File No: NA/200

Date:3 January 1995

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

DISPERSE RED 370

This Assessment has been compiled in accordance with the provisions of *the Industrial Chemicals (Notification and Assessment) Act 1989,* and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by Worksafe Australia which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment, Sport, and Territories and the assessment of public health is conducted by the Department of Human Services and Health.

For the purposes of subsection 78(1) of the Act, copies of this full public report may be inspected by the public at the Library, Worksafe Australia, 92-94 Parramatta Road, Camperdown NSW 2050, between the hours of 10.00 a.m. and 12.00 noon and 2.00 p.m. and 4.00 p.m. each week day except on public holidays.

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

DISPERSE RED 370

1. APPLICANT

Yorkshire Australia Pty Ltd of 30-32 Commercial Drive, Dandenong VIC 3175 has submitted a limited notification for assessment of Disperse Red 370 .

2. IDENTITY OF THE CHEMICAL

Disperse Red 370 has been classified as hazardous by Worksafe Australia due to its skin sensitisation properties. However for commercial reasons, the chemical identity, spectral data, and import volume have been granted exemption from publication in the Full Public Report and the Summary Report. The conditions of this being permitted are:

- The C.I. name be used to identify the substance in public reports and the MSDS.
- The relevant employee unions shall be informed of the conditions of use of Disperse Red 370.
- The full chemical name shall be provided to any health professionals in the case of a legitimate need where exposure to the chemical may involve a health risk,
- The full chemical name shall be provided to those on site who are using the chemical and to those who are involved in planning for safe use, etc. in the case of a legitimate need.
- The Director of NICNAS will release the full chemical name etc in the case of a request from a medical practitioner,
- Confidentiality will expire after a 3 year period,
- That the chemical be identified as a sensitiser in the Health Effects Section of the MSDS, and that reference to its assessment be made on the MSDS,
- These conditions shall be published in the Chemical Gazette,

Trade name: Serilene Red FB-LS (Product)
Contains on an average 33% of Disperse Red 370

Method of detection and determination:

Separation and structure elucidation by ultra-violet spectroscopy, infra-red spectroscopy and nuclear magnetic resonance (NMR).

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	red powder
Melting Point:	the substance decomposes on heating without melting.
Density:	1.483 x 10^3 kg/m
Vapour Pressure:	3.58 kPa at 25°C
Water Solubility:	< 0.1 mg/L at 20°C
Fat Solubility:	< 0.002 mg/kg
Partition Co-efficient (n-octanol/water) log P_{ow}:	4.38
Hydrolytic Stability:	no test performed. The notifier argues that in view of the chemical's low water solubility it is not technically possible to perform this test. Based on the chemical structure of the notified substance, significant degradation by hydrolysis is not expected. The acetate group can hydrolyse but due to the insolubility in water, this reaction is unlikely. This is acceptable for the environmentally relevant pH range.
Soil adsorption/desorption:	test not performed. The notifier argues that the method of use will not present any opportunities for release of any significant quantity of the substance into the environment which could result in contamination of soil. Strong adsorption to soil/sediment is expected.
Dissociation Constant:	test not performed. The notifier argues that, as the dyestuff is not soluble in water, it is not expected to dissociate.
Flash Point:	not applicable as the substance is a solid.
Flammability Limits:	nonflammable
Decomposition Temperature:	215°C
Decomposition Products:	not known
Autoignition Temperature:	> 400°C
Explosive Properties:	not explosive, but under certain circumstances may form explosive dust clouds.
Reactivity/Stability:	stable under ambient conditions, does not have oxidising properties.
Particle size distribution:	range 12-150 µm mean typical size 15 µm

Comments on physico-chemical properties

Tests were performed according to EEC test guidelines and at facilities complying with OECD principles of Good Laboratory Practice

4. PURITY OF THE CHEMICAL

Degree of purity: 81.6%
Lower limit: 79.6%
Upper limit: 83.6%

Toxic impurities: None

5. INDUSTRIAL USE

Disperse Red 370 will be imported into Australia as the primary component of Serilene Red FB-LS, a dispersive dye preparation and will be used in textile dyeing.

6. OCCUPATIONAL EXPOSURE

Disperse Red 370 will not be manufactured in Australia but will be imported as a component of Serilene Red FB-LS in 25 kg plastic lined cardboard containers. The chemical will normally be supplied to the cutomer as imported. It may be reformulated or repackaged if customers require a modification to colour or quantities less than 25 kg.

Reformulation or repackaging may be performed at Yorkshire Australia. Repackaging will be done manually while reformulation will be performed in a dry blending machine fitted with an extraction system. During reformulation or repackaging exposure is expected is expected to be for approximately 5-10 mins/day for approximately 10 days/year.

Disperse Red 370 will be transported to user sites by road. It will then be stored in the powder form in the warehouse or colour kitchen store. No storage of the aqueous dye dispersion will occur. It is not anticipated that any worker exposure will occur during transport or storage.

Disperse Red 370 will be used at approximately 4 dyehouses. Upto 4 employees per site may potentially be exposed to the chemical. In addition, one employee at Yorkshire Australia will be exposed to the chemical during reformulation or repackaging.

The colour kitchen operators in the dyehouses open the packages, weigh out the dye powder and transfer it manually to the wet area where the dye dispersion is prepared. The colour kitchen is fitted with dust extraction equipment. During preparation of the dye dispersion the dye powder is gradually added to hot water with the help of an impeller. Before mixing, the dry powder is wetted to prevent dust formation. The workers will be exposed to the chemical for 20 mins/day, 40 days per year.

The aqueous dye dispersion is transferred to the dyeing machine. Transfer is through the closed pipes at larger sites but may be done manually at smaller sites. The dyehouse operators may be exposed to the chemical for 5 mins/day, 40 days/year. The dyeing processes occur in a closed system and exposure of workers during the dyeing process is not expected.

The potential for exposure to Disperse Red 370 during maintenance of the dyeing equipment is low as the equipment would be thouroughly washed by an automatic process before maintenance. Up to 40 maintenance personnel could be exposed to the dye in solution.

7. PUBLIC EXPOSURE

No public exposure to the notified chemical is expected to occur during its distribution by road to dyehouses or during the reformulation or repackaging of Serilene Red FB-LS. Preparation of the dye dispersion will be conducted in a 'colour kitchen' using a dust extraction system. Therefore, public exposure is not expected to occur. Disposal of the chemical is not expected to result in significant public exposure.

Public contact with the notified chemical resulting from the use of treated fabrics may be extensive. However, the notified chemical will be bound to the fabrics and therefore public exposure levels are expected to be low.

8. ENVIRONMENTAL EXPOSURE

. Release

During dyeing of synthetic fibres a 95-98% level of fixation on the fibres is expected. The remainder will be discharged into the dyehouse's effluent.

Spills that occur during transport or handling will be cleaned up according to the Material Safety Data Sheet and consigned to secure landfill or incinerated.

. Fate

The bulk of the dye will become bound to fibres and in this state is not expected to adversely impact on the environment.

The unfixed residues from dyeing operations will enter the aquatic environment after discharge from the dyehouse and subsequent treatment at the sewage treatment plants. As a result of the dye's low water solubility, high K_{ow} and hydrolytic stability, it is likely that significant quantities will be absorbed to the sludge.

The dye was tested for its biodegradability according to EEC method C6 (EEC Directive 84/449, [closed bottle test]). (The method was modified in that an inert carrier, glass filter paper, was used to maintain the sample in the test bottles). The resultant 14% degradation in 28 days, shows that the dye is not readily biodegradable but is likely to be inherently biodegradable.

The bioaccumulation potential of the dye was not investigated. It's probable inherent biodegradation and likely loss of the acetate by enzymatic degradation, giving a more polar compound, indicate that significant bioaccumulation should not occur. Further, compounds with a variety of functional groups have limited capacity to bioaccumulate (1).

9. EVALUATION OF TOXICOLOGICAL DATA

The Industrial Chemicals (Notification and Assessment) Act 1989 does not require toxicology data to be submitted on chemicals imported in quantities of < 1 tonne/year. Some tests have been conducted on the notified chemical and were submitted as part of the notification statement.

9.1 Acute Toxicity

Table 1 Summary of the acute toxicity of Disperse Red 370

Test	Species	Outcome
Acute Oral Toxicity	Rat	LD_{50} > 2000 mg/kg
Acute Dermal Toxicity	Rat	LD_{50} > 2000 mg/kg
Skin irritation	Rabbit	Slight irritant
Eye irritation	Rabbit	Slight irritant
Skin sensitisation	Guinea pig	Moderate sensitiser

Summary data but not the detailed reports were provided for some of the tests.

9.1.1 Oral Toxicity

The study was performed in accordance with OECD guideline No.401 (2).

Disperse Red 370 was administered orally to Sprague Dawley rats (5/sex/group) at a dose of 2000 mg/kg in arachis oil BP.

Two out of females died one day after dosing. Clinical signs observed were mainly lethargy and loss of righting reflex, and less commonly hunched posture, decreased respiratory rate, noisy respiration and ptosis. At necropsy, the dead females had haemmorhagic lungs and dark liver. Dark kidneys and/or dark livers were noted in 2 males at necropsy.

The data indicate that females may be more sensitive and the oral LD_{50} of Disperse Red 370 was > 2000 mg/kg.

9.1.2 Dermal Toxicity

This study was performed in accordance with Method B3 of Commission Directive 84/449/EEC (3).

Disperse Red 370 was applied to skin moistened with arachis oil BP vehicle to Sprague Dawley rats (5/sex/group) at a dose of 2000 mg/kg. This was covered by a semi-occlusive dressing. Exposure was for 24 hours.

No mortality was observed. No signs of dermal irritation, systemic toxicity or abnormalities at necropsy were observed.

It was concluded that the dermal LD_{50} of Disperse Red 370 to rats was > 2000 mg/kg.

9.1.4 Skin Irritation

This study was performed in accordance with method B4 of Commission Directive 84/449/EEC (3).

A single dose of 500 mg Disperse Red 370 (moistened with distilled water was applied by semi-occlusive application to three New Zealand White rabbits (sex not specified). Exposure was for 4 hrs. Skin reactions were assessed for 72 hrs after removal of the chemical. Site of application and preparation of the application site were not described.

Very slight erythema (3/3 animals) and/or oedema (1/3 animals) were observed. One animal had desquamation 7 days after treatment.

It was concluded that Disperse Red 370 is a slight skin irritant.

9.1.5 Eye Irritation

This study was performed in accordance with Method B5 of Commission Directive 84/449//EEC (3).

A single dose of 0.62 g of Disperse Red 370 was given to New Zealand White rabbits. No details were provided on which eye was treated with dye, as well as site and method of application. Vehicle used was not specified. Eyes were examined for 72 hours.

Draize scores for conjunctival redness and chemosis, corneal opacity and iridic irritation were less than or equal to one. Pink coloured staining prevented accurate evaluation of iridial effects in two treated eyes one hour after treatment and after 24 and 48 hours.

The results of the study indicate that Disperse Red 370 is slightly irritant to the eye in rabbits.

9.1.5 Skin Sensitisation - Disperse Red 370

This study was performed in accordance with Method B6 of Commission Directive 84/49/EEC and OECD Guideline No. 406 (4).

The Magnusson and Kligman maximization test (5) was used. Test animals used were female albino Dunkin-Hartley guinea-pigs (20 in test group and 10 in negative control group).

In the preliminary sighting test no irritating effects were observed at up to 10% w/v in arachis oil BP after intradermal administration. After topical application of 25% w/w in arachis oil over 48 h, a maximum grade of 1 was noted at 24 h and 48 h, while after topical application of 5% w/w in arachis oil no dermal irritation was observed.

Based upon initial sighting tests, the following concentrations of chemical and vehicle were chosen for the induction steps:

a) intradermal induction	10% (w/v) in arachis oil BP 10% (w/v) in Freund's Complete Adjuvant plus arachis oil BP in a ratio of 1:1
b) topical induction	25% (w/v) in arachis oil

The concentration of chemical used in topical challenge was 5% in arachis oil.

Staining prevented evaluation of irritation reactions in all test group skin sites during induction. Controls revealed no treatment-related effects.

After challenge 8/20 test animals showed sensitisation at both the 24 and 48 hour observations. Seven test animals had desquamation at 48 hours, while 4 animals had oedema at both 24 and 48 hour observation points.

Based upon a 40% sensitisation rate, Disperse Red 370 is classified as a moderate skin sensitizer.

9.1.6 Skin Sensitisation - Serilene Red FB-LS Blend 1RY (6)

This study was performed in accordance with Method B6 of Commission Directive 84/49/EEC (3) and OECD Guideline No. 406 (4). GLP and QA statements were provided.

The Magnusson and Kligman maximization test (5) was used. Test animals used were female albino Dunkin-Hartley guinea pigs (20 in test group and 10 in negative control group). The study used a

preparation termed Serilene Red FB-LS Blend 1RY which contained the dye at a concentration of 30-35%.

Based upon initial sighting tests, the following concentrations of chemical and vehicle were chosen for the induction steps:

a) intradermal induction	25% (w/v) in distilled water 25% (w/v) in Freund's Complete Adjuvant plus distilled water in a ratio of 1:1
b) topical induction	50% (w/w) in distilled water

The concentrations of chemical used in topical challenge were 5% and 10% w/v in distilled water.

Induction

On day 1 animals were injected intradermally (on either side of the midline of a clipped area of the shoulder area) with FCA: distilled water (1:1), 25% (w/v) dilution of Disperse Red 370 in distilled water and a 25% (w/v) dilution of Disperse Red 370 in a 1:1 preparation of FCA:distilled water. On day 7, the same area was treated with a topical application of Disperse Red 370 (50% w/v in distilled water). The test material was applied on filter paper and held in place by an occlusive dressing for 48 hrs. Skin reactions were assessed by the Draize method 24 and 48 hrs after patch removal. Controls were treated according to the same procedure but without Disperse Red 370.

Due to staining no accurate evaluation of reactions was possible during the induction period. Dense red coloured staining was noted at the induction site of all test animals. No adverse reactions were noted in controls.

Challenge

On day 18 one test animal was killed due to the presence of an open wound.

On day 21, a filter paper patch coated with Disperse Red 370 (5% and 10% w/w in distilled water) was applied to clipped right flanks of test and control animals. The left flank was clipped and treated with vehicle alone. The patches were occluded for 24 h and sensitisation reactions were assessed 24 h and 48 h after patch removal.

Body weight gain of one test animal was decreased during the study.

Red staining at challenge sites did not prevent evaluation of results.

After application of 10% w/v Disperse Red 370, a positive skin reaction (grade 1) was noted in one test animal at the 24 and 48 hr observation points and desquamation was noted in one test animal at the 48 hr observation point. At the 5% w/w Disperse red 370 application sites desquamation was noted in two test animals. No adverse reactions were noted at the vehicle control sites of either test or control animals.

The results of the study indicate that Serilene Blend FB-LS Blend 1RY has a weak skin sensitisation potential in guinea-pigs as it produced a 5% (1/19) sensitisation rate. According to the Approved Criteria (7) a chemical is classified a skin sensitiser if it produces a response in at least 30% of the animals tested by the adjuvant-type test method.

9.2 Repeated Dose Toxicity (8)

14 Day Dose Range Finding Study

Sprague Dawley rats (3/sex/group) were given Disperse Red 370 in arachis oil BP orally at doses of 0, 150, 400 or 1000 mg/kg for 14 days. Clinical signs, body weights, clinical chemistry and haematology were monitored during the study. Gross necropsy was performed at the end of the study.

No mortalities were recorded during the study.

Lethargy was observed in all high dose (HD) males and one HD female on day 1. The other two HD females exhibited more toxic signs on day 1 including hunched posture, pilo-erection, body tremors, ataxia and increased respiratory rate, while on day 2 they exhibited exophthalmos. All signs were transient. Pink coloured extremities were observed at all dose levels but this phenomenon is not of toxicological significance. HD animals also had dark urine and faeces and showed increased salivation.

Gross necropsy showed pink staining of the glandular and non-glandular portions of the stomach and of the adipose tissue. Histopathology was not performed.

28 Day Study

This study was performed in accordance with the recommendations of the OECD guidelines for testing of chemicals No. 407 (9). QA and GLP statements were provided.

Sprague Dawley rats (5/sex/group) were given Disperse Red 370 in arachis oil BP PO at doses of 0, 15, 150 or 1000 mg/kg for 28 days. Doses chosen in this study were based upon the 14 day dose range finding study described above. Clinical signs, body weights, clinical chemistry and haematology were monitored during the study. Gross necropsy and histopathology were performed at the end of the study.

Unless stated no treatment-related effects were observed in low dose (LD) animals during the study.

Dose-dependent clinical signs were observed in MD and HD animals on day 1. These were lethargy, loss of righting reflex, ataxia, decreased respiratory rate, pilo-erection, chromodacryoorrhoea, vocalization and tremors. Pink colored extremities were observed from day 2 in MD and HD animals and from day 8 in LD animals. HD animals had dark urine and faeces and also exhibited increased salivation.

HD males had slightly reduced bodyweight gain in comparison to females. All other animals had comparable weight gains to controls. Food and water consumption were not affected by treatment.

Haematology was not affected by treatment.

Clinical chemistry revealed significant increases in alanine aminotransferase and bilirubin levels in MD and HD animals in comparison to controls. MD and HD females also had elevated plasma albumin levels, while HD females also had elevated total protein.

Necropsy revealed that MD and HD animals had dark livers and pink staining of internal organs including prostate gland, sciatic nerve, brain, testes and non-glandular portions of the stomach. All animals had pink staining of the adipose tissue.

MD and HD animals had increased liver weights, both absolute and relative to bodyweight.

Histopathology revealed dose-dependent effects in severity in the liver of MD and HD animals characterised by inflammatory cell infiltrates, focal hepatocyte necrosis, centrilobular hepatocyte vacuolation, increased hepatocytoplasmic and hepatocyte enlargement. Increased inflammatory cell infiltration was observed in some LD animals, being associated with focal hepatocyte necrosis in 2 males and with hepatocyte enlargement in one female. Increased inflammatory cell infiltration was observed in some LD animals, being associated with focal hepatocyte necrosis in 2 males and with hepatocyte enlargement in one female. The observed gross and histopathological changes in the liver reflected the results of the clinical chemistry.

The NOEL in rats was not established in this study as liver effects were observed at the lowest dose used. It was concluded that Disperse Red 370 produces toxic effects and the major organ of toxicity is the liver.

9.3 Genotoxicity

9.3.1 Salmonella typhimurium Reverse Mutation Assay

This study was performed in accordance with Method B14 of Commission Directive 84/449/EEC (3). The report provided consisted only of a summary.

Disperse Red 370 was tested in the *Salmonella typhimurium* Reverse Mutation Assay using the plate incorporation procedure in the test strains TA 98, TA 100, TA 1535, TA 1537 and TA 1538 with or without metabolic activation. It was not stated how often each experiment was performed.

Concentration ranges used in the test were as follows:

.	with metabolic activation:	experiment 1	8-5000 µg/mL
		experiment 2	156.25-5000 µg/mL
.	without metabolic activation:	experiment 1	8-5000 µg/mL
		experiment 2	156.25-5000 µg/mL

Toxicity was observed for TA 98 only at > 5000 µg/mL in the presence of metabolic activation and > 2500 µg/mL in the absence of metabolic activation.

No increases in number of revertant colonies were observed for any bacterial strain at any dose used either in the presence or absence of metabolic activation. The positive controls (not specified) gave the appropriate responses.

Under the conditions of this assay Disperse Red 370 is not considered to be mutagenic.

9.3.2 Chromosome Aberrations in Human Lymphocytes

This study was performed in accordance with Method B10 of the Commission Directive 84/449/EEC (3).

Lymphocyte cells were exposed to the following concentration ranges of Disperse Red 370:

. in the presence of metabolic activation: 78.13 to 312.5 µg/mL (20 h harvest) and 625 to 2500 µg/mL (30 h harvest); exposure time was 4 h

in the absence of metabolic activation: 39 to 156.24 µg/mL; exposure time was 20 h

With metabolic activation toxicity was observed at 312.5 µg/mL (20 h harvest) and at 2500 µg/mL (30 h harvest). Without metabolic activation, toxicity was observed at 78.1 µg/mL and above. No increase in chromosome aberrations was observed at any dose of Disperse Red used or in controls either in the absence or presence of metabolic activation.

The positive controls produced increases in the frequency of aberrations as expected.

Based upon the results of this assay Disperse Red is not classified as clastogenic in human lymphocytes *in vitro*.

9.4 Overall Assessment of Toxicological Data

Based upon acute toxicity testing Disperse Red 370 has low acute oral and dermal toxicity in the rat (LD_{50s} > 2000 mg/kg). It had slight skin and eye irritant potential based upon studies in the rabbit.The

data submitted indicated that Disperse Red 370 is a skin sensitiser and the formulated product Serilene Red FB-LS, had skin sensitisation potential in guinea-pigs. In a 28 day oral toxicity study in rats, the major target organ of toxicity was the liver. No other toxic effectes were noted. Pink staining of the internal organs is to be expected after administration of a highly coloured substance and is of no toxicological significance.

Genotoxicity studies *in vitro* indicated that Disperse Red 370 had no mutagenic potential. No *in vivo* genotoxic studies were performed.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

While not required under the *Act* for chemicals imported at levels <1 tonne, ecotoxicity tests were performed using Serilene Red FB-LS dye and the results (table 2) were provided by the notifier. No precipitates or other irregularities were noted in these tests. Two fish test results were presented by the notifier, both using rainbow trout, one a summary report and the other a complete report (tests done by Safepharm Laboratories Ltd and Binnie Environmental Ltd respectively). Nominal concentrations were used as the measured concentration (by spectrophotometry) were within 2.1% of nominal values for the fish (Safepharm) and 8% of nominal for the daphnia studies. These tests were performed in accordance with standard OECD test methods and at facilities complying with OECD principles of GLP.

Table 2: Ecotoxicity Studies
Nominal concentration; * not analysed

Species	Test	Result
Rainbow Trout, *Oncorhynchus myfiss*	96 hour acute TG 203 (performed by Binnie)	NOEC = 5.6 mg/L* LC_{50} = 11mg/L*
Rainbow Trout *Oncorhynchus myfiss*	96 hour acute TG 203 (performed by Safepharm)	NOEC = 0.18 mg/L LC_{50} = 1.3 mg/L
Daphnia *Daphnia magna*	48 hour immobilisation TG 202	NOEC = 1.0 mg/L EC_{50} = 3.5 mg/L
Waste water bacteria	EEC Commission Directive 87/302, A5/3	NOEC > 1000 mg/L

The above results show that Serilene Red FB-LS is moderately toxic to fish and daphnia.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

As indicated above, 95-98% of the dye is fixed in the dyeing process, thus 5% of the dye used could be discharged into effluents of the dyehouses where it is used. The notifier has calculated the concentration of discharge for three model dyehouses, a country dyehouse directly discharging to waterway, a metropolitan based dyehouse discharging to a municipal treatment works and the other city based discharging to a municipal treatment works with biological treatment. These were chosen to represent a range of situations. The following calculations are those provided by the notifier and are based on the use of the notified dye for only 7.5 weeks in the year (approximately 40 days):

Use of Disperse Red 370 per year	= 1000 kg of dye (3.03 tonnes of blender powder)
Number of dyehouses	4
Amount of dye used per day per dyehouse	= 6.67 kg
Quantity of fabric dyed per day	3335 kg
Volume of water used	200,000 L
Fixation rate	98%
Country dyehouse direct discharge	0.67 mg/L
Metropolitan Based 1:10 dilution in treatment works	0.067 mg/L
City Based 1:10 dilution in treatment works and 50% biodegradation	0.034 mg/L

The calculations do not allow for dilution from other waste streams in the dyehouse and only have a nominal dilution in the treatment works of 1:10. The calculations listed below are based on the above but have a fixation rate of 95% and include additional dilution factors due to dyehouse waste waters, treatment plant discharges and volume of receiving waters.

Fixation rate	95%	
Total volume of dyehouse wash waters:	Rural City	= 1,500,000 L = 3,000,000 L
Effluent concentration	Rural City	= 0.22 ppm = 0.11 ppm
Rural treatment plant 5 ML per day		= 66 ppb (100% discharged),
City based 290 ML per day		= 0.6 ppb (100% discharged)
Inland waterway (3:1 dilution) rural		= 33 ppb
Ocean discharge from city (10:1 dilution)		= 0.06 ppb

These calculations are based on no removal of Disperse Red 370 in the sewage treatment plant and therefore should be considered worst case. Due to its low water solubility (<1mg/L) and high partition coefficient (log P_{ow} = 4.38), significant sorption to the treatment works sludge can be expected which will significantly reduce the concentration of the dye. The calculations give expected environmental concentrations significantly below the LC_{50} for fish (1.3 mg/L, Safepharm) and daphnia (3.5 mg/L) and unlikely to significantly affect algae. Prolonged direct discharge of dyehouse effluent to waterways may cause environmental effects and should be avoided. The dye is not expected to bioaccumulate.

Spills of the dye should not present an environmental hazard when cleaned up according to the MSDS recommendations.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Disperse Red 370 is a powder with a partition coefficient of 4.38, and low fat solubility and is unlikely to accumulate in biological tissue. The mean particle size is 15 µm with a range of 12 - 150 µm. The potential for entering the lungs is therefore low.

Based on animal tests, Disperse Red 370 is likely to be of low oral and dermal toxicity in humans. Disperse Red 370 is a skin sensitiser in guinea-pigs while the product Serilene Red FB-LS was found not to be a sensitiser in animal studies. In a 28 day oral toxicity study in rats, the major target organ of toxicity was the liver. *In vitro* genotoxicity studies indicated that Disperse Red 370 had no mutagenic potential. No *in vivo* genotoxicity studies were performed.

Exposure could occur during the weighing process but local exhaust ventilation is normally used and the potential for exposure is low. During preparation of the aqueous dye dispersion the dye powder is gradually added to hot water with the help of an impeller. The workers will be exposed to the chemical for 20 mins/day, 40 days/year. The dyehouse operators will be using the dye in closed systems. Some machines expose the aqueous dye dispersion to the atmosphere. However the chemical is not volatile and exposure is not expected to occur.

Under the conditions described by the notifier, Disperse Red 370 presents a low risk to those working with the chemical.

Public exposure to the notified chemical is not expected to occur during its distribution by road to dyehouses or during the reformulation or repackaging of Serilene Red FB-LS
While public contact with Disperse Red 370 may be significant, it is bound to the synthetic fibres, and therefore, public exposure levels are expected to be low. On the basis of the low public exposure levels anticipated and the toxicity of Disperse Red 370, Disperse Red 370 is not expected to present a significant toxicological hazard.

13. RECOMMENDATIONS

To minimise occupational and environmental exposure to Disperse Red 370 the following guidelines and precautions should be observed.

If engineering controls and work practices are insufficient to reduce exposure to a safe level, the following personal protective equipment should be used:

. respiratory protection conforming to Australian Standard 1715 (10) and Australian Standard 1716 (11);

. chemical-type goggles conforming to Australian Standards 1336 (12) and 1337 (13);

. impervious gloves conforming to Australian Standard 2161 (14); and

. protective clothing conforming to Australian Standards 3765.1 (15) or 3765.2 (16).

. Good work practices should be implemented to avoid generation of dust and liquid spills.

. Spills should be cleaned up promptly.

. Good personal hygiene practices, such as washing of hands prior to eating food, should be observed.

. A copy of the Material Safety Data Sheet for products containing the notified chemical should be easily accessible to all employees.

. The dye should not be used in dyehouses that directly discharge to waterways. Effluent containing the dye should be treated at treatment plants.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the product Serilene Red FB-LS (Attachment 1) was provided in Worksafe Australia format (17). The MSDS was provided by Yorkshire Australia Pty Ltd as part of their notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of Yorkshire Australia Pty Ltd.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989*, secondary notification of Disperse Red 370 shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

16. REFERENCES

1. Connell, D.W., *Bioaccumulation of Xenobiotic Compounds*, CRC Press, Boca Raton, Florida, 1990.

2. OECD Guidelines for Testing of Chemicals - *Acute Oral Toxicity* No: 401, 1987.

3. EEC Methods for the Determination of Toxicity, Directive 84/449/EEC (OJ No. L251, 19.9.84)

4. OECD Guidelines for Testing of Chemicals - *Skin Sensitisation* No: 406, 1992

5. Magnusson, B. and Kligman, A.M., *Allergic Contact Dermatitis in the Guinea-pig*. Thomas Publ., USA 1970.

6. *Serilene Red FB-LS Blend 1RY: Magnusson & Kligman Maximisation Study in the Guinea-Pig.* Data on file. Safepharm Laboratories Ltd, U.K. Project No 27/153, April 1992.

7. Worksafe Australia, March 1994, Approved Criteria for Classifying Hazardous Substances [NOHSC:1008 (1994)], Australian Government Publishing Service, Canberra.

8. *Serilene Red FB-LS Blend 1RY: Twenty-eight Day Subacute Oral Toxicity Study in the Rat.* Data on file. Safepharm Laboratories Ltd, U.K.Project No.27/144, November 1991.

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