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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Red JB 747

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Red JB 747

1. APPLICANT

Clariant (Australia) Pty Ltd of 675 Warrigal Road CHADSTONE Victoria 3148 has submitted a standard/limited notification statement in support of their application for an assessment certificate for Red JB 747.

2. IDENTITY OF THE CHEMICAL

Red JB 747 is considered to be hazardous based on the nature of the chemical and the data provided. The chemical name, CAS number, molecular and structural formulae, molecular weight and spectral data have been exempted from publication in the Full Public Report and the Summary Report on the following basis:

- A descriptive generic name be used to identify the substance in public reports and the Material Safety Data Sheet (MSDS),
- The relevant employee unions shall be informed of the conditions of use of Red JB 747,
- 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,
- The chemical be identified as Red JB 747 in the Health Effects Section of the MSDS, and that reference to its assessment by NICNAS be made on the MSDS,

These conditions shall be published in the Chemical Gazette.

Other Names:	Red JB 747
Trade Name:	Sandoderm Red G Liquid (contains 15% of the notified chemical)

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	dark red powder

Melting Point:	> 300°C (decomposed)
Density:	1.67 g/cm^3 at 21°C
Vapour Pressure:	6 x 10^{-37} kPa at 25°C
Water Solubility:	32 500 mg/L at 20°C
Surface Tension:	54.6 mN/m at 22±0.5 °C (surface active)
Partition Co-efficient (n-octanol/water):	log P_{ow} -2.9 at 22°C
Hydrolysis as a Function of pH:	$T_{1/2}$ at pH 4.0 at 25°C > 1 year $T_{1/2}$ at pH 7.0 at 25°C > 1 year $T_{1/2}$ at pH 9.0 at 25°C > 1 year
Particle Size Distribution	31% < 2 μm (NB only imported as liquid)
Flammability Limits:	could not be ignited with a flame
Autoignition Temperature:	299°C
Explosive Properties:	not explosive (flame)

Comments on Physico-Chemical Properties

The vapour pressure result is estimated on a calculated boiling point; an estimate based on the decomposition temperature resulted in a value of less than 9.2 x 10^{-6} kPa at 25°C; either way the vapour pressure is negligible and is unlikely to have any relevant effect on the environment.

Adsorption/desorption data were not submitted; the dye is expected to have a low affinity for soil and sediment due to the high water solubility and low partition coefficient. The dye is expected to have a high degree of dissociation in water; the notified chemical has a high water solubility and is considered to be surface active. It can be assumed that the molecule will dissociate close to 100% in the pH range 4-9. By definition, a chemical has surface activity when the surface tension is less than 60mN/m (3). This indicates that the chemical has the potential to adsorb to soil/sediment, in spite of high water solubility.

The notified chemical has no reactive groups that could support an oxidation and is not considered reactive.

4. PURITY OF THE CHEMICAL

Degree of Purity: 88 (80-95)%

Additives/Adjuvants: none

5. USE, VOLUME AND FORMULATION

The chemical is a dyestuff used for dyeing leather. It will be imported as an aqueous solution containing 15% of the notified chemical; the formulation is called Sandoderm Red G Liquid. The notified chemical has also been notified in Europe and is made in Spain by Clariant Productos, S. A.

The quantity of the formulation, Sandoderm Red G Liquid, to be imported over the next five years is 4 tonnes per year this equates to 0.65 tonnes of the notified chemical each year.

6. OCCUPATIONAL EXPOSURE

The notified chemical is imported as a component of a liquid dye formulation Sandoderm Red G Liquid. Exposure during transport and warehousing will not normally occur as there is no repackaging or reformulation, exposure is only likely in the event of accidental spillage.

The dye formulation will be supplied direct to three tanneries in plastic drums. At each tannery three workers will potentially be exposed to the notified chemical for periods of one hour/week. This will occur during the following processes:

- decanting and weighing dye
- addition to mixing vessel
- handling of wet skins
- maintenance and cleaning of dye drums and associated equipment

There will be contact with the dye on the dyed skins. The notifier has stated that once the skins are dried the dye will be chemically bound to the substrate. The leather will be used in applications such as furniture making, here the exposed leather will be further treated with resin, this will reduce direct contact with the dye in the finished product.

As the notified chemical will only be imported in a liquid formulation the likelihood of inhalational exposure will be reduced. Inhalational exposure can still occur if mists are produced, this would only occur under certain conditions such as leaks from a pressurised system. The low vapour pressure of the notified chemical indicates that inhalational exposure from the liquid formulation is unlikely. The main exposure pathway will be via the skin. There is also the possibility of eye contact through splashing of the dye.

7. PUBLIC EXPOSURE

Sandoderm Red G liquid will be used at tanneries to dye upholstery leather. The product will not be available to the public directly. Dyed leather is covered by a resin coating on the outer side. Although widespread contact by the public with leather dyed with the product can be expected, in most circumstances direct skin contact will be limited by clothing and, as the dye has a molecular weight of 1477, is chemically bound to the leather and sealed by the resin coat, the biological availability of the dye will be minimal.

Sandoderm red G liquid is packed in plastic drum containers and will be transported throughout Australia primarily by road. In the event of a transport accident the notified chemical is unlikely to be widely dispersed and can be readily recovered with absorbent materials, for subsequent disposal as normal landfill. As the product is an aqueous solution, leaching into waterways is possible, however significantly contaminated water bodies are likely to be readily identifiable due to the nature of the notified chemical.

8. ENVIRONMENTAL EXPOSURE

Release

The notifier claims that a fixation rate of 90-95% is conservative, and the uptake is likely to be higher. A test report provided indicated that Sandoderm Red G Liquid has an exhaustion (fixation) rate of 98.7%. Manufacturer's details show the dye has an affinity number of 96 for high affinity leather. The affinity number expresses the percentage of applied dyestuff that is bound to the substrate in the first half of a defined dyeing process. The notified dye will be

used mainly for high-affinity leather.

Waste process water containing the dye goes to treatment plants on site, and effluent to the sewer is subject to water authority regulations.
The dye drums will be drained as completely as possible, and residues are estimated at < 100 mL. These drums will be consigned to landfill.

Fate

The bulk (> 90% fixation) of the dye will become chemically bound to the leather and in this state is not expected to impact on the environment. Some minor losses to the environment might occur through spills at the warehouse, during transit, or at the tannery. The major route for environmental release has been identified as the unfixed dye that has been washed from the treated leather.

These unfixed residues (< 10%) will enter the aquatic environment after discharge from the tannery and subsequent treatment at sewage treatment plants. The exact fate of the dye residues is unclear, due to uncertainties relating to the degree of sorption onto sediments.

After entering the sewage works, unfixed residues may be removed through degradation (chemical or biological) or sorption to sludge. In view of the high water solubility, it is likely that significant quantities of the dye will remain in the aquatic compartment. However, the dye's surface activity will increase its adsorption potential, any dye partitioned to the sediment will be removed with the sludge during treatment at the dyehouse and sewage works. While azo dyes are generally stable under aerobic conditions, they are susceptible to reductive degradation under the anaerobic conditions characteristic of sediment (4).

Biodegradation

The dye was tested for its ready biodegradability in the "Manometric Respirometry Test". The biodegradation of the test article was determined by exposing it to activated bacterial sludge from a domestic waste water sewage plant. The notified chemical appeared to be not readily biodegradable within 28 days as the amount of oxygen taken up by the microbial population during biodegradation of the notified chemical was about equal to the amount taken up during biodegradation of the inoculum blank. No inhibitory effect on the micro-organisms was observed.

The inherent biodegradability of the dye was tested in the Modified MITI-Test. It was shown that the oxygen demand of the inoculated and non-inoculated flasks with the notified chemical remained equal to or below the inoculum blanks throughout the exposure period. The dye was found not to be inherently biodegradable.

Bioaccumulation

The dye is unlikely to bioaccumulate due to its high water solubility (32.5 g/L) and low log P_{OW} (-2.9). Also, the dye's large molecular size is likely to inhibit membrane permeability and prevent uptake during exposure (5,6).

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of Red JB 747

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 2 000 mg/kg	7
acute dermal toxicity	rat	LD_{50} > 2 000 mg/kg	9
skin irritation	rabbit	not an irritant	10
eye irritation	rabbit	not an irritant	12
skin sensitisation	guinea pig	sensitiser	13

9.1.1 Oral Toxicity (7)

Species/strain:	Wistar rat (SPF)
Number/sex of animals M/F:	5/5
Observation period:	14 days
Method of administration:	gavage maximal dose 2 000 mg/kg
Clinical observations:	none
Mortality:	nil
Morphological findings:	nil
Test method:	according to OECD Guidelines for Testing Chemicals (8)
LD_{50}:	> 2 000 mg/kg
Result:	low acute oral toxicity

9.1.2 Dermal Toxicity (9)

Species/strain:	Wistar rat (SPF)
Number/sex of animals M/F:	5/5
Observation period:	14 days
Method of administration:	test article in distilled water applied to shaved skin and covered with a semi-occlusive dressing for 24 hours, then removed
Clinical observations:	no signs of systemic toxicity; discolouration of skin at application site persisted until day 6
Mortality:	nil

Morphological findings: nil

Draize scores (10): 0

Test method: according to OECD Guidelines for Testing Chemicals (8)

Result: LD_{50} > 2 000 mg/kg, low dermal toxicity

9.1.4 Skin Irritation (11)

Species/strain: New Zealand white rabbit

Number/sex of animals: 1M/2F

Observation period: 72 hours

Method of administration: 4 hour semi-occlusive dressing

Draize scores (10):

Time after treatment (days)	***Animal #***		
	1	***2***	***3***
Erythema			
1	[a]0	2	1
3	0	0	0
Oedema			
1	0	2	1
3	0	0	0

[a] see Attachment 1 for Draize scales

Test method: according to OECD Guidelines for Testing Chemicals (8)

Result: not classified as an irritant according to Worksafe Australia's *Approved Criteria for Classifying Hazardous Substances* (12)

9.1.5 Eye Irritation (13)

Species/strain: New Zealand white rabbits

Number/sex of animals: 1M/2F

Observation period: 72 hours

Method of administration: 0.1 g of test article placed in conjunctival sac of left eye of each rabbit

Draize scores (10) of unirrigated eyes:

	Time after instillation					
Animal	***1 day***		***2 days***		***3 days***	
Cornea	***o[a]***		***o[a]***		***o[a]***	
1	[1]3		0		0	
2	0		0		0	
3	0		0		0	
Iris						
1	1		0		0	
2	0		0		0	
3	0		0		0	
Conjunctiva	***r[c]***	***c[d]***	***r[c]***	***c[d]***	***r[c]***	***c[d]***
1	3	4	1	1	0	0
2	0	0	0	0	0	0
3	0	0	0	0	0	0

[1] see Attachment 1 for Draize scales
[a] opacity [c] redness [d] chemosis

Test method: according to OECD Guidelines for Testing Chemicals (8)

Result: not classified as an irritant according to Worksafe Australia's *Approved Criteria for Classifying Hazardous Substances* (12)

9.1.6 Skin Sensitisation (13)

Species/strain: albino Dunkin Hartley guinea pigs

Number of animals: 20/test, 10/control; all males

Induction procedure: induction, intradermal injections as follows:
1. Freund's Complete Adjuvant (FCA)/ physiological saline (PS)1:1
2. test article diluted to 5% with bidistilled water
3. test article diluted to 5% by emulsion in a 1:1 (v/v) mixture of FCA and PS
and control groups; on day 7 sodium lauryl sulfate (SLS) rubbed into test area; on day 8 a 25% solution in bidistilled water was used for the epidermal application as this was found to be the highest non-irritating concentration; this was via a filter paper applied to test site for 48 hours

Challenge procedure: on day 22 , 25% solution in bidistilled water applied to test area via a filter paper applied to test site for 24 hours

Challenge outcome:

Challenge concentration	Test animals		Control animals	
	*24 hrs**	*48 hrs**	*24 hrs*	*48 hrs*
25%	**14/20	12/20	0/20	0/20

* time after patch removal
** number of animals exhibiting positive response

Test method: according to OECD Guidelines for Testing Chemicals (8)

Result: sensitiser according to Worksafe Australia's *Approved Criteria for Classifying Hazardous Substances* (12)

9.2 Subacute 28 Day Repeated Dose Toxicity (15)

Species/strain: Wistar rat (SPF)

Number/sex of animals: 5/5 per dose group

Method of administration: gavage

Dose/Study duration:: 0, 50, 200, 1 000 mg/kg bodyweight/day

Clinical observations: 20% of high dose animals had ruffled fur in the first part of the treatment period; dose groups 200 and 1 000 mg/kg also had discoloured faeces

Clinical chemistry/Haematology dose groups 200 and 1 000 mg/kg had increased total bilirubin concentration; males in dose group 1 000 mg/kg had decreased haemoglobin, abnormalities in reticulocyte fluorescence ratio; both sexes of 200 and 1 000 mg/kg dose groups had increased reticulocyte counts;

Histopathology: in high dose groups increased splenic extramedullary haematopoiesis was observed at necropsy; in high dose groups females were found to have increased spleen and liver weights

Test method: according to OECD Guidelines for Testing Chemicals (8)

Result: haematological anomalies are considered treatment related and suggest methoglobinemia; increase in haematopoietic activity indicated by increase in reticulocytes; this relates to the increased spleen weight and infers that this is the target organ

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (16)

Strains:	TA98, TA100, TA1535, TA1537
Concentration range:	33.3 - 5 000 µg/ plate with and without liver microsomal activation
Test method:	according to OECD Guidelines for Testing Chemicals (8)
Result:	not mutagenic in this system

9.3.2 Chromosome aberration assay in Chinese Hamster V79 Cells *in vitro* (17)

Doses:	5-50 µg/ plate with and without metabolic activation; highest dosage was close to solubility limit in solvent DMSO; solvent controls (DMSO) and positive controls (without metabolic activation - ethylmethanesulfonate (EMS), with - cyclophosphamide (CPA))
Test method:	according to OECD Guidelines for Testing Chemicals (8)
Result:	not clastogenic; no increase in frequency of cells with polyploid metaphase compared to controls; positive controls and solvent controls gave appropriate response

9.4 Overall Assessment of Toxicological Data

The notified chemical had a low acute dermal and oral toxicity to rats with LD_{50} values greater than 2 000 mg/kg. Both the skin and eye irritation tests in rabbits resulted in evidence of irritation. In the dermal study this was evident in the first 24 hours following application of the notified chemical. In the eye irritation study the effects persisted for 48 hours. In both studies the effects were below the level requiring the notified chemical to be classified as hazardous according to Worksafe Australia's *Approved Criteria for Classifying Hazardous Substances* (12). The notified chemical is a skin sensitiser in guinea pigs with 70% of animals giving a positive response 24 hours after being challenged.

A 28 day sub acute feeding study in rats at doses upto 1 000 mg/kg/day produced a number of dose related effects. These included an increased total bilirubin concentration. Males from the highest dose group had decreased haemoglobin, decreased HFR and LFR reticulocyte fluorescence ratio; both sexes in the 200 and 1 000 mg/kg dose groups had increased reticulocyte counts. The haematological results suggest methoglobinemia and an increase in haematopoietic activity, the later indicated by increase in reticulocytes. The spleen is the likely target organ; this is supported by the increased spleen and liver weights which were found in the high dose females. Other supporting histopathological evidence was found in high dose groups, increased splenic extramedullary haematopoiesis was observed.

In two genotoxicity studies the notified chemical was found to be non-mutagenic (Ames test) and non-clastogenic (Chinese hamster V79 cells chromosome aberration test).

On the basis of the sensitisation study the notified chemical would be classified as hazardous according to Worksafe Australia's *Approved Criteria for Classifying Hazardous Substances* (12).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicological data are required for chemicals with import volumes < 1 tonne per year according to the Act. However, the notifier has provided ecotoxicity test reports as outlined in Table 1.

Tests were performed according to OECD test guidelines (algae test modified - see below) at facilities complying with OECD Principles of Good Laboratory Practice. Test media were slightly coloured by the notified chemical at the lowest concentration tested (1.0 mg/L nominal). This may have hampered observations.

Test	Species	Results (mg/L)
Acute Toxicity (semi-static)	Rainbow Trout *Oncorhynchus mykiss*	96 h LC_{50} >77.3 [a,b] (nominal: 100)
Acute Immobilisation (static)	Water Flea *Daphnia magna*	48 h EC_{50} >100 [c,d,e]
Growth Inhibition [f] (static) - Area (I_A) (= b, biomass) and Growth Rate (I_m)	Algae *Scenedesmus subspicatus*	Experiment A [a,g] 72h E_bC_{50} = 29.5 72h E_mC_{50} = 119.1 [h] Experiment B [a,g] 72h E_bC_{50} = 48.5 72h E_mC_{50} = 154.6 [h]
Respiration Inhibition [i]	Aerobic Waste Water Bacteria	30 min EC_{50} > 100

a. Reported biological results are related to the nominal test concentration as well to the mean measured test substance concentrations; **b.** Nominal concentrations of 4.6, 10, 21, 46 & 100 mg/L. Analytically determined test substance concentrations in the freshly prepared test media varied in the range from 86.4% to 120.1% of the nominal values. However, during the test medium renewal periods of 48 hours, the test concentrations had decreased to a range from 58.0% to 116.7% of the nominal (due to sedimentation); **c.** Reported biological results are related to the nominal concentration of the test substance; **d.** Analytically determined test substance concentrations in the test medium decreased from 100.7% in the samples from the freshly prepared test medium to 83.1% of the nominal after 48 hours (due to sedimentation). However, all measured values were higher than 80% of the nominal, and the mean value of the measured concentrations at the start and the end of the test amounted to 91.9% of the nominal value; **e.** No toxic effects to Daphnids up to the concentration of nominal 100 mg/L were identified in the limit test, thus the only concentration tested was nominal 100 mg/L; **f.** This test was modified to differentiate between a reduced growth of algae due to real toxic effects of the notified chemical on the algal cells (Experiment A) and that due to an indirect effect only, namely a reduced algal growth by light absorption in coloured test solutions (Experiment B) - see text for more details; **g.** Nominal test concentrations were 1.0, 3.2, 10.0, 32.0 & 100 mg/L. Analytically determined test concentrations in the freshly prepared test media varied from 85.0% to 92.6% of the nominal values. However, after 72 hours, lower test concentrations were found (57.8% to 80.4% of the nominal values); **h.** The EC_{50}-value should be taken with caution, because the inhibition of m exceeds in none of the tested concentrations 50% (*ie* figures represent extrapolation of curve to 50%); **I.** Respiration rate is the oxygen consumption of aerobic sludge or waste water micro-organisms, expressed as "mg O_2./L/min".

The ecotoxicity data for the substance shows that the dye is at worst slightly toxic to rainbow trout and practically non-toxic to water fleas; which is consistent with the high water solubility and high molecular weight of the chemical.

The company performed a modified algae growth test. In one experiment (Experiment B), the dye was not incorporated in the algal culture medium, but was interpolated between the light source and the culture dish; this allows assessment of the effect of light quality and quantity (due to the dye) on the algae. In the second experiment (Experiment A), the dye is actually included in the algal culture medium; the effects on algae here will be due to both light and any direct chemical toxicity.

Impacts on algal growth were measured as 'percentage inhibition area' (under the growth curve) (I_A) (= b, biomass) and 'percentage inhibition growth rate' (I_m) (= m, length). A somewhat higher inhibition effect on the algal growth was observed in Experiment A, implying that the effects on algal growth were due both to direct chemical toxicity, and to changes in the quality or quantity of light. This is reflected in lower EC_{50}-values in Experiment A. Analysis of the results from Experiments A & B shows that the growth inhibition effects were caused, in a high degree, due to the deterioration of light quantity or quality reaching the algae.

The notified chemical was found to have practically no inhibition on the respiration rate of aerobic waste water bacteria (in activated sludge) when exposed to test article concentrations of 3.2 to 100 mg/L. The 30 min-EC_{50} is reported as $\geq$ 100 mg/L.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

As indicated above, 90-95% of the dye is fixed in the dyeing process, thus 5-10% of the applied dye could be discharged into effluents at the tanneries where it is used. The notifier has calculated a worst case environmental release concentration when the dye is used alone. Dyeing of 600 kg of leather at a dye concentration of 7% involves the following steps:

Process	Volume (L)
Wash	1 500
Neutralise	900
Wash	1 500
Dyeing	1 500
Wash (x2)	3 000
	8400

Dye Addition Rate 7%: 42 kg (600 kg x 7%)

Fixation: 90%

Concentration of Active Dye: 16.4%

Thus

42 kg is used in the dyeing process, with 4.2 kg lost to waste water:

$$\frac{4.2 \text{ kg (Sandoderm Red G Liquid)} \times 16.4\%}{8400 \text{ L (total volume)}} = 82 \text{ ppm}$$

Further dilution of 1:10 is likely to occur in the on-site waste water treatment plant. Therefore, dye lost to the sewerage system is estimated to be ~8.2 ppm for this dyeing process.

As two of the tanneries are located in metropolitan regions where the sewerage flow is greater than 100 ML/day, the dye lost to the sewer system will be further diluted to ppb levels. Further dilution will occur in the receiving waters in the order of 1:10 (ocean outfall), resulting in an estimated environmental concentration (EEC) for the dye of 0.69 ppb.

The dye in waste water from the third tannery, located in a town in country Victoria (where the EPA has estimated the sewage flow to be 3 ML/day[1]), is expected to be further diluted to 0.23 ppm. Further dilution will occur in receiving waters in the order of 1:2 (river outfall), resulting in an EEC for the dye of 0.11 ppm.

It has been assumed in these calculations that no removal of the dye would take place during the wastewater treatment process. However, some of the dye would probably be removed due to possible complexation of the dye (18). Also, a high dye addition rate (7%) and low fixation rate (90%) have been used. More typical rates would be 5.5% and 96% respectively. In any event, the dye's high solubility suggests that once released to the waterways, dilution would be expected to swiftly reduce the environmental concentration to undetectable levels.

As the EECs are several orders of magnitude lower than the acute toxicity values for fish, aquatic invertebrates and algae, it is unlikely that the dye will present a hazard to the environment.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified chemical will be used as a leather dye, it will be imported in a liquid formulation containing 15% of the notified chemical. The notified chemical is highly water soluble and has a low octanol/water partition coefficient; it is therefore unlikely to bioaccumulate. As the molecular weight of the notified chemical is greater than 500 Daltons absorption across biological membranes such as skin is unlikely.

The notified chemical is classified as hazardous on the basis of guinea pig sensitisation studies, where a high proportion of the animals tested responded positively when challenged. In addition it should be noted that although the notified chemical would not be classified as hazardous according to Worksafe Australia's *Approved Criteria for Classifying Hazardous Substances* (12) on the basis of eye and skin irritation studies in rabbits, there were effects indicating that it has irritant potential. In acute dermal and oral toxicity studies it had a low toxicity, however in sub acute studies in rats it was found to produce systemic dose related effects with the likely target organ being the spleen. In two *in vitro* genotoxicity studies there was no evidence of mutagenic or clastogenic effects.

The dye is used in tanneries to dye hides. In total nine personnel will be potentially exposed for periods of one hour/week. Exposure will occur during the decanting and measuring procedures, during addition to the dye baths, when handling dyed skins and during maintenance and cleaning. The notifier has indicated that the dye is chemically bound to the substrate once the hides are dried, this would infer that workers using the dyed hides will have only limited exposure to the notified chemical. The greatest exposure will occur during the dyeing process when handling the concentrated formulation. The low vapour pressure of the notified chemical and the formulation (liquid) indicates that the main routes of occupational exposure are likely to be via the skin. Inhalational exposure is unlikely unless mists are formed. Eye contact could occur in the event of splashing.

The sensitisation potential of the notified chemical and the mode of usage indicate that occupational exposure through dermal exposure should be minimised. In the event of continued exposure there is the potential for employees to become sensitised to the notified chemical with resultant health effects.

The dye is strongly bound to the treated leather which is subsequently coated with a protective resin on its upper surface. As a consequence of the properties of the chemical and its intended application, significant exposure of the public to the free chemical under normal circumstances is unlikely.

[1] Calculated from a town population of approximately 20 000 with a 150 L/day/person.

13. RECOMMENDATIONS

To minimise occupational exposure to Red JB 747 the following guidelines and precautions should be observed:

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (19) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (20);
- Industrial clothing should conform to the specifications detailed in AS 2919 (21) and AS 3765.1 (22);
- Impermeable gloves or mittens should conform to AS 2161 (23);
- All occupational footwear should conform to AS/NZS 2210 (24);
- Spillage of the notified chemical should be avoided, spillages should be cleaned up promptly with absorbents which should then be put into containers for disposal;
- Good personal hygiene should be practised to minimise the potential for ingestion;
- A copy of the MSDS should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (25).

This MSDS was provided by the applicant as part of the notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, secondary notification of the notified chemical 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. National Occupational Health and Safety Commission 1994, *List of Designated Hazardous Substances* [NOHSC:10005(1994)], Australian Government Publishing Service Publ., Canberra.

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3. European Economic Community (EEC), EEC Directive 92/69, Annex V, Part A, *Methods for the determination of physico-chemical properties*, A.5 "Surface Tension" EEC Publication No. L383. December 1992.

4. Yen, C.P., Perenich, T.A., and Baughman, G.L. 1991. "Fate of Commercial Disperse Dyes in Sediments". *Environmental Toxicology and Chemistry,* 10: 1009-1017.

5. Anliker, R., Moser, P. & Poppinger, D. 1988, "Bioaccumulation of dyestuffs and organic pigments in fish. Relationships to hydrophobicity and steric factors". *Chemosphere* 17(8): 1631-1644.

6. Gobas, F.A.P.C., Opperhuizen A. & Hutzinger O. 1986, "Bioconcentration of hydrophobic chemicals in fish: relationship with membrane permeation". *Environmental Toxicology and Chemistry* 5: 637-646.

7. Crouch, C. N. 1994, Acute oral toxicity study with Red JB 747/PP in rats. Project No. 364678. Research and Consulting Ltd, Itingen, Switzerland.

8. Organisation for Economic Co-operation and Development, *OECD Guidelines for Testing of Chemicals*, OECD, Paris.

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Attachment 1

The Draize Scale for evaluation of skin reactions is as follows:

Erythema Formation	*Rating*	*Oedema Formation*	*Rating*
No erythema	0	No oedema	0
Very slight erythema (barely perceptible)	1	Very slight oedema (barely perceptible)	1
Well-defined erythema	2	Slight oedema (edges of area well-defined by definite raising	2
Moderate to severe erythema	3	Moderate oedema (raised approx. 1 mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4

The Draize scale for evaluation of eye reactions is as follows:

CORNEA

Opacity	*Rating*	*Area of Cornea involved*	*Rating*
No opacity	0 none	25% or less (not zero)	1
Diffuse area, details of iris clearly visible	1 slight	25% to 50%	2
Easily visible translucent areas, details of iris slightly obscure	2 mild	50% to 75%	3
Opalescent areas, no details of iris visible, size of pupil barely discernible	3 moderate	Greater than 75%	4
Opaque, iris invisible	4 severe		

CONJUNCTIVAE

Redness	*Rating*	*Chemosis*	*Rating*	*Discharge*	*Rating*
Vessels normal	0 none	No swelling	0 none	No discharge	0 none
Vessels definitely injected above normal	1 slight	Any swelling above normal	1 slight	Any amount different from normal	1 slight
More diffuse, deeper crimson red with individual vessels not easily discernible	2 mod.	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
Diffuse beefy red	3 severe	Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
		Swelling with lids half-closed to completely closed	4 severe		

IRIS

Values	*Rating*
Normal	0 none
Folds above normal, congestion, swelling, circumcorneal injection, iris reacts to light	1 slight
No reaction to light, haemorrhage, gross destruction	2 severe