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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

PROCION CRIMSON H-EXL

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

PROCION CRIMSON H-EXL

1. APPLICANT

ICI Australia (Operations) Pty Ltd of 1 Nicholson Street, Melbourne VIC 3000 has submitted a standard notification for the assessment of Procion Crimson H-EXL.

2. IDENTITY OF THE CHEMICAL

Trade name: Procion Crimson H-EXL

Procion Crimson is not considered to be hazardous based on the nature of the chemical and the data provided. Therefore the chemical name, CAS number, molecular weight, molecular formula, structural formula and spectral data have been exempted from publication in the Full Public Report and the Summary Report.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	Solid - dark brown granular powder
Odour:	Not stated
Melting Point:	>300°C
Glass-transition Temperature:	Not stated
Specific Gravity/Density:	Not provided
Vapour Pressure:	Test not performed since high molecular weight and high melting point indicates that the vapour pressure will be less than 10^{-5} Pa at 25°C.
Water Solubility:	Soluble in water (31% w/w at 21°C)
Fat Solubility:	0.009 mg/100 g solvent using standard fat HB 307
Partition Co-efficient (n-octanol/water) log P_{OW}:	-5.7
Hydrolysis as a function of pH:	Less than 10% at pH 7.9, 50% hydrolysis at pH 4
Adsorption/Desorption:	Test not performed due to high water solubility and low partition coefficient which indicates a low affinity for soil or sediment

Dissociation Constant pKa**:**	Test not performed but is expected to be highly dissociated in dilute solution as it is a sodium salt of complex aminosulphuric acids
Flash Point:	Test not performed - not applicable to solids
Flammability Limits:	Not classified as flammable. Not classified as a highly flammable solid (test substance charred on exposure to the ignition source, but did not ignite and did not propagate combustion).
Autoignition Temperature:	The substance does not spontaneously ignite (no ignition below 400°C, the upper limit of this test).
Explosive Properties:	Not explosive under the influence of a flame nor sensitive to shock or friction.
Reactivity/Stability:	Not an oxidiser
Surface Tension (of aqueous solutions) **:**	57.6 Nm^{-1} at 22°C
Particle size distribution:	Range 50-250 µm

Note: the test chemical is chemically stable. Particles are claimed to be non-respirable and essentially of low inhalability.

4. PURITY OF THE CHEMICAL

The notified chemical contains a number of impurities with unknown toxicity. However, as all tests were conducted on the chemical containing these impurities, and the test substance was found to be non-hazardous, the identity of these impurities have been exempted from publication in the Full Public Report and the Summary Report.

5. INDUSTRIAL USE

Procion Crimson H-EXL is a dyestuff which will be applied to yarn or fabric manufactured from cellulose fibre or cellulosic fibre blends. It has been notified as a new chemical substance in Europe (application made in 1992).

An estimated 1-10 tonnes of chemical in granular form will be imported into Australia annually for the first 5 years.

6. OCCUPATIONAL EXPOSURE

Procion Crimson H-EXL will be imported from the UK in 25 kg metal drums with metal lid clamps. It will be transported within Australia by road freight. Exposure of transport workers is will occur only in the event of accident. The clean-up procedures and personal

protective equipment detailed in the MSDS for Procion Crimson H-EXL should ensure worker exposure is kept to a minimum.

The chemical will be used for laboratory development and shade matching at ICI Valchem and will then be supplied to customers (potentially 25 throughout Australia) where the chemical will be prepared and applied to yarn or fabric.

At ICI Valchem, exposure will be limited to up to 3 persons for 1/2 h per day. Workers will handle small quantities (1 kg/year). At the customer sites, exposure will be for approximately 8-12 h/day, with an anticipated total of 90-100 employees at maximum sales levels.

Workers employed in the customer colour kitchens will be involved in storage and retrieval of dyestuff drums, weighing of dyestuff; dissolving of dyestuff and transferring dissolved dyestuff to dyeing machines. Workers will typically be exposed for 1-2 minutes during weighing operations. The dyestuff will be dissolved in water in a high speed stirrer. During dissolution, workers are expected to be present only during the initial addition of dye to the machines as well as the during removal and rinsing of the stirrer (~1-2 minutes in total).

Workers involved in dyehouse operations will add the dissolved dyestuff to the dyeing machines (rinsing the container into the machine) and will sample the fabric and liquor after dyeing. Transfer time to the machines will depend on the distances involved. The applicant states a typical transfer time of 1 minute. Transfers will typically be conducted using trolleys. Addition to the machines, including rinsing of the containers into the machine is expected to take 1-2 minutes.

The applicant lists a number of engineering controls and personal protective equipment to control worker exposure. Workers handling the granulated dye will be instructed to wear overalls, safety glasses and impervious gloves. Exhaust ventilation systems will be employed in the colour kitchens to control exposure to dust. Indoor air will be under slight negative pressure in the weighing and mixing areas to ensure lifted granules are carried away from the work areas and operators.

Once the dyestuff is chemically fixed to the fibre, worker exposure should not be significant.

7. PUBLIC EXPOSURE

On the basis of the information available, public exposure to the notified chemical would not be expected to occur during colour kitchen and dyehouse processes. Technical requirements for the dyeing process (in effect, quality control procedures) require the minimisation of spillage, and the need to prevent loss and /or cross-contamination. Safety procedures adopted during these processes include the wearing of protective clothing and minimisation of generation and inhalation of dust. These requirements and procedures, together with standard engineering controls on manufacturing processes, such as exhaust ventilation systems, should minimise escape of this substance to the general environment.

Following fixation by establishing a mildly alkaline pH, 82% of Procion Crimson H-EXL will eventually be permanently fixed to cellulosic fibre or yarn. Of the 18% of dyestuff not covalently fixed to the fibre, 10% will be in solution in a hydrolysed form, with the other 8% attached to the fibre in a hydrolysed form by hydrogen bonds. This will later be removed by hot rinsing and 'soap-off' stages to ensure fastness (permanence) on the treated fabric. The remainder will be discharged to trade waste sewers typically at concentrations below 100 ppm (estimated to be in the range 24-87 ppm depending on use). Dilution with other waste streams and removal during treatment are likely to reduce

concentrations to much lower levels (<1 ppm) before discharge to the environment. This low-level release of Procion Crimson H-EXL residues to the sewer or to specialised trade waste treatment plants is not expected to have a significant public health impact.

Significant accidental spillages of granules will be collected and disposed of to approved land disposal sites. Minor spillages and dissolved dyestuff spills can be washed to sewered discharge points. Neither technique should have any significant public health impact.

The public may come in contact with yarn or fibre products dyed with the notified chemical. However, as the dye stuff is chemically fixed to the fibre, public exposure is expected to be negligible.

8. ENVIRONMENTAL EXPOSURE

. Release

Release to the environment is only from the spent dye liquors and the washing baths. In normal usage there shouldn't be any release to the environment during transport, when used in the colour kitchens or during dyeing.

· Fate

The dye is stable and unlikely to hydrolyse at environmental pHs. Once released to the environment the dye is expected to partition to the sediments, as other dyes of this type have been shown to partition to sediment (1). In the sediments the dye is likely to be reduced by anaerobic bacteria (2) and is therefore unlikely to accumulate in the environment.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

All testing was performed by the ICI Central Toxicology Laboratory in accordance with ICI QA Standard Operating procedures and is claimed to be compatible with OECD 1982 (Good Laboratory Practice in the Testing of Chemicals - Final Report of the OECD Expert Group on Good Laboratory Practice, ISBN 9264 12367 9) (3). The test samples contained 71.6% (w/w) substance and 10.5% (w/w) water.

Table 1. Summary of the acute toxicity of Procion Crimson H-EXL

Test	Species	Outcome	Reference
Acute oral toxicity	Rat	LD_{50} >2000 mg/kg	(4)
Acute dermal toxicity	Rat	LD_{50} >2000 mg/kg	(5)
Skin Irritation	Rabbit	Moderate	(6)
Eye irritation	Rabbit	Moderate	(7)
Skin sensitisation	Guinea-pig	Not a sensitiser	(8)

9.1.1 Oral Toxicity (4)

Procion Crimson H-EXL (purity 71.6%) was administered to a group of SPF Wistar-derived rats (5/sex/group) by gavage at a single oral dose of 2000 mg/kg. Clinical observations were made over 15 days. Necropsies were conducted at the end of the study.

No signs of systemic toxicity were observed and there were no mortalities during the study. All animals lost weight initially, due to the pre-dose fast, and the majority had exceeded their initial (day -1) bodyweight by day 3 and continued to gain weight until the end of the study. The faeces, urine, coat and tail of the animals were stained red by the test sample but this was considered not to be of toxicological significance.

Necropsy of sacrificed animals revealed no significant macroscopic lesions.

The study indicated that Procion Crimson H-EXL had an oral LD_{50} > 2000 mg/kg for both male and female rats.

9.1.2 Dermal Toxicity (5)

Procion Crimson H-EXL (purity 71.6%) was applied as an aqueous paste to the clipped backs of SPF Wistar-derived albino rats (5/sex/group) at a single dose of 2000 mg/kg, covered with a gauze patch, and kept in contact with the skin using occlusive dressings for 24 hours, when the dressings were removed and the application site cleaned. Clinical observations were made over 15 days.

No mortalities occurred during the study. Most animals had exceeded their initial (day 1) bodyweight by day 8 and all animals continued to gain weight until the end of the study. There were no signs of toxicity. Slight skin irritation, indicated by oedema, was observed in all animals on day 2 but had disappeared in the majority of animals by day 3. The test substance stained all the application sites red. This stain was persistent in the majority of animals, and prevented accurate assessment of irritation. Necropsies of sacrificed animals revealed no significant macroscopic lesions in any of the animals.

The study indicated that Procion Crimson H-EXL had a dermal LD_{50} >2000 mg/kg.

9.1.3 Inhalation Toxicity

This test was not performed.

9.1.4 Skin Irritation (6)

Procion Crimson H-EXL (purity 71.6%) was applied to the clipped right flank of a group of three young adult female New Zealand White albino rabbits. A test sample (approximately 500 mg) was moistened with a small amount (0.5 mL) of deionised water and applied to the test site (approximately 2.5 cm x 2.5 cm) on the left flank of each animal. The treated area was covered with surgical gauze and secured by tape, then covered by an impermeable dressing. The dressings were left in place for approximately four hours, then removed, and the application site cleaned. Clinical observations were made over 3 days.

No mortalities occurred during the study. Following application, the application sites of all three animals were stained red; this staining prevented assessment of erythema but did not prevent assessment of oedema. Slight oedema was observed in one rabbit and slight to moderate oedema was observed in the remaining two animals up to 3 days after application of the test sample. Wrinkling of the skin was observed in two animals. The histopathological findings on skin of sacrificed animals indicate an irritant effect of slight

to moderate intensity in two animals. The lack of necrosis suggested that the effects may be reversible.

The results of the study indicate that Procion Crimson H-EXL is a moderate skin irritant in rabbits.

9.1.5 Eye Irritation (7)

Procion Crimson H-EXL (100 mg) (purity 71.6%) was instilled into the conjunctival sac of the left eye of one of three young adult female New Zealand White albino rabbits. The right eye served as the untreated control. Eight days later the test sample was applied in the same way into the test eye of the remaining two animals. The Draize scale was used to assess the grade of ocular reaction. Fluorescein was used as an aid in the assessment of corneal damage.

Application of the test sample into the conjunctival sac caused slight initial pain in all three rabbits. The test sample stained the tissues of the eye and prevented a complete assessment of ocular irritation. Slight to mild chemosis, slight to severe discharge and other signs of ocular irritation were observed in all animals up to day 3 of the study. Fluorescein staining indicated possible corneal damage in one rabbit up to day 3. No signs of irritation were evident from day 4 after dosing.

The results of the study indicate that Procion Crimson H-EXL is a moderate irritant to the rabbit eye.

9.1.6 Skin Sensitisation (8)

The skin sensitisation potential of Procion Crimson H-EXL (purity 71.6%) was studied in guinea-pigs according to the Buehler procedure.

In an initial dose sighting study, the test sample stained the skin and prevented a full assessment of skin response. As no overt signs of irritation were seen during either the induction or challenge phases, animals in the main study were induced with the maximum concentration tested in the sighting study (75% w/v), and challenged with all concentrations tested in the sighting study (75%, 30%, 10% and 3% w/v).

In the main study, twenty female Dunkin-Hartley guinea-pigs were used for testing, and ten animals served as controls. An area in the scapular region of each animal was clipped free of hair and treated with a topical application of either a 75% w/v preparation (approximately 400 mg) of the test material or 0.4 ml of deionised water (controls). The preparation was applied to a lint patch which was covered with an occlusive dressing for 6 hours. This induction procedure was repeated at the same site over two weeks giving a total of three six-hour exposures, with a 7-day interval between exposures. The animals were left for two weeks after the final induction prior to the challenge. A 30% w/v aqueous formaldehyde solution served as the positive control. In the challenge phase, each animal was exposed to 75, 30, 10 and 3% w/v preparations of the test material (0.1-0.2 mL of liquid, or 100-200 mg paste), placed on the shorn flanks, covered by an occlusive dressing for approximately six hours. Erythematous reactions were quantified and recorded.

Slight irritation was seen in two animals during the induction phase. Staining by the test material prevented assessment of responses in up to 5 animals during challenge. No sensitisation response was seen in any of the remaining test or control animals. The positive control elicited a moderate skin sensitising response following challenge.

The results of the study indicate that Procion Crimson H-EXL is not a skin sensitiser in guinea-pigs.

9.2 Repeated Dose Toxicity

9.2.1 28 Day Oral Toxicity Study in Rats (9)

Testing was performed by the ICI Central Toxicology Laboratory in accordance with ICI QA Standard Operating procedures and is claimed to be compatible with OECD Good Laboratory Practice guidelines.

Groups of five male and five female Wistar rats were dosed orally, by gavage, with Procion Crimson H-EXL (purity 71.6 % w/v) at dose levels of 0, 50, 250 or 1000 mg/kg/day for 28 consecutive days. Additional groups at 0 and 1000 mg/kg/day were allowed a 14 day non-dosing recovery period prior to scheduled kill. All surviving animals were killed on day 29 or 43. Haematological and clinical chemical analyses were conducted on samples obtained at sacrifice, and urinalysis was conducted with all groups approximately 7 days prior. Gross and histological examination was performed on tissues obtained at recovery and terminal kills.

There were no treatment-related deaths or toxicologically significant effects on clinical condition, or food consumption. There were no treatment-related effects on bodyweight during weeks 1 to 4 of treatment. During the recovery period, group mean bodyweight for animals from the 1000 mg/kg/day group was slightly, but not statistically significantly, lower than that of the concurrent controls. Slight but statistically significant reductions in mean haemoglobin, haematocrit and red cell count were noted for females at 1000 mg/kg/day at terminal and recovery kill. Mean plasma alanine transaminase and/or alkaline phosphatase activities were also reduced for males and/or females at 250 and/or 1000 mg/kg/day, only at terminal kill. Higher group mean urinary pH and/or protein levels for females at 250 and/or 1000 mg/kg/day were noted at week 4 or week 6 (recovery week 2). In addition, large quantities of renal epithelial cells were present in the urine sediments from all animals receiving 1000 mg/kg/day at weeks 4 and 6.

Statistically significantly higher group mean kidney weights (absolute and bodyweight adjusted) were noted for males at 250 mg/kg/day and males and females at 1000 mg/kg/day at terminal kill, and for females at 1000 mg/kg/day at recovery kill. Kidney weights for two males from the 1000 mg/kg/day group were also higher at recovery kill. A statistically significant increase in bodyweight adjusted group mean liver weights was seen in 1000 mg/kg/day males at recovery kill.

Increased hyaline droplet formation in the proximal tubules of the kidneys of all males at 1000 mg/kg/day, and a dose-related degeneration of the proximal tubules of all females at 250 or 1000 mg/kg/day, were noted at terminal kill. Minimal to slight mononuclear infiltration in the kidneys in 1000 mg/kg/day females was considered secondary to tubular degeneration. At recovery kill, proximal tubular degeneration and mononuclear cell infiltration were seen in males and females at 1000 mg/kg/day. Other histopathological changes considered to be related to treatment included minimal or slight mononuclear cell infiltration of the periportal areas of the liver from animals receiving 1000 mg/kg/day, at both terminal and recovery kills.

Widespread pink/purple staining of tissues and colouration of plasma, urine and/or faeces was seen for animals receiving 250 and 1000 mg/kg/day throughout the dosing and/or recovery periods and was considered to be due to the highly coloured nature of the test material.

There were no effects following daily oral administration to male and female rats for 28 days at a dose of 50 mg/kg/day.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* and *Escherichia coli* Bacterial Mutagenicity Assays (10)

The mutagenicity assays were conducted using the S*almonella* bacterial mutation assay described by Maron and Ames (1983) (11), updated by the United Kingdom Mutagen Society's sub-committee on Guidelines for Mutagenicity Testing (Gatehouse, *et al,* 1990). The protocols also complied with OECD Guideline Numbers 471 and 472 (12 & 13) (1983).

The test sample was initially assayed using the standard plate incorporation protocol over a dose range of 200-6983.2 mg per plate, both in the presence or absence of a liver S-9 mix prepared from AROCLOR 1254-induced Charles River CD rats. Four *Salmonella* tester strains were used (TA1535, TA1537, TA98 and TA100) and two *E. coli* strains (WP2P and WP2P *uvrA*). The compound was subsequently re-tested in all six strains over the same dose range. The +S9 phase of this second assay was conducted using a defined pre-incubation protocol. In the light of slight effects observed in this second +S9 experiment, the compound was re-tested in strains WP2P and WP2P *uvrA* (+S9 only), again using a pre-incubation protocol. The incubation period for each experiment was 3 days (at 37°C). For each experiment, positive control compounds were tested to validate the bacterial strains and to confirm the activity of each batch of S9-mix used.

In each experiment, the positive controls confirmed the sensitivity of the assay.

In these two separate experiments the substance did not induce any significant, reproducible increases in the observed number of revertent colonies in *Salmonella typhimurium* or *Escherichia coli* strains either in the presence or the absence of the S9 metabolising system.

9.3.2 *In vitro* Cytogenetic Assay in Human Lymphocytes (14)

An evaluation of the clastogenic potential of Procion Crimson H-EXL was made in human lymphocytes from two donors (one male, one female), treated *in vitro* with a range of concentrations of test material both in the presence and absence of a rat liver metabolic activation system (S9-mix). Cultures were harvested at 72 hours after culture initiation (cultures from both donors) and 96 hours (cultures from male donor) after culture initiation.

Two independent cytogenetic studies were conducted using a range of concentrations of the test substance, from 140-6990 mg/mL (in absence of S9-mix) and from 700-6990 mg/mL (in presence of S9-mix). Cultures from both donors treated with the test substance at concentrations of 350, 1400 and 3500 mg/mL (in absence of S9-mix) and 700, 3500 and 6990 mg/mL, were selected for chromosomal aberration analysis at 72 hours. Cultures from the male donor treated at 1400 and 6990 mg/mL (absence and presence of S9-mix, respectively) were selected for analysis at 96 hours.

No statistically or biologically significant increases in percentage of aberrant cells, compared to the medium control values, were seen at any of the test substance concentrations tested, in the presence or absence of S9-mix, at either of the sampling times investigated.

The sensitivity of the test system, and the metabolic activity of the S9-mix employed, were confirmed by the positive control agents (mitomycin C and cyclophosphamide).

In conclusion, under the conditions of this assay, Procion Crimson H-EXL is not clastogenic to cultured human lymphocytes *in vitro.*

9.4 Overall Assessment of Toxicological Data

Animal studies indicate that Procion Crimson H-EXL has low acute oral and dermal toxicity in the rat (LD_{50} >2000 mg/kg). It was a moderate skin and eye irritant in rabbits. It was not a skin sensitiser in the guinea-pig.

In a 28-day repeat-dose study, renal tubular damage was seen at 250 and 1000 mg/kg/day. Renal damage was still evident after a 2-week recovery period. No adverse effects were seen at 50 mg/kg/day.

Procion Crimson H-EXL was not mutagenic in bacterial reverse mutation assays *in vitro*, and was not clastogenic in cultured human lymphocytes *in vitro*.

No adverse symptoms in humans related to the use of the notified chemical have been reported from limited experience overseas.

On the basis of submitted data, the notified chemical would not be classsified as hazardous in accordance with Worksafe Australia's *Approved Criteria for Classifying Hazardous Substances* (15) in relation to Acute lethal effects (oral, dermal); Irritant effects (skin, eye); Sensitising effects (skin); or Severe effects after repeated or prolonged exposure (oral route).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following ecotoxicity studies have been provided by the notifier.

Table 2. Ecotoxicity test results

Test	Species	Result
Acute toxicity	Rainbow trout	96h LC_{50} > 100 $mg.L^{-1}$
Acute toxicity	*Daphnia magna*	48h EC_{50} > 100 $mg.L^{-1}$
Acute toxicity	Earthworm	14d LC_{50} > 1000 $mg.kg^{-1}$

The ecotoxicity studies show that the dye is practically non-toxic to aquatic organisms. The company has not provided any information on the toxicity of the dye to algae. As the other ecotoxic data presented showed no significant toxicological effect and a test on a similar dyestuff (NA/271) indicates an absence of algal toxicity, the notified substance is not expected to be toxic to algae.

The dye is not expected to have significant environmental effects when released into the environment.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The applicant has not specified the location of the dyehouses in which the dye is likely to be used, but has stated that about 90% of the expected customers are located in cities. The environmental hazard has been determined for dyehouses located in two general locations, one metropolitan based dyehouse and the other country based. These calculations assume that no dye is removed in treatment of the different waste effluents.

The company has provided the following information on use:

Amount of chemical used: 10 kg

Volume of wastewater from dye bath	50,000L
Fixation to fibre	82%
Purity of chemical	71.6%

From the above information,

Concentration of dye in dye bath waste 26 ppm

For a country based dyehouse the assumptions are: 3 dye baths discharging a total of 150,000 L of waste into the municipal sewer with a flow 5 ML which is then discharged to a river in drought conditions.

Concentration of dye in dyehouse effluent	8.6 ppm
Concentration in sewer outflow	0.26 ppm
Concentration in river (2:1 dilution)	0.13 ppm

For a city based dyehouse the assumption are: 10 dye baths, discharging into the municipal sewer with a flow of 250 ML which is discharged to the sea.

Concentration of dye in dyehouse effluent	2.6 ppm
Concentration in sewer outflow	0.005 ppm
Concentration in sea (10:1 dilution)	0.0005 ppm

The company has estimated the concentration of the dye to be between 24-87 ppm (from the dye bath). Using the above assumptions and the worst case as presented by the company, the concentration in the country scenario is 0.44 ppm (in the river) and for the city 0.0017 ppm (1.7 ppb in the ocean). As this type of dye have been shown to partition to sediments (1) and it was assumed there was no dye removed in the waste treatment plants, the actual concentration in the receiving waters is likely to be lower than that calculated.

These calculations show that the exposure to aquatic organisms is several magnitudes below the fish and daphnia EC50 levels. Therefore there is unlikely to be any significant effect on these organisms from use of the dye. There is also unlikely to be any effect on algae due to the high molecular weight and the minimal effect on the other aquatic organisms tested.

The only other sources of environmental contamination is from accidental spills etc. The MSDS is adequate to limit the environmental exposure and therefore limit the environmental effects.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified chemical is a stable dark brown granular powder at room temperature and pressure. The chemical is not respirable, however, the granular powder has a propensity to form dust.

The chemical exhibits low oral and dermal toxicity. Inhalation toxicity is also expected to be low based on the low toxicity by the oral and dermal routes. The chemical is a moderate eye and skin irritant. The chemical is not a skin sensitiser in guinea-pigs. Chronic exposure to high levels of chemical may result in kidney and liver effects. The chemical is not expected to be genotoxic. As the notified chemical is a reactive dye, and respiratory sensitisation has been associated with reactive dyes, this chemical should be considered a possible respiratory sensitiser.

The notified chemical contains a number of impurities with unknown toxicity. However, as the chemical has been tested in its unpure form, hazards associated with the impurities should not warrant any additional concerns.

The major toxicological hazards associated with the chemical will be skin and eye irritation and possible respiratory effects. During weighing, transferring and sampling operations the potential for skin contact will be high. Eye and inhalational exposure, however, will only result if dust is generated, or in the event of spills. The engineering controls which the applicant describes (exhaust ventilation in colour kitchens and negative pressure ventilation in weighing and mixing areas) should be adequate to reduce eye and inhalational exposure to safe levels. The use of impervious gloves and protective clothing will reduce dermal exposure to safe levels. Therefore, under normal use situations, Procion Crimson H-EXL should not pose a significant health concern to workers.

The public may come in contact with the yarn or fibre products dyed with the notified chemical. However, as the dye stuff is chemically fixed to the fibre, public exposure is expected to be negligible. The notified chemical is therefore considered not to constitute a significant health risk when used in the proposed manner.

13. RECOMMENDATIONS

To minimise occupational exposure to Procion Crimson H-EXL the following guidelines and precautions should be observed:

- when using the notified chemical the following protective equipment should be worn:
  - impervious rubber gloves conforming to Australian Standards (AS) AS 2161 (16),
  - protective clothing conforming to AS 2919 (17), and
  - protective footwear conforming to AS/NZS 2210 (18).
- if dust is generated, and engineering controls are not sufficient to control exposure to dust, the following protective equipment should also be worn:
  - respiratory protection conforming to AS/NZS 1715 (19), and
  - protective eye goggles conforming to AS 1337 (20).
- good work practices should be implemented to prevent generation of dust and spills.
- good personal hygiene practices should be observed.
- a copy of the Material Safety Data Sheet (MSDS) should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The attached MSDS for Procion Crimson H-EXL was provided in Worksafe Australia format (21). This MSDS was provided by ICI Australia (Operations) 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 ICI Australia (Operations) Pty Ltd.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989*, secondary notification of Procion Crimson H-EXL 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

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2. K. T. Chung and S. E. Stevens Jr., *Environmental Toxicology & Chemistry* Vol 12, 2121-2134, 1993.

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4. Duerden L. Acute oral toxicity to the rat. Report No. CTL/P/3617, ICI Central Toxicity Laboratory, Alderley Park, Macclesfield, Cheshire, UK, (study no. AR5349), February 1992.

5. Duerden L. Acute dermal toxicity to the rat. Report No. CTL/P/3618, ICI Central Toxicity Laboratory, Alderley Park, Macclesfield, Cheshire, UK, (study no. CR2935), February 1992.

6. Lees D. Skin irritation to the rabbit. Report No. CTL/P/3615, ICI Central Laboratory, Alderley Park, Macclesfield, Cheshire, UK, (study no. EB4062), February 1992.

7. Lees D. Eye irritation to the rabbit. Report No. CTL/P/3623, ICI Central Toxicity Laboratory, Alderley Park, Macclesfield, Cheshire, UK, (study no. FB4576), February 1992.

8. Lees D. Skin sensitisation to the guinea-pig. Report No. CTL/P/3714, ICI Central Toxicity Laboratory, Alderley Park, Macclesfield, Cheshire, UK, (study no. GG5561, GG5543), April 1992.

9. Horner S.A. 28 day oral dosing study in rats. Report No. CTL/P/3622, ICI Central Toxicity Laboratory, Alderley Park, Macclesfield, Cheshire, UK, (study no. KR1142), April 1992.

10. Callandar R.D. An evaluation of mutagenic potential using *S. typhimurium* and *E. coli*. Report No. CTL/P/3536, ICI Central Toxicity Laboratory, Alderley Park, Macclesfield, Cheshire, UK, (study no. YV3108), December 1991.

11. Maron and Ames (1983), as updated by the United Kingdom Mutagen Society's sub-committee on Guidelines for Mutagenicity Testing (Gatehouse, *et al,* 1990).

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