to occur under very controlled conditions. Dermal exposure during handling and application of finished paints (<1% notified chemical) is most likely, but accidental ocular or oral exposure may also occur. Inhalation exposure may also occur where application is performed using spray equipment and the paint products form airborne droplets on the worker's breathing zone. Industrial use environments will include the use of dedicated spray booths, where excess paint released by the spray process is likely to be minimised. Professional painters are expected to wear a minimum of overalls, goggles and gloves during application with brush or roller, and appropriate respiratory protection (dictated by the sprayed formulation) during spray application.

Exposure of printer operators during the use of bulk inks in photogravure printing is expected to be minimal, due to it being a largely enclosed system. Limited dermal and/or ocular exposures (to <1% concentration) are possible during connection of the printing machine to the ink drums or cans, and during wiping away of ink residues on the printing plates with a cloth.

Use of printer cartridges

Printer operators will not normally be exposed to the notified chemical during the normal use of ink cartridges. The ink solidifies immediately after printing and so no direct exposure will be possible under normal conditions.

Accidental dermal exposure of these workers to small amounts of ink containing the notified chemical may occur while replacing empty cartridges.

Printer technicians may experience some dermal or possible accidental ocular exposure to the notified chemical while cleaning or repairing the printer. Printer technicians will be trained personnel who will wear gloves and goggles while performing their duties.

Exposure to dried inks or paints
All users of paints and inks containing the notified chemical are expected to make dermal contact with dry painted or printed surfaces. However, once the paint or ink has dried upon a surface, the notified chemical will be trapped within the dried polymeric matrix. Thus, it is not expected to be available to cause exposure to workers.

6.1.2. Public exposure

The paints, inks and ink cartridges, containing Red SA as a component, are intended only for industrial or professional use, and will not be available for use by the general public. Members of the public are very likely to make dermal (and possibly oral) exposure with painted or printed surfaces containing the notified chemical. However, once paints or inks have dried upon surfaces, the notified chemical will be trapped within the paint matrix and is not expected to be available to cause exposure. Given its general lack of solubility, significant leaching is unlikely from the polymeric matrices of painted/printed surfaces.

6.2. Human health effects assessment

All toxicological data provided by the notifier were for the substance Red SA, comprised of <50% notified chemical. The results from toxicological investigations conducted on Red SA, summarised below, are considered to reflect those of the notified chemical.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral	LD_{50} >2000 mg/kg bw
Rabbit, skin irritation	Slightly irritating
Rabbit, eye irritation	Slightly irritating
Guinea pig, skin sensitisation - adjuvant test (1) *	Inconclusive
Guinea pig, skin sensitisation - adjuvant test (2) *	No evidence of sensitisation
In vitro bacterial reverse mutation test	Non-mutagenic
In vitro mammalian chromosome aberration test	Non-clastogenic

* Details of these studies can be found in Appendix B.

Toxicokinetics
Given its general lack of solubility in both water and *n*-octanol, the notified chemical is not expected to be significantly absorbed following any route of exposure. This hypothesis is supported by the available toxicological studies, in which no suggestion of absorption can be observed.

The notified chemical is largely comprised of particles that are not considered small enough to be readily inhaled. Particles of inhalable size (<100 μm) are expected to deposit in the upper airways and these may be removed through expectoration. However, inhaled respirable particulates of the notified chemical (<10 μm) may not be readily cleared from the deep lung by normal mechanisms (mucociliary and cellular), due to its lack of solubility. Higher concentrations of exposure may be expected to result in increased impairment of clearance mechanisms, as has been observed for insoluble toner particles (Bellmann *et al*, 1991). The notified chemical has a relatively low level of respirable-sized particulates (~3.5-4%).

Acute toxicity
The notified chemical, formulated as a suspension in arachis oil, was found to be of low toxicity in a rat acute oral toxicity study according to OECD 401 (Safepharm, 1994c). In this study, there were no deaths, no clinical signs of systemic toxicity, and no findings observed at necropsy. The oral LD_{50} was thus determined to be >2000 mg/kg bw.

No acute dermal or inhalation studies were provided. However, due to its probable lack of absorption, systemic effects that might result in acute lethality by these routes are not expected.

Irritation
In a rabbit acute dermal irritation study according to OECD 404, a four-hour semi-occluded application of the notified chemical (moistened with distilled water) caused only very slight erythema that recovered by the 72-

hour observation point (Safepharm, 1994d). No corrosive effects were observed up to the final observation (72 hours).

The notified chemical was slightly irritating to rabbit eyes in an acute eye irritation study, conducted according to OECD 405 (Safepharm, 1994e). Mild iridial inflammation was noted in one animal at 24 hours, and conjunctival redness, chemosis and discharge were noted 24 hours after exposure in the majority of animals (≥2 of 3). All effects had recovered by 72 hours, with the exception of the presence of residual test material around the treated eye.

Sensitisation
An initial guinea pig maximisation test (GPMT) was inconclusive, due to the high number of mortalities and the extent of irritation observed in control animals upon challenge with <25% notified chemical (Safepharm, 1994f). As a result, a second study was conducted, with reduced challenge concentration. In this study (Safepharm, 1995), no effects were observed (sensitisation rate 0%). Details of these studies can be found in Appendix B.

In conclusion, on the basis of the available test data, the notified chemical is considered to be a non-sensitiser.

Repeated dose toxicity
No repeated dose toxicity information was available for the notified chemical. Repeated inhalation exposure to respirable particulates of insoluble chemicals may result in lung overload effects, but it is uncertain to what extent this might occur for the notified chemical (especially given that it contains only 3.87% of particles small enough to reach the deep lung).

Genotoxicity
The notified chemical (Red SA) was not found to be mutagenic in two separate bacterial reverse mutation tests according to OECD 471, with and without metabolic activation with S9 liver microsomes (Safepharm, 1994g; CERI, 2005a). Significant precipitation of the test substance was observed in both studies (≥8 µg/plate when suspended in arachis oil, but ≥1250 µg/plate when suspended in DMSO), but this did not prevent the scoring of the number of revertant colonies. The positive control substances showed the appropriate increases in revertant colonies, demonstrating the sensitivity of the test for both detection of mutations and for metabolic activity.

The notified chemical was also found to be non-clastogenic in a chromosome aberration test in cultured CHL cells, conducted according to the requirements of the Japanese New Chemical Substance Law (METI) (Safepharm, 2005). The cells were exposed to the test substance (Red SA) for 6 hours (+18 hours culture) with and without S9 microsomal activation, and for 24 hours of continuous exposure without S9. Precipitation of the test substance occurred at ≥19.5 µg/mL in the 6-hour exposures and at ≥0.15 µg/mL in the 24-hour exposures, and this interfered with the scoring of metaphases at the highest test concentrations. Some small but statistically significant increases in the number of cells showing structural chromosome aberrations were observed in the presence of S9; however, due to the lack of dose-response and reproducibility these were considered spurious.

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

6.3. Human health risk characterisation

6.3.1. Occupational health and safety
The notified chemical has no identified hazards, and due to its lack of solubility is not expected to be significantly absorbed following occupational exposures. Therefore, the dermal and/or ocular exposure that may occur during most uses of the notified chemical is unlikely to pose a significant risk to the health of workers. Given the results from the studies in rabbits, slight skin or eye irritation is possible, but these are likely to be minimal in most uses due to the low concentrations that will be use and the engineering controls or PPE that may be worn by workers.

Repeated inhalation of airborne dusts of the notified chemical, or inhalation of high airborne concentrations, may present some risk of lung overloading effects. This scenario may be possible during the formulation of paints/inks, where inhalation exposure to airborne particulates of the notified chemical may occur. However, given the low proportion of respirable particulates in Red SA, high airborne concentrations may be less likely to occur during its use.

The Australian recommended exposure standard for nuisance dust is 10 mg/m^3 [NOHSC 3008:(1995)], but the American Conference of Governmental Industrial Hygienists (ACGIH) recommends an exposure limit of 3 mg/m^3 for “respirable (insoluble) particulates (not otherwise regulated)” (ACGIH, 2006).

The risk associated with the use of paints and inks, or the use of imported printer cartridges, is expected to be

low, based on the low hazard that is expected for the concentrations present in these formulations. In addition, these professional uses are likely to present a lower risk, resulting from the PPE that may be used.

Worker exposure to dried or cured inks or paints is unlikely to result in exposure to the notified chemical, so the risk presented by the notified chemical in this scenario is expected to be commensurably negligible.

6.3.2. Public health

Given the limited potential for public exposure to the notified chemical in the proposed uses, and its lack of solubility or identified health hazard, the introduction of the notified chemical is not expected 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 is supplied to ink/paint manufacturers in a pigment that containing 1-5% notified chemical by weight. The notified chemical is supplied in paper bags that are lined with four layers of polyethylene, so there should be no release of the notified chemical into the environment during shipment.

Production of inks/paints will involve mixing the notified chemical in a mixing vessel. After mixing, the solution goes through kneading, viscosity adjustment and filling into drums. The equipment used in the above process will be washed with a solvent to remove residues. The solvent used for washing, which likely contains notified chemical, will be collected and is later incinerated. The paper bags will be incinerated after use. All of the above indicates that the amount of the notified chemical released into the environment during manufacture is low.

RELEASE OF CHEMICAL FROM USE

It is difficult to estimate the exposure to the environment from accidental release, as this will not usually occur during normal operating procedure. There are however a number of ways in which this is limited:

- During transport, the paint is contained within 200 L metal drums and so minimal release to the environment is expected if the procedures in the MSDS are followed.
- The paint storage tank used at the automotive manufacturing factory will be surrounded by a protective bunding, to stop any spillage that may occur. If the collection methods stated in the MSDS are followed then only minimum release to the environment will be possible.
- Industrial spray application of paints containing the notified chemical will be conducted inside dedicated booths within the factory. Thus, excess paint spray will be collected in oil by air scrubbers and then treated to avoid environmental release. For cars and fire extinguishers it may be assumed a maximum of 30% of overspray of paint containing the notified chemical will result from application. This will be collected, dried and landfilled.
- Ink cartridges contain only <1% Red SA in the ink; there is therefore a maximum accidental release of <4 g per ruptured cartridge.

Empty ink and paint drums will be washed in solvent, which will then be sent to a specialised industrial waste dealer for incineration. Waste paper bags and waste paint will also be sent to the specialised industrial waste dealer for incineration. A residue of <1% of the ink will remain in the ink cartridge, which will be sent to a specialised industrial waste dealer for either recycling or disposal to landfill. Bulk ink wastes will be collected automatically during photogravure printing, and these will be disposed through industrial waste dealers. Incidental releases of the notified chemical during the printing/spray painting process are expected to be low, as ink/paint that adheres to printing/spraying machinery will be wiped off with a cloth that will later be incinerated.

RELEASE OF CHEMICAL FROM DISPOSAL

The emptied drums after use are expected to contain a maximum of 1% of the notified chemical, which will be disposed of to landfill.

7.1.2 Environmental fate

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

The notified chemical attained 21% degradation after 28 day indicating that it cannot be considered as readily biodegradable. The bioaccumulation study reported that the Bioconcentration Factor (BCF) was calculated to be 51 after 28 days, indicating that the notified chemical is not highly bioconcentrating.

Articles painted with paints containing the notified chemical will be recycled or disposed to landfill at the end of their useful life. Consequently, the notified chemical will share the fate of the article to which it has been applied.

The notified chemical is practically insoluble in water and the incorporation into cured paint matrix will further reduce the water solubility. Due to its low solubility in water, the notified chemical will not be mobile in soil. In landfill, the notified polymer is expected to degrade slowly by abiotic and biotic processes to HCl, metal salts, water and oxides of carbon and sulfur.

While environmental exposure is limited during ink use, the majority of the import volume of the notified chemical will ultimately be disposed of in either landfill or be incinerated. The widespread use pattern indicates that landfills throughout Australia would receive the notified chemical bound into the ink matrix within steel and plastic containers and on paper products. The notified chemical would be expected to remain within the container unless breached. On paper the notified chemical will be bound within in the stable polymer matrix.

During recycling processes, waste paper is repulped using a variety of alkaline, dispersing and wetting agents, water-emulsifiable organic solvents and bleaches. These agents enhance fibre separation, ink detachment from the fibres, pulp brightness and the whiteness of paper. These aqueous wastes are expected to go to sewer. Very little of the notified chemical is expected to partition to the supernatant water which will be released to the sewer. Sludge generated during the washing process will be dried and incinerated or sent to landfill for disposal.

Most of the notified chemical used in automotive finishes will eventually be incorporated in metal recycling programs or sent to landfill for disposal following its life-cycle. During reclamation, the notified chemical would be destroyed in furnaces and converted to HCl, water vapour and oxides of sulfur and carbon.

7.1.3 Predicted Environmental Concentration (PEC)

During the printing/spray painting process the release of the notified chemical into the environment is low. This is because ink/paint that adheres to printing/spraying machinery is wiped off with cloth and this is later incinerated. Ink containers and paint drums are estimated to have a maximum of 1% of the notified chemical remaining, which will be disposed to landfill or recycled. The major route of exposure to the aquatic environment is through recycling of paper products with ink containing the notified chemical. Simpletreat modelling predicts 87% removal of the notified chemical (1% to air, 4% degraded and 82% partitioning to sludge). Assuming 50% use in inks, a PEC is calculated based on a worst-case scenario of 5% loss to the aquatic environment (i.e. the loss of 2.5% of the import volume to the sewer).

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	<500	kg/year
Proportion expected to be released to sewer	2.5%	
Annual quantity of chemical released to sewer	<12.5	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	0.034	kg/day
Water use	200	L/person/day
Population of Australia (Millions)	21.161	million
Removal within STP	87%	Mitigation
Daily effluent production:	4,232	ML
Dilution Factor - River	1	
Dilution Factor - Ocean	10	
PEC - River:	<0.00113	µg/L
PEC - Ocean:	<0.000113	µg/L

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 >0.18 mg/L	Not toxic to fish to its limit of water solubility
Daphnia Toxicity	LC50 >0.002 mg/L	Not toxic to *Daphnia magna* to its limit of water solubility.

7.2.1 Predicted No-Effect Concentration

Two toxicity studies have been provided indicating that the notified substance is not toxic to *Daphnia magna* or fish to the limit of its water solubility. On this basis the PNEC has been determined using the *Daphnia* NOEC and applying an assessment factor of 100 to allow for intraspecies variation and extrapolation from lab studies to the field.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
NOEC (Invertebrates)	0.002	mg/L
Assessment Factor	100	
Mitigation Factor	1	
PNEC	0.02	µg/L

7.3. Environmental risk assessment

Risk Assessment	*PEC (µg/L)*	*PNEC (µg/L)*	*Q*
Q - River	<0.00113	0.02	<0.057
Q - Ocean	<0.000113	0.02	<0.0057

The PEC/PNEC ratios presented above indicate that the risk to the aquatic environment as a result of the use of the notified substance in inks is acceptable for both freshwater and coastal discharge.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

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

and

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

	Hazard category	***Hazard statement***
Environment	Category 4	Not toxic to solubility limit Not degradable

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

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

Environmental risk assessment

On the basis of the PEC/PNEC ratio, the chemical is not considered to pose a risk to the environment based on its reported use pattern.

Recommendations

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical as introduced in powdered form:
  - *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 powdered form:
  - *Avoid the formation of airborne dusts*

- 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 form:
  - *Gloves and goggles/safety glasses*
  - *Dust mask sufficient for respirable particulates (where high airborne concentrations occur)*

  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 NOHSC *Approved Criteria for Classifying Hazardous Substances*, 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.

Storage

- Keep containers tightly closed in a dry, cool and well-ventilated place.

Emergency procedures

- Spills or accidental release of the notified chemical should not be allowed to enter surface water or sewer system. The spilled material should be collected and disposed to landfill.

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.

or

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

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

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

Material Safety Data Sheet

The MSDS of 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

All physicochemical test data provided by the notifier were for the substance Red SA, comprised of <50% notified chemical. The properties of Red SA are considered to reflect those of the notified chemical.

Melting Point Not determined (>241ºC)

Method	EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks	The notified chemical decomposed at 514 ± 0.5 K prior to melting.
Test Facility	Safepharm (1994a)

Density 1710 kg/m^3 at 25 ± 0.5ºC

Method	OECD TG 109 Density of Liquids and Solids.
Remarks	Gas comparison pycnometer method.
Test Facility	Safepharm (2006a)

Vapour Pressure <$1.1x10^{-7}$ kPa at 25ºC

Method	OECD TG 104 Vapour Pressure. EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks	No statistical analyses were performed because the vapour pressure balance readings were too low and variable for a line of best fit to have any meaning. Instead it was considered more appropriate to impose a regression slope on a chosen data point to provide an estimate of the maximum value for the vapour pressure at 25ºC.
Test Facility	Safepharm (2006b)

Water Solubility <$2.01x10^{-5}$ g/L at (20.5 ± 0.5)ºC

Method	EC Directive 92/69/EEC A.6 Water Solubility.
Remarks	Column Elution Method with spectrophotometric analysis.
Test Facility	Safepharm (1994a)

Adsorption/Desorption Not determined

Remarks	Testing according to OECD TG 121 was not applicable for the test material. The test material was a salt of a complex mixture. Due to the ionic nature of strong acids, the HPLC method is not appropriate for estimation of logKoc from the capacity factors of unionised calibration standards of known logKoc. Experimental testing was attempted to possibly assess the adsorption coefficient of any unsalted components of the test material. However, it was concluded that any unsalted components of the test material, for which the HPLC estimation method remained valid, could not be confidently identified and quantified within the chromatograms generated. The use of computer-based estimation programs and/or Quantitative Structure Activity Relationships (QSARs) for the test material were also considered invalid. Finally, OECD TG 106 would also be inapplicable for this test material, due to its extremely low water solubility. The adsorption coefficient end point was considered essentially meaningless due to the negligible solubility of the test material on accidental release into the environment. This property, combined with the presence of anionic functional groups, prevented any quantification of this parameter.
Test Facility	Safepharm (2006b)

Dissociation Constant pKa ≤1 (acidic)
pKa -4.9 and -8.7 (basic)

Method	OECD TG 112 Dissociation Constants in Water.
Remarks	No experimental testing was possible using OECD TG 112, as the test material was a

complex mixture that had been determined to be essentially insoluble in water.

Irrespective of this, the test material was predicted from structural information to contain no functional groups with dissociation constants relevant to the environmental assessment.

The pKa of the two basic functional groups were predicted to be -4.9 and -8.7 using the modelling software ACD/pKa 8.03. The pKa of the acid functional groups was estimated, as strong acids have pKa values typically less than or equal to 1.

Test Facility Safepharm (2006a)

Particle Size Inhalable fraction (<100 µm): 33.3%
Respirable fraction (<10 µm): 3.87%

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

Range (µm)	*Mass (%)*
<100	33.3%
<10.2	3.87%
<5.4	0.619%

Remarks Too few particles were of a size smaller than 10.2 µm to allow accurate determination of the Mass Median Aerodynamic Diameter (MMAD).

Test Facility Safepharm (2006a)

Flammability Not highly flammable

Method EC Directive 92/69/EEC A.10 Flammability (Solids).
Remarks The notified chemical did not propagate combustion in the preliminary screening test.
Test Facility Safepharm (1994b)

Autoignition Temperature 400ºC

Method EC Directive 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Remarks After the test, the sample cube contained grey/white, charred remains.
Test Facility Safepharm (2006b)

Explosive Properties Not expected to be explosive

Method EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks Based on the chemical structure of the test material (absence of explosophores) the result of any explosive properties testing was predicted to be negative.
Test Facility Safepharm (2006b)

Oxidizing Properties Not expected to be oxidising

Method EC Directive 92/69/EEC A.17 Oxidizing Properties (Solids).
Remarks Based on the chemical structure, the result of any testing for oxidising properties was predicted to be negative.
Test Facility Safepharm (2006b)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

All toxicological test data provided by the notifier were for the substance Red SA, comprised of <50% notified chemical. The toxicity of Red SA is considered to reflect that of the notified chemical.

B.1. Guinea pig, skin sensitisation - adjuvant test (1)

TEST SUBSTANCE: Red SA

METHOD: OECD TG 406 Skin Sensitisation – Maximisation test
EC Directive 96/54/EC B.6 Skin Sensitisation – Maximisation test

Species/Strain: Guinea pig/Dunkin-Hartley

PRELIMINARY STUDY: Maximum Non-irritating Concentration:
- intradermal: 25% in arachis oil
- topical: 75% in arachis oil

MAIN STUDY

Number of Animals: Test Group: 10 F Control Groups: 5 F (1st challenge)
5 F (2nd challenge)

INDUCTION PHASE: Induction Concentration:
- intradermal: 25% in arachis oil
- topical: 75% in arachis oil

Signs of Irritation: Pink coloured staining was noted at the test substance intradermal induction sites at 24 and 48 hours, and at topical sites at 1 and 24 hours. This staining interfered with the scoring of some skin responses. Very slight to well-defined erythema was noted at the intradermal induction sites in control animals.

CHALLENGE PHASE

1st challenge: topical: 50% and 25% in arachis oil

2nd challenge: topical: 25% and 10% in arachis oil

Remarks - Method: Pink coloured staining was noted at all challenge sites at 24 and 48 hours, but this staining did not interfere with the scoring of skin responses.

RESULTS

Animal	*Challenge Concentration (% in arachis oil)*	*Number of Animals Showing Skin Reactions after: 1st challenge*		*2nd challenge*	
		24 h	*48 h*	*24 h*	*48 h*
Test Group	50	10/10	0/10	-	-
	25	7/10	0/10	3/9*	0/9*
	10	-	-	0/9*	0/9*
Control Group	50	2/2*	0/2*	-	-
	25	2/2*	0/2*	0/5	0/5
	10	-	-	1/5	0/5

* Total animal numbers reduced due to mortality (see below).

Remarks - Results: All skin reactions reported after the both of the two challenge phases were very slight erythema.

One control animal was found dead on each of days 20 and 22 (the day before and the day after 1st challenge). No cause of death was identified. Another had to be killed due to breathing difficulties on day 22. One test animal was found dead on day 30 (2 days before 2nd challenge).

While these deaths, in isolation, were not considered to have affected the integrity of the study, in combination with the level of skin irritation induced by the test substance, they rendered the test inconclusive.

CONCLUSION: The notified chemical may have skin sensitising properties, but on the basis of inadequate evidence, no conclusion is made.

TEST FACILITY: Safepharm (1994f)

B.2. Guinea pig, skin sensitisation - adjuvant test (2)

TEST SUBSTANCE	Red SA
METHOD	OECD TG 406 Skin Sensitisation – Maximisation test. EC Directive 96/54/EC B.6 Skin Sensitisation - Maximisation test.
Species/Strain	Guinea pig/Dunkin-Hartley
PRELIMINARY STUDY	Maximum Non-irritating Concentration: - intradermal: 25% in arachis oil - topical: 75% in arachis oil
MAIN STUDY	
Number of Animals	Test Group: 10 F Control Group: 5 F
INDUCTION PHASE	Induction Concentration: - intradermal: 25% in arachis oil - topical: 75% in arachis oil
Signs of Irritation	Dense purple or pink-coloured staining was noted at the test substance intradermal induction sites at 24 and 48 hours, and at topical sites 1 and 24 hours. This staining interfered with the scoring of some skin responses after 1 and 24 hours. Well-defined to moderate erythema was noted at 48 hours in the intradermal induction sites in test animals (compared with very slight erythema in the control animals at 24 and 48 hours).
CHALLENGE PHASE	
1st challenge	topical: 25% and 10%in arachis oil
Remarks - Method	Pink coloured staining was noted at all challenge sites at 24 and 48 hours, but this staining did not interfere with the scoring of skin responses. No 2nd challenge was required.

RESULTS

Animal	*Challenge Concentration (%)*	*Number of Animals Showing Skin Reactions after challenge:* *24 h*	*48 h*
Test Group	25	0/10	0/10
	10	0/10	0/10
Control Group	25	0/5	0/5
	10	0/5	0/5

Remarks - Results	No mortality occurred.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	Safepharm (1995)

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). Referenced as Method C.4-C of commission Directive 02/69/EEC.
Inoculum	A mixed population of microorganisms
Exposure Period	28 days
Auxiliary Solvent	Dimethylsulfoxide
Analytical Monitoring	BOD with a closed system oxygen consumption measuring apparatus, HPLC.
Remarks - Method	No significant protocol deviations.

RESULTS

Test substance		*Aniline*	
Day	*% Degradation*	*Day*	*% Degradation*
7	-2	7	51
14	-3	14	70
21	-3	21	71
28	-1	28	73

Remarks - Results	Aniline attained 73% degradation after 28 days thereby confirming the suitability of the inoculum and test conditions. HPLC confirmed the lack of primary degradation (1%)
CONCLUSION	The notified chemical is not considered to be readily biodegradable.
TEST FACILITY	CERI (2005c)

C.1.2. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD 301 B Ready Biodegradability: CO_2 Evolution Test. EC Directive 92/69/EEC C.4-C Biodegradation: Determination of the " Ready" Biodegradability: Carbon Dioxide Evolution Test
Inoculum	A mixed population of activated sludge microorganisms.
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	TOC
Remarks – Method	No significant protocol deviations.

RESULTS

Test substance		*Sodium benzoate - Reference Substance*	
Day	*% degradation*	*Day*	*% degradation*
1	2	1	4
6	5	6	87
8	6	8	108
14	16	14	99
20	18	20	100
27	21	27	101
28	21	28	100
29	25	29	103

Remarks – Results

Degradation values in excess of 100% are considered to be due to sampling and/or analytical variation.

Day 29 values corrected to include any carry-over of CO_2 detected in absorber 2 on Day 29. The results of the inorganic carbon analyses on day 29 showed there to be no significant carry-over of CO_2 into the second absorber vessel at the end of the study and that as there is no significant difference between the day 28 an 29 degradation values, the day 28 value should be taken as being the true level of biodegradation achieved, i.e. no significant amounts of CO_2 were present as inorganic carbonate in solution.

10% degradation was achieved after 10 days and total degradation at the end of the test was 21%.

The inhibition control, containing both Red SA and sodium benzoate, attained 47% degradation after 28 days thereby confirming that the test material, Red SA, was not toxic to sewage treatment microorganisms used in the study.

The abiotic control attained 0% degradation after 28 days thereby confirming that abiotic degradation of the test material, Red SA, did not occur during the study. Sodium benzoate attained 103% degradation after 28 days thereby confirming the suitability of the inoculum and test conditions.

CONCLUSION — The notified chemical cannot be classed as readily biodegradable.

TEST FACILITY — Safepharm (1994h)

C.1.3. Bioaccumulation

TEST SUBSTANCE — Notified chemical

METHOD — OECD TG 305 Bioconcentration: Flow-through Fish Test.
EC Directive 98/73/EC C.13 Bioconcentration: Flow-Through Fish Test.

Species — *Cyprinus carpio*

Exposure Period — Exposure: 28 days Depuration: Nil days

Auxiliary Solvent — Dimethylsulfoxide

Concentration Range — Nominal: Low exposure level 0.0002 mg/L
High exposure level 0.002 mg/L.

Analytical Monitoring — HPLC

Remarks - Method — The notified chemical was dissolved in dimethylsulfoxide to prepare a 50 mg/L stock solution. The stock solution was then dispersed in dechlorinated water to give the test concentrations which remained at >80% of nominal.

Results

Bioconcentration Factors — Since there were a series of peaks detected by HPLC, individual factors for these were calculated.

CT50

Peak	*Level 1*	*Level 2*
Peak 2	3.8-24	≤ 24
Peak 4	5.8-55	≤ 10-33
Peak 5	≤ 4.6-29	≤ 47
Peak 6	≤ 1.9-17	≤ 19
Peak 7	3.5-22	≤ 5.6-41
Peak 8	6.2-23	≤ 12-73

Remarks - Results

The BCF at the higher level was calculated to be 51 after 28 days.

The lipid content in the fish after termination of experiment was within ±25% compared to the average of the content before initiation of experiment.

This study may not be regarded as definitive according to current standards as the substance was tested at slightly above the water

solubility using solvent/dispersant. However, it can be used to show that the notified substance is not bioaccumulative.

CONCLUSION The notified chemical is not highly bioconcentrating.

TEST FACILITY CERI (2005b)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE Notified chemical

METHOD As part of bioaccumulation test using Japanese Industrial Standard (JIS K0102-1998-71). Semi-static renewed every 24 h.

Species	*Orizias latipes*
Exposure Period	96 hours
Auxiliary Solvent	dimethylsulfoxide
Water Hardness	Not given
Analytical Monitoring	HPLC
Remarks – Method	Few details provided.

RESULTS

LC50	>0.18 mg/L at 96 hours.
NOEC	0.18 mg/L at 96 hours.

CONCLUSION The notified chemical is not toxic to *Orizias latipes* up to the limit of its solubility.

TEST FACILITY CERI (2005b)

C.2.2 Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified chemical

METHOD EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia

Species	*Daphnia magna*
Exposure Period	48 hours (acute study)
Auxiliary Solvent	Dimethylformamide
Water Hardness	270 mg $CaCO_3$/L
Analytical Monitoring	Spectrophotometer
Remarks – Method	The notified chemical was dispersed in dimethylformamide to give a 10 mg/500 mL solvent stock solution. An aliquot (200 µL) of this stock solution was dispersed in 2 L of reconstituted water to prepare the 0.002 mg/L test concentration, which was apparently clear. The notified chemical content was below the limit of spectrophotometric quantitation.

RESULTS

Nominal Concentration (mg/L)	*Number of* D. magna	*Number Immobilised*	
		24 h	*48 h*
0.0020	40	0	0

LC50	>0.002 mg/L at 48 hours
NOEC	0.002 mg/L at 48 hours
Remarks – Results	The test concentration of 0.002 mg/L was the highest attainable test concentration due to the limited water solubility of the notified chemical.

CONCLUSION The notified chemical is not toxic up to the limit of its solubility.

TEST FACILITY	Safepharm (1997)

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