File No: NA/281

Date: 10th November 1995

# NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

## **FULL PUBLIC REPORT**

Orașol Blue 761B, Anthraquinone dye

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

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

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**

# Orașol Blue 761B, Anthraquinone dye

## 1. APPLICANT

Ciba-Geigy Australia Ltd of 140 Bungaree Road, Pendle Hill, NSW 2145 has submitted a standard notification statement with their application for an assessment certificate for Orasol Blue 761B, an anthraquinone dye.

# 2. <u>IDENTITY OF THE CHEMICAL</u>

Orasol Blue 761B has been classified as hazardous by Worksafe Australia due to its eye irritation properties. However, for commercial reasons, the chemical identity, composition of ther chemical including impurities and additives/adjutants, methods of detection and determination, and spectral data have been granted exemption from publication in the Full Public Report and Summary Report. The conditions of this being permitted are:

- A descriptive generic name be used to identify the substance in public reports and the MSDS.
- The relevant employee unions shall be informed of the conditions of use of Orasol Blue 761B.
- 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 an eye irritant 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.

**Trade name(s):** Orasol Blue 761B, Orasol Blue BL,

## 3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa: Blue solid (powder)

**Odour:** Slight musty odour

Melting point: 100-144 °C

Boiling point: Not determined

Specific gravity: 1.21 g.cm<sup>-3</sup> at 20 °C

Vapour pressure: Not determined. Solid substance (salt) with

high molecular weight, vapour pressure

likely to be very low.

Water solubility: Between 9-300 mg.L<sup>-1</sup> at 20°C

**Hydrolysis:** Hydrolytically stable. Less then 10%

hydrolysis observed after 5 days at 50 °C at conditions tested (pH 4, 7 and 9)

(estimated half life >1 year).

**Partition coefficient:**  $log P_{OW} = 3.1-4.6$ , estimated from the

solubility in (n-octanol/water)n-octanol and

water.

Adsorption/desorption: Test not performed.

**Dissociation constant:** Test not performed.

**Fat Solubility:** 2000-7600 mg/100 g fat (simulated fat) at

37 °C

**Surface Tension:** 49.5 mN/m at 20 °C (90% saturated

solution). The notified compound is a

surface active material.

Flash Point: Not determined

Flammability Limits: Combustible, but not flammable

Combustion Products: Unknown

Pyrolysis Products: Unknown

**Decomposition Temperature:** >200°C

**Decomposition Products:** Unknown

**Autoignition Temperature:** >400°C

**Explosive Properties:** Not explosive

Reactivity/Stability: Unknown

Particle size distribution: range - 5μm - >250μm

mean - estimated 40µm

<10μm 0.2% 10-20μm 3.0% 20-50μm 16.6% 50-63μm 5.1% 63-250μm 67.8%

>250µm 7.2%

## **Comments on physico-chemical properties:**

All physico chemical data were determined by internationally acceptable methods.

The notified substance contains aromatic amines and is therefore a weak base. The dissociation constant is expected to lie be between 7-10 pK<sub>a</sub>.

The water solubility of the substance could not be exactly determined due to the abnormal behaviour of the chemical substance in the test. At low pH values the solubility is expected to increase due to formation of the amine salt.

As a result of the high  $P_{OW}$ , strong adsorption is expected under alkaline conditions. At low pH values the  $P_{OW}$  is expected to be lower due to ionisation and consequently have weaker adsorption

#### 5. INDUSTRIAL USE

Orasol Blue 761B is an industrial dyestuff for use in printing inks (major) and industrial lacquers (minor). It is a solvent soluble dye and is to be used in speciality areas where the highest transparency is required. It is to be mainly used in the printing of metallic foils and metal coated plastics. The notified chemical is expected to be used at concentration between 1-5% in the formulated printing inks and between 12-18% in industrial lacquers.

The volume to be imported will be less than one tonne per annum. The notifier has estimated that 90% will be used in printing inks and the rest in lacquers for specialised uses.

## 6. OCCUPATIONAL EXPOSURE

The notified chemical will be imported into Australia as a blue powder in cardboard boxes with antistatic plastic liners. The notifier states that it is stored and transported in Australia in unbreakable containers, indicating that if the boxes are dropped the plastic liner is unlikely to split. Reformulation of the notified chemical into either industrial lacquers or printing ink will be undertaken at between 4 and 6 establishments. The notifier has indicated these are in the Melbourne area.

The total numbers of staff employed in the roles of plant operators and laboratory technicians is a maximum of 152, of these, only 20 will be potentially exposed to the notified chemical during reformulation. There will also be approximately 10-30 other workers exposed to the formulations containing the notified chemical as printers and spray painters, it should be noted that all of these formulations also contain volatile solvents at much higher concentrations than the notified chemical. The notified chemical will be at concentrations of between 1-5% in these formulations.

Worker exposure to the notified chemical will be greatest during weighing and mixing. During mixing, the notified chemical is added slowly to prevent lumps forming and hence increasing the mixing required for the batch. Where there is the risk of aerosol formation such as during weighing and batching then local exhaust ventilation is implemented. Following mixing the formulation will be dispensed to containers. As the formulations contain solvents and resins, protective measures associated with this exposure will also reduce exposure to the notified chemical. Laboratory staff will also be exposed, exposure will be limited to small quantities of the notified chemical (<100g) for periods of less than one hour every few months.

## 7. PUBLIC EXPOSURE

The notified chemical, Orasol Blue 761B, will be imported directly into Australia. The chemical will be used as a blue soluble dyestuff and incorporated, at concentrations ranging from 1% to 18%, into solvent based printing inks and industrial lacquers. The notifier estimates that 90% of the dyestuff will be used in printing inks, and the remainder in lacquers. The proposed uses for the printing inks include packaging material for luxury items, distinctive labels and fancy cards, printing onto aluminium foil, metallised films and other metallic surfaces. The notified chemical will not be used for general paper printing. The lacquers, for example, may be used for transparent coatings applied to metallic surfaces such as aluminium lamp shades and metallic boxes. The notifier claims that the general public do not normally have access to the printing inks or industrial lacquers.

The majority of public exposure will result from contact with articles which have been coloured using the printing ink or lacquer containing the notified chemical. If the notified chemical is not 100% bound to the article, small amounts of the chemical may be released from the ink or lacquer during handling, resulting in dermal, and possibly ocular, contact. However, the notifier claims that "Once the [chemical] is incorporated into printing inks or lacquers and applied to articles, it will be encapsulated in resin [and ink] and bound to a substrate". Since the dye is used at a low concentration in inks or lacquers (1-5%), significant public exposure from the above articles is unlikely.

Minor public exposure may result from accidental spillage during transport and storage of the dye.

## 8. ENVIRONMENTAL EXPOSURE

## - Release

Releases to the environment should be limited. Waste generated (chemical lost) during formulation of the ink and lacquers has been estimated to be less then 5 kg/year. Some of this waste will be as dust and disposed of with the dust collectors/air filters as hazardous waste. The remaining waste is expected to be released to the waste water system of the formulator and then to the municipal sewer.

When used in inks or lacquers and applied to articles, the notified chemical will be diluted and embedded in a resin matrix which will limit any environmental release. Articles containing small amounts of the notified chemical could be disposed of with the normal household waste. Any release that does occur from articles will be slow, gradual and widely dispersed.

## - Fate

The fate of most of the notified chemical is identical to that of the articles to which it is bound. The notifier expect most of these articles to be disposed of with the normal domestic waste, ie by incineration or landfill.

The fate of the waste released to the air (as dust) during formulation will be as landfill or incinerated with the dust collectors/air filters. The remaining waste released during formulation will be to the sewer and is expected to be trapped with the solids in the sludge, which is normally landfilled or incinerated.

As the inks and lacquers containing the dye are solvent based, solvents must be used in cleaning up any spills of these inks and lacquers or cleaning any equipment used in applying these products. If the amount of material to be cleaned is relatively small, rags etc are likely to be used which are normally disposed of by incineration or landfill. When larger quantities of solvents are used these will be disposed of as solvent waste by incineration or the solvents recycled and the residue disposed of by either incineration or landfill.

The notified chemical was classified as not readily biodegradable (EEC C.4, modified Sturm test). However, as approximately 10% degradation occurred, with the limiting factor suggested as being the low solubility in water, slow degradation in the environment is possible.

The notified chemical is not expected to bioaccumulate in the environment due to the relatively high molecular weight, the variety of functional groups (both limiting the capacity for bioaccumulation) and the low environmental exposures expected.

## 9. EVALUATION OF TOXICOLOGICAL DATA

# 9.1 Acute Toxicity

Table 1 Summary of the acute toxicity of Orasol Blue 761B

Test	Species	Outcome	Reference
Acute oral toxicity	Rat	LD <sub>50</sub> >2000mg/kg	(1)
Acute dermal toxicity	Rat	LD <sub>50</sub> >2000mg/kg	(2)
Skin Irritation	Rabbit	Slight irritant	(3)
Eye irritation	Rabbit	Severe irritant	(5)
Skin sensitisation	Guinea-pig	Negative	(6)

# **9.1.1 Oral Toxicity (1)**

Albino outbred Wistar rats (5 per sex; approximately 9 weeks old) were administered a single gavage dose of 2000 mg of the notified chemical (Orasol Blue 761B)/kg. The animals were maintained for 15 days. Mortality was assessed twice daily, and clinical signs of toxicity were determined several times on the day of chemical dosing, and once daily thereafter. Body weight was determined on days 1 (pre-dosing), 8 and 15. An autopsy was performed on all animals at the completion of the study.

No mortalities or treatment related findings were noted during the study. At autopsy, greyish coloured abdominal fat, and enlarged stomachs, were noted in female rats.

The acute oral LD50 of the notified chemical was greater than 2000 mg/kg in male and female rats.

# 9.1.2 Dermal Toxicity (2)

A dose of 2000 mg of the notified chemical (Orasol Blue 761B)/kg was applied to shaved, intact skin of Wistar rats (5 per sex, approximately 8 weeks old). The area was occluded for 24 hours, after which, the residual chemical was removed using a water moistened tissue. The study was terminated after 15 days. Mortality and clinical signs of toxicity were assessed several times on the day of test compound application, and twice daily (for mortalities) and daily (for clinical signs of toxicity) thereafter. Body weight was determined on days 1, 8 and 15. Skin irritation was assessed daily. An autopsy was performed on all animals at the completion of the study.

No deaths were recorded, no toxicologically related lesions were seen on autopsy, and no evidence of skin irritation was noted during the study. Reduced body weight gain was noted amongst 4 of 5 males, and 1 of 5 females during the first week of the study.

The acute dermal LD50 of the notified chemical was greater than 2000 mg/kg in male and female rats.

# 9.1.3 Inhalation Toxicity- Not done

# 9.1.4 Skin Irritation (3)

The fur was removed from the back of 3 female Albino New Zealand White rabbits, and 500 mg of the notified chemical (Orasol Blue 761B) was applied to the intact skin for 4 hours. Residual chemical was then removed. Animals were examined daily for clinical signs of toxicity. Body weight was determined on the day of chemical application. Skin reactions were assessed approximately 55 minutes, 24, 48 and 72 hours after chemical removal. The severity of the reactions were determined by the degree of erythema, eschar formation and oedema, as described by Draize.

Very slight erythema (grade 1) was noted in 3 of 3 animals, 24 hours after chemical application, which resolved within 48 hours. The degree of erythema prior to 24 hours was difficult to assess due to the blue discolouration of the skin.

The notified chemical was a slight dermal irritant in rabbits. The extent of the irritation was below the criteria that would require it to be classified as hazardous (4).

## 9.1.5 Eye Irritation (5)

A dose of approximately 55 mg of the notified chemical (Orasol Blue 761B) was instilled into the left conjunctival sac of 3 female New Zealand White rabbits. Eyes were washed 2 days after chemical installation. The study was terminated after 21 days. Clinical signs of toxicity were assessed on a daily basis. Body weight was determined on the day of application. The eyes were examined 1, 24, 48 and 72 hours, and 7, 14 and 21 days, after chemical installation, and the degree of irritation assessed using the Draize method. To assess the presence, and severity, of corneal damage, a 2% fluorescein solution was instilled into the eyes after observations on days 2, 4, 8, 15 and 22.

Corneal opacity (grade 1), and corneal epithelium damage, was noted in all 3 animals 24 hours after installation. Corneal opacity and/or evidence of corneal injury remained in 2 of 3 animals at the conclusion of the study. Conjunctival redness (grade 1-3) was noted in 3 of 3 eyes for the duration of the study, and conjunctival discharge (grade 2) was noted in all animals up to 72 hours. Chemosis (grade 1-3) was evident in all animals up to 72 hours after chemical installation. Total Draize score after 72 hours was 54, after 7 days was 19, and after 21 days was 11.

The notified chemical was a severe ocular irritant in rabbits.

## 9.1.6 Skin Sensitisation (6)

Five female Himalayan albino guinea pigs (approximately 9 weeks old) were used in a preliminary induction dose finding study. Subsequently, thirty female Himalayan albino guinea pigs were divided into a control (n = 10) and a treatment group (n = 20). The hair was removed, using clippers, from a region behind the right shoulder. The induction doses consisted of a series of intradermal injections given either side of the clipped area. The intradermal injections were either the test substance dissolved to 5% (w/w) with propylene glycol, 50:50 Freunds Complete Adjuvant with water, or 50:50 test substance dissolved to 10% with propylene glycol mixed with Freunds Complete Adjuvant. Seven days after intradermal injections, an epidermal induction dose of 0.5 mL of a 50% w/w suspension of the notified chemical (Orasol Blue 761B) in vaseline was applied to the exposed skin of the treatment group. An occlusive dressing was applied, and after 48 hours the chemical, and dressing, were removed. Application sites were assessed for erythema and oedema following removal of the dressing. The control group was treated in a similar fashion to that described, but the notified chemical was omitted. In addition, intradermal injections of 0.1 mL of Freunds Complete Adjuvant were administered either side of the application area to the control and treatment groups, on day 5. The challenge dose for each animal consisted of 0.05 mL of a 10%, 25% and 50% suspension of the notified chemical (Orasol Blue 761B) in vaseline, or as a control, vaseline alone, and was applied, at four separate sites, to a clipped region on the left flank. The residual test material was removed after 24 hours. The application sites were assessed for redness and swelling 24 and 48 hours after removal of the test material. In addition, animals were examined for clinical signs of toxicity on a daily basis, and body weights were determined at the beginning and end of the study.

One of 20 animals showed red spots after the 50% challenge dose, and 1 of 20 animals showed red spots in response to the 10% challenge dose.

The notified chemical (Orasol Blue 761B) did not cause skin sensitisation in the guinea pig.

# 9.2 Repeated Dose Toxicity (7)

Groups of 5 Wistar rats per sex (approximately 6 weeks old) were administered 0, 50 mg (LD), 200 mg (MD) or 1000 mg (HD) of the notified chemical (Orasol Blue 761B, in propylene glycol)/kg/day, by gavage, for 28 days. Separate groups (n = 5 per sex) of rats which had been untreated, or had received 1000 mg/kg/day for 28 days, were maintained, untreated, for an additional 14 day recovery period. Clinical signs of toxicity were assessed daily, animal viability was determined twice daily, food consumption and body weight was determined weekly, and an ophthalmic examination was carried out during week 4 (all animals) week 6 (recovery animals). Blood was collected for haematology and clinical biochemistry at the completion of the study. Autopsies, which included selected organ histopathology, and organ weight determinations, were carried out at study termination.

Hunched posture was noted in 5 of 5 LD males, 1 of 5 LD females, 4 of 5 MD males, 5 of 5 MD females, and all HD males and females in the latter half of the treatment period. The hunched posture was still evident in the HD male and female group at the completion of the study. Body weight was reduced in the MD and HD male groups, and in the HD female group. Body weight gain was reduced in HD males and females, with the reduction remaining evident in HD males at the conclusion of the recovery period. A corresponding reduction in food consumption, which was reversible, was noted in HD male and female groups. Evidence of anaemia, as indicated by a reduction in RBC numbers and a corresponding reduction in haematocrit, was noted in MD and HD males. An increase in total WBC numbers was a feature of the HD female group. Such haematogical alterations were reversible, with a compensatory increase in RBC numbers in HD males at the end of the recovery period. ALT, cholesterol and triglyceride levels were elevated in HD males and females, and AST was elevated in HD females, at the end of the treatment period. The elevated ALT remained at the conclusion of the recovery period.

The relative weights of the livers, kidneys, adrenals and testes from HD males, and the weight of the livers from HD females, were elevated at the end the treatment period. Very slight to slight hepatocellular hypertrophy, which was reversible, was noted in the HD male and female group at the end of the treatment period. At the end of the recovery period, the relative weight of the testes remained elevated in HD males, as did the relative weight of the livers and spleens from the HD females.

The notified chemical was associated with signs of ill-health (hunched posture) even at the lowest dose.

9.3 GenotoxicitySummary of genotoxicity studies using Orasol Blue 761B.

STUDY TYPE	TEST OBJECT	CONC.	RESULT	REF.
Reverse mutation	S. typhimurium strain TA98, TA100, TA 1535, TA1537 and TA 1538, and <i>E. coli</i> , strain WP2 <i>uvrA</i>	3.3-5000 mg/plate (± rat liver S9 fraction activation)	-ve	8
Micro- nucleus formation	Mouse erythrocytes	150, 500 or 1500 mg/kg (5 males and females).	-ve	9
In vivo/In vitro UDS	Rat hepatocytes	200 or 2000 mg/kg	-ve	10
Clastogenic effects	Chinese hamster V79 cells	3-100 µg/l	+ve	11

# 9.4 Overall Assessment of Toxicological Data

The studies demonstrated that the notified chemical (Orasol Blue 761B) has low acute oral and dermal toxicity, is a slight dermal and a severe ocular irritant, and does not cause dermal sensitisation. Twenty eight day repeat dose studies in rats indicated that the target organ is the liver. Reversible hepatocellular hypertrophy was seen after administration of 1000 mg of the notified chemical/kg/day for 4 weeks. The substance was shown to be weakly genotoxic in the presence of metabolic activation (S9-mix) using Chinese hamster V79 cells. The compound, when assessed in other *in vitro* and *in vivo* test systems was not mutagenic.

On the basis of an assessment of the information provided by the notifier Orasol Blue 761B would be classified as hazardous according to the criteria of Worksafe Australia.

#### 10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following ecotoxicity studies have been provided by the notifier. These studies were conducted according to international standards (EEC directives and OECD Guidelines). A dispersing agent (Cremophor RH40) was used in the fish and daphnia tests.

Test	Species/	Result
Acute toxicity	Carp	96h LD50 between 0.1 and 0.3 mg.L <sup>-</sup> 1, NOEC < 0.01 mg L <sup>-1</sup>
Acute toxicity	Daphnia magna	48h EC50 =0.97 mg.L <sup>-1</sup> 48 hr NOEC = 0.6 mg L <sup>-1</sup>
Growth inhibition	Algae	72h EbC50 =0.061 mg.L <sup>-1</sup> , 72 hr ErC50 =0.087 mg L <sup>-1</sup> 72 hr NOE <sub>b</sub> C and NOE <sub>r</sub> C =0.02 mg L-1
Activated Sludge	Bacteria	EC50> 200 mg/L

The ecotoxicity studies show that the dye is toxic to aquatic organisms and can be rated as highly toxic to fish and daphnia and very highly toxic to algae. The notified chemical could have significant effects on aquatic organisms and releases to waterways should therefore be kept to a minimum.

## 11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The company has not specified the exact location of the manufacturing facilities where the dye will be incorporated into the printing inks and lacquers. However the company has indicated that these are in the Melbourne area and that between 4 and 6 facilities could use the chemical.

Assuming that each batch of ink or lacquer formulated uses 10 kg of the dye per day, of which 1% (stated by the company to be <1%) is discharged to the sewer. Then:

Amount of chemical discharged to the sewer

100 g

Most industrial effluent from Melbourne based industry is treated at Werribee, average flow approximately 500 ML per day.

Concentration discharged to environment

0.2 ppb

The estimated concentration is 100 times below the NOEC for the most sensitive species tested, algae. This calculation assumes that there was no removal of the notified chemical by the sewage treatment process and that all of the chemical is released via the waste water. As the Pow is expected to be high, the chemical should adsorb in the alkaline sewer to the sludge and therefore reduce the actual concentration that is discharged to the environment. Also there is further dilution upon discharge into Port Phillip Bay.

Articles coated with printing inks and lacquers containing the notified chemical are expected to be disposed of in the domestic garbage, which is incinerated or landfilled.

Incineration of the notified chemical will generate oxides of carbon, nitrogen and sulphur as well as water. As the chemical is expected to have a high  $P_{OW}$  and that sent to landfill will be in trapped in a resin matrix, the waste consigned to landfill is unlikely to leach and will stay in the landfill. The environmental hazard from the disposal of printing inks and lacquers waste containing the chemical is rated as low.

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

The overall environmental hazard can be rated as low. Should the company increase the amount to be imported to >1 tonne or proposes uses resulting in higher releases to the aquatic compartment, the environmental hazard will have to be reassessed.

# 12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Orasol Blue 761B has low oral and dermal toxicity is not a skin sensitiser or classified skin irritant. It is however classified as a severe eye irritant. Repeat-dose oral toxicity is low. The dye was not mutagenic but weakly genotoxic. Based on the toxicological data given, specifically the eye irritancy, Orasol Blue 761B is classified as hazardous according to Worksafe Australia criteria.

The level of exposure to Orasol Blue 761B during air freight and transport to the warehouse is expected to be negligible as the notified chemical will be in lined cardboard boxes. Significant exposure to the notified chemical may occur in the event of an accident if the boxes are ruptured.

There is a limited amount of handling of the colourant (Orasol Blue 761B) prior to its incorporation into formulations. It is estimated that a total of 20 employees will be exposed to Orasol Blue 761B during weighing, formulation and associated laboratory work. Where there is a possibility of aerosol formation then local exhaust ventilation is used, and protective safety clothing worn. Orasol Blue 761B is formulated into printing

inks and lacquers for specialised uses. Exposure to these formulations during application is limited as they are solvent based and protective measures to reduce exposure to the solvents will also reduce exposure to the notified chemical.

Public exposure to the notified chemical will occur with the final formulations when applied to items general use. This will be limited due to notified chemicals bound state, being encapsulated in resins and bound to a substrate. The concentration in these formulations is also low (1-5%). Due to these factors public exposure to the notified chemical will be minimal. The notified chemical is unlikely to constitute a risk to public health.

#### 13. RECOMMENDATIONS

To minimise occupational exposure to Orasol Blue 761B the following guidelines and precautions should be observed:

- . If engineering controls and work practices are not sufficient to reduce exposure to a safe level the following personal protective equipment should be used:
  - The appropriate respiratory device should be selected and used in accordance to Australian Standard/New Zealand Standard (AS/NZS) 1715 (13) and should comply to AS/NZS 1716 (14).
  - Eye protection (chemical goggles or face shields) should be selected and fitted in accordance to AS 1336 (15) and used in accordance to AS/NZS 1716 (16).
  - Industrial clothing must conform to the specifications detailed in AS2919 (17).
  - . Impervious industrial gloves should conform to the standards detailed in AS 2161 (18).

All occupational footwear should conform to AS/NZS 2210 (19).

The standard for nuisance dusts should be observed at all times.

Work practices should minimise the formation of dusts.

Ensure that good general exhaust ventilation is installed in areas where dust aerosols can be generated.

At all times avoid physical eye contact with unfixed dye or dyebath contents.

A copy of the Material Safety Data Sheet should be easily accessible to employees.

## 14. MATERIAL SAFETY DATA SHEET

The Material Safety Data Sheet (MSDS) for Orasol Blue 761B was provided in Worksafe Australia format (12).

This MSDS was provided by Ciba-Geigy Australia Ltd. as part of their notification statement. The accuracy of this information remains the responsibility Ciba-Geigy Australia Ltd.

## 15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals* (*Notification and Assessment*) *Act 1989*, secondary notification of Orasol Blue 761B 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. Daamen, P A M, 1993. Assessment of acute oral toxicity with Orasol Blue 761B in the rat., Report No.: 076804, data on File. RCC NOTOX BV, The Netherlands. May 1993. QA; GLP; EEC Directive 84/449/EEC, Annex V of the EEC Directive 67/548/EEC, Part B; OECD, Health Effects No. 401.
- 2. Daamen, P A M, 1993. Assessment of acute dermal toxicity with Orasol Blue 761B in the rat. Report no.: 076815, data on file. RCC NOTOX BV, The Netherlands, May 1993. QA; GLP; EEC Directive 84/449/EEC, Annex V of the EEC Directive 67/548/EEC, Part B; OECD, Health Effects No. 402.
- 3. Pels Rijcken, WRP, 1993. *Primary skin irritation/corrosion study with Orasol Blue 761B in the rabbit (4 hour semi-occlusive application)*, Report No.: 076826, data on file. RCC NOTOX BV, The Netherlands, June 1993. QA; GLP; EEC Directive 84/449/EEC, Annex V of the EEC Directive 67/548/EEC, Part B; OECD, Health Effects No. 404.
- 4. National Occupational Health and Safety Commission, 1994, *Approved criteria for classifying hazardous substances* [NOHSC:1008(1994)], AGPS, Canberra.
- 5. Pels Rijcken WRP. *Acute eye irritation/corrosion study with Orasol Blue 761B in the rabbit.* Report No.: 076837, data on file. RCC NOTOX BV, The Netherlands, July 1993. QA; GLP; EEC Directive 84/449/EEC, Annex V of the EEC Directive 67/548/EEC, Part B; OECD, Health Effects No. 405.
- 6. Daamen, P A M, 1993. Assessment of contact hypersensitivity to Orasol Blue 761B in the albino guinea pig. Report No.: 076848, data on file. RCC NOTOX BV, The Netherlands, June 1993. QA; GLP; EEC Directive 84/449/EEC, Annex V of the EEC Directive 67/548/EEC, Part B.6; OECD, Health Effects No. 406.
- 7. Reijnders, JBJ. Subacute 28-day oral toxicity with Orasol Blue 761B by daily gavage in the rat followed by a 14 day recovery period. Report No.: 076861, data on file. RCC NOTOX BV, The Netherlands, July 1993. QA; GLP; EEC Directive 92/69/EEC, Annex V of the EEC Directive 67/548/EEC, Part B; OECD, Health Effects No. 407.
- 8. Poth A, 1992. Salmonella typhimurium and Escherichia coli reverse mutation assay with Orasol Blue 761B. Report no.: 302815, data on file. CCR GMBH and Co KG, FRG., September 1992. QA, GLP.
- 9. Fautz, *R*,1992. *Micronucleus assay in bone marrow cells of the mouse with Orasol Blue 761B.* Report No.: 415607. CCR GMBH and Co KG, FRG., July 1993. QA, GLP.

- 10. Fautz, R,1993. *In vivo/in vitro unsheduled DNA synthesis in rat hepatocytes with Orașol Blue 761B.* Report No.: 418004, data on file. CCR GMBH and Co KG, FRG., September 1993. QA, GLP.
- 11. Heidemann A, 1983. Chromosome aberration assay in Chinese hamster V79 cells in vitro with Orasol Blue 761B. Report No.: 302826, data on file. CCR GMBH and Co KG, FRG., August 1983.
- 12. National Occupational Health and Safety Commission, 1990. *Guidance Note for the Completion of a Material Safety Data Sheet,* 2nd. edition, AGPS, Canberra.
- 13. Standards Australia, Standards New Zealand, 1994. *Australian/New Zealand Standard 1715 1994 Selection, Use and Maintenance of Respiratory Protective Devices*. Standards Association of Australia Publ., Sydney, Australia, Standards Association of New Zealand Publ., Wellington, New Zealand.
- 14. Standards Australia/ Standards New Zealand, 1991. *Australian/New Zealand Standard 1716 1991 Respiratory Protective Devices.* Standards Association of Australia Publ., Sydney, Australia.
- 15. Standards Australia, 1994, *Australian Standard 1336-1994, Recommended Practices for Eye Protection in the Industrial Environment*, Standards Association of Australia Publ., Sydney, Australia.
- 16. Standards Australia, Standards New Zealand 1992, Australian/ New Zealand Standard 1337-1992, Eye Protectors for Industrial Applications, Standards Association of Australia Publ., Sydney, Australia, Standards Association of New Zealand Publ. Wellington, New Zealand.
- 17. Standards Australia, 1987, *Australian Standard 2919 1987 Industrial Clothing,* Standards Association of Australia Publ., Sydney, Australia.
- 18. Standards Australia, 1978, Australian Standard 2161-1978, Industrial Safety Gloves and Mittens (excluding Electrical and Medical Gloves), Standards Association of Australia Publ., Sydney, Australia.
- 19. Standards Australia, Standards New Zealand 1994, Australian/ New Zealand Standard 2210 1994 Occupational Protective Footwear, Part 1: Guide to Selection, Care and Use. Part 2: Specifications, Standards Association of Australia Publ., Sydney, Australia, Standards Association of New Zealand Publ. Wellington, New Zealand.