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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

NAVY JB609

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For Enquiries please contact the Administration Coordinator at:

Street Address: 92 Parramatta Rd Camperdown, NSW 2050, AUSTRALIA
Postal Address: GPO Box 58, Sydney 2001, AUSTRALIA
Telephone: (61) (02) 565-9466 **FAX (61) (02) 565-9465**

Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

NAVY JB 609

1. APPLICANT

Clariant (Australia) Pty Ltd of 675 Warrigal Road CHADSTONE Victoria 3148 has submitted a limited notification statement in support of their application for an assessment certificate for Navy JB 609.

2. IDENTITY OF THE CHEMICAL

Navy JB 609 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 Navy JB 609,
- 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 Navy JB 609 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:	Navy JB 609
Trade Name:	Sandoderm Navy RB Liquid (contains 17.6% of the notified chemical)

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	black-blue powder

Melting Point:	> 225°C (decomposed)
Density:	1720 kg/m^3 at 20°C
Vapour Pressure:	< 6.3 x 10^{-19} kPa at 25°C
Water Solubility:	400 g/L at 20°C
Surface Tension:	70.1 mN/m at 20°C (at concentration of 1.069)
Partition Co-efficient (n-octanol/water):	log P_{ow} -5.9 at 22°C
Hydrolysis as a Function of pH:	stable at pH 7.0 at 25°C > 1 year unstable at pH 4.0 and 9.0
Particle Size Distribution	15.2% < 20 μm (NB only imported as liquid)
Flammability Limits:	could not be ignited with a flame
Autoignition Temperature:	270°C
Explosive Properties:	not explosive (flame)

Comments on Physico-Chemical Properties

Tests were performed according to EEC/OECD test guidelines at facilities complying with OECD Principles of Good Laboratory Practice.

No melting point was observed; reaction or decomposition occurred above 225°C.

At high concentration levels, the notified chemical forms very viscous mixtures with water that can hardly be stirred. No phase separation was observed during water solubility testing.

During hydrolysis testing at both pH 4 and 9, after an initial decrease in the test substance concentration, the concentration started to fluctuate. It was found that after 287 hours (~ 12 days) the amount of hydrolysis was still below 20%. For this reason, the company concluded that it is not probable that a larger decrease in concentration would be found if testing continued.

The partition coefficient was estimated to be log P_{OW} < -5.9; because this value lies outside of the applicability range of the flask-shaking method, the main study was not performed and the result had to be interpreted as an estimated value.

The dye is a penta sodium salt and has good water solubility. It can be assumed that the molecule will dissociate close to 100% in the pH range of 4-9.

High water solubility and a low log partition coefficient indicate that the chemical will have a low affinity for soil and sediment.

The notified chemical is not expected to be surface active. By definition, a chemical has surface activity when the surface tension is less than 60 mN/m (1).

4. PURITY OF THE CHEMICAL

Degree of Purity: 90.0% ± 5%

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 17.6% of the notified chemical; the formulation is called Sandoderm Navy RB Liquid. The notified chemical has also been notified in Europe.

The quantity of the formulation, Sandoderm Navy RB Liquid, to be imported over the next five years is 3 tonnes this equates to 0.53 tonnes of the notified chemical each year.

6. OCCUPATIONAL EXPOSURE

The notified chemical is imported as a component of a liquid dye formulation Sandoderm Navy RB 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 96% of Sandoderm Navy RB Liquid containing the notified chemical will be chemically bound to the substrate. The leather will be used in applications such as upholstry, 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 Navy RB 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 1433, is chemically bound to the leather and sealed by the resin coat, the biological availability of the dye will be minimal.

Sandoderm Navy RB 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

A test report provided indicates that Sandoderm Navy RB Liquid has an exhaustion (fixation) rate of 99.9%. 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 ($\geq$ 96% 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 ($\leq$ 4%) will enter the aquatic environment after discharge from the tannery and subsequent treatment at sewage treatment plants. In view of the high water solubility, it is likely that significant quantities of the dye will remain in the aquatic compartment. After entering the sewage works, unfixed residues may be removed through degradation (chemical or biological). While azo dyes are generally stable under aerobic conditions, they are susceptible to reductive degradation under the anaerobic conditions characteristic of sediment (2). Any dye that may partition to the sediment will be removed with the sludge during treatment at the dyehouse and sewage works.

Biodegradation

The dye was tested for its ready biodegradability in the 'Modified Sturm Test' (84/449/EEC C.6). The biodegradation of the test article was determined by exposing it to activated bacterial sludge from a municipal waste water sewage plant and measuring theoretical CO_2 evolution. The notified chemical appeared to be not readily biodegradable within 28 days as < 10% CO_2 was evolved. No inhibitory effect on the micro-organisms was observed.

The inherent biodegradability of the dye was tested in the 'Modified Zahn-Wellens Test' (OECD TG 302B). The dissolved organic carbon (DOC) concentration of the notified chemical remained unchanged throughout the exposure period of 28 days. The dye was found to be not inherently biodegradable.

Bioaccumulation

The dye is unlikely to bioaccumulate due to its high water solubility (>400 g/L) and low log P_{OW} (< -5.9) (3). Also, biological membranes are not permeable to polymers of very large molecular size and therefore bioaccumulation of the notified polymer is not expected (4,5).

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of Navy JB 609

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 2 000 mg/kg	6
acute dermal toxicity	rat	LD_{50} > 2 000 mg/kg	8
skin irritation	rabbit	not an irritant	9
eye irritation	rabbit	slight irritant	12
skin sensitisation	guinea pig	sensitiser	13

9.1.1 Oral Toxicity (6)

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 (7)
LD_{50}:	> 2 000 mg/kg
Result:	low acute oral toxicity

9.1.2 Dermal Toxicity (8)

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 (7)

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

9.1.4 Skin Irritation (9)

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	0	0	0
2	0	0	0
3	0	0	0
Oedema			
1	0	0	0
2	0	0	0
3	0	0	0

[a] see Attachment 1 for Draize scales

Test method: according to OECD Guidelines for Testing Chemicals (7)

Result: not classified as an irritant according to Worksafe Australia's *Approved Criteria for Classifying Hazardous Substances* (11)

9.1.5 Eye Irritation (12)

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]0			0			0		
2	0			0			0		
3	0			0			0		
Iris									
1	0			0			0		
2	0			0			0		
3	0			0			0		
Conjunctiva	***r[c]***	***c[d]***	***d***	***r[c]***	***c[d]***	***d***	***r[c]***	***c[d]***	***d***
1	1	2	1	1	1	0	0	0	0
2	2	1	0	1	1	0	1	1	0
3	2	1	1	1	1	0	1	1	0

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

Test method: according to OECD Guidelines for Testing Chemicals (7)

Result: not classified as an irritant according to Worksafe Australia's *Approved Criteria for Classifying Hazardous Substances* (11)

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 , 10%, 25% and 50% solution in distilled 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*
10%	**2/20	**8/20	0/20	1/20
25%	**4/20	**11/20	0/20	0/20
50%	**3/20	**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 (7)

Result: sensitiser according to Worksafe Australia's *Approved Criteria for Classifying Hazardous Substances* (11)

9.2 Subacute 28 Day Repeated Dose Toxicity (14)

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: one female receiving 1000 mg/kg/day was noted with hunched posture; excessive salivation noted in the 1000 mg/kg dose

Clinical chemistry/Haematology 1 000 mg/kg dose group had increased total bilirubin concentration in males and females and increase triglycerides in females

Macroscopic examination: in 200 and 1000 mg/kg dose groups increase in spleen weight was observed, also the high dose group had enlarged spleens

Histopathology: increases in splenic haemopoiesis and haemosiderin depsits as well as congestion observed with 200 and 1000 mg/kg dose groups but was not observed in 1000 mg/kg dose group after recovery

Test method: according to OECD Guidelines for Testing Chemicals (7)

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 (15)

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 (7)
Result:	up to the highest dose a clear reproducible dose dependent increase in revertant colony numbers was observed in strain TA 1537 without S9 mix. the notified chemical is considered to be mutagenic in this system

9.3.2 Gene mutation assay in Chinese Hamster V79 Cells *in vitro* (16)

Doses:	5-600 µg/ plate with and without metabolic activation; solvent controls (DMSO) and positive controls (without metabolic activation - ethylmethanesulfonate (EMS), with - 7,12-dimethylbenz (a) anthracene (DMBA))
Test method:	according to OECD Guidelines for Testing Chemicals (7)
Result:	not mutagenic; no increase in gene mutations at the HPRT locus in V79 cells; positive controls and solvent controls gave appropriate response

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

Doses:	
Experiment 1	18h: 3, 10, 30 µg/ml 28h: 30 µg/ml (without metabolic activation) 18h: 10, 30, 100 µg/ml 28h: 100 µg/ml (with metabolic activation)
Experiment 2	18h: 3, 10, 30 µg/ml 28h: 30 µg/ml (without metabolic activation) 18h: 1, 3, 10 µg/ml 28h: 10 µg/ml
	rat liver S9
Metabolic activation:	
Test method:	according to OECD Guidelines for Testing Chemicals (7)
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 was of low acute toxicity via the oral and dermal routes in the rat with LD_{50} values of >2000 mg/kg for both routes of administration. It was a slight irritant to the eye and a non-irritant to the skin of rabbit. It is a skin sensitiser in guinea pigs. When rats were treated orally with up to 1000 mg/kg/day dose group, the spleen was the likely target organ; this is supported by the increased spleen weight in 200 and 1000 mg/kg dose groups and enlarged spleens in the high dose group. Other supporting histopathological evidence was found in two higher dose groups with increased splenic haemopoiesis and haemosiderin deposits.

The notified chemical was found to be mutagenic *in vitro* to *Salmonella typhimurium* strain TA 1537 and non-mutagenic *in vitro* Chinise hamster V79 cells and non-clastogenic in an *in vitro* cytogenetic assay using Chinese hamster V79 cells.

On the basis of submitted data, the notified chemical would be classified as hazardous in accordance with the Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1994)] (Approved Criteria) in relation to sensitising effects (skin).

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 EEC/OECD test guidelines 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.

Table 1: Ecotoxicity test results

Test	Species	Results (Nominal) (mg/L)
Acute Toxicity (static)	Carp *Cyprinus carpio*	96 h LC_{50} > 49 [a]
21-day Toxicity [b] (flow-through)	Rainbow Trout *Onchorhynchus mykiss*	NOEC 3.2 [c] 4 day LC_{50} = 17.5 [c] 21 day LC_{50} = 8.56 [c,d]
Acute Immobilisation (static)	Water Flea *Daphnia magna*	48 h EC_{50} > 100 [e,f]
Growth Inhibition [g] (static) - Area (I_A) (= b, biomass) and Growth Rate (I_μ)	Algae *Scenedesmus subspicatus*	72 h E_bC_{50} = 2.67 72 h $E_\mu C_{50}$ = 7.34
Respiration Inhibition [h]	Aerobic Waste Water Bacteria	3 h IC_{50} > 100

a. During the exposure period, the actual concentrations remained > 90% of nominal at all three concentrations sampled; **b.** After 21 days of exposure, no effect on the fish growth (weight and size) and no mortality were observed at test concentrations of 1.28 and 3.2 mg/L. At test concentrations of 8.0, 20 and 50 mg/L, mortality rates of 40%, 100% and 100% were observed respectively, and there was significant influence on the fish size; **c.** The results are based on mortality only due to the intense dark blue colouration of the test medium, therefore observation of clinical signs was not possible; **d.** There were no observations made on the trout post-test; **e.** The daphnia could not be observed at 24 hours due to the opacity of the test solutions. At the end of the test, these daphnia were transferred to a clear medium for observation; **f.** The actual test concentrations were $\geq$ 89% of nominal throughout the 48 hour exposure period. **g.** This test was modified to try to differentiate between a reduced growth of algae due to real toxic effects of the notified chemical on the algal cells (algicidal effects) and that due to an indirect effect only, namely a reduced algal growth by light absorption in coloured test solutions (algistatic effects) - see comments in text; and **h.** Respiration rate is the oxygen consumption of aerobic sludge or waste water micro-organisms, expressed as "mg O_2./L/min".

The dye is at worst slightly toxic to carp under acute toxicity conditions. When rainbow trout were exposed to the chemical over four days it was shown to be slightly toxic. When this exposure was increased to a period of 21 days, it was found to be moderately toxic. The notified chemical was shown to be practically non-toxic to the water flea.

Impacts on algal growth were assessed in terms of either biomass (E_bC_{50}) and growth rate ($E\mu C_{50}$). An additional growth test was performed, where after 72 hours of incubation in the test medium, the algae were centrifuged and placed in fresh media without the test substance present. These algal suspensions were incubated for an additional 72 hours. This additional growth test showed total recovery of cell growth in the algal suspension originating from the test concentration of 10 mg/L. The company concluded that effects on cell growth recorded at 10 mg/L (and lower) were not due to a toxic effect (algicidal). However, the EPA does not necessarily agree with this conclusion since the additional test may only show that not all algae cells had died during the original test, with enough cells left to initiate sustained re-growth of the culture when placed in a fresh, clean medium. Also, whether or not the dye did cause algistatic effects is inconsequential, as algistatic effects could still lead to an undesirable environmental impact if exposure is continuous.

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 1.0 to 51.5 mg/L. The 3 h-IC_{50} is reported as $\geq$ 100 mg/L.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

As indicated above, 96% of the dye is fixed in the dyeing process, thus 4% 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 5% involves the following steps:

Process	Volume (L)
Wash	1 500
Neutralise	900
Wash	1 500
Dyeing	1 500
Wash (¥2)	3 000
	8400

Dye Addition Rate 5%: 30 kg (600 kg x 5%)

Fixation: 96%

Concentration of Active Dye: 17.6%

Thus

30 kg is used in the dyeing process, with 1.2 kg lost to waste water:

$$\frac{\text{1.2 kg (Sandoderm Navy RB Liquid) x 17.6\%}}{\text{8400 L (total volume)}} = 24 \text{ ppm}$$

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 2.4 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 0.2 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 ~70 ppb. Further dilution will occur in receiving waters in the order of 1:2 (river outfall), resulting in an EEC for the dye of ~34 ppb.

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 (5%) and the minimum likely fixation rate (96%) have been used. More typical rates would be 3-4% 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.

[1] Calculated from a town population of approximately 20 000 with a 150 $L.day^{-1}.person^{-1}$.

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 17.6% 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* (11) on the basis of eye irritation studies in rabbits, there were effects indicating that it has a slight 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 an *in vitro* genotoxicity study there was evidence of mutagenic effects but 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.

13. RECOMMENDATIONS

To minimise occupational exposure to Navy JB 609 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. 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.
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3. Connell D.W, 1989. "General characteristics of organic compounds which exhibit bioaccumulation". *In* Connell D.W, ed. *Bioaccumulation of Xenobiotic Compounds*. CRC Press, Boca Raton, USA.
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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