File No: NA/799

2 January 2001

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME**

# FULL PUBLIC REPORT

**DS-3175A-E**

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Director
Chemicals Notification and Assessment

# FULL PUBLIC REPORT

## DS-3175A-E

## 1. APPLICANT

Amtrade International Pty. Ltd of Level 2, 570 St. Kilda Road, Melbourne, Victoria 3004 (ACN 006 409 936), has submitted a limited notification statement in support of their application for an assessment certificate for DS-3175A-E.

## 2. IDENTITY OF THE CHEMICAL

The chemical name, CAS number, molecular and structural formulae, molecular weight, spectral data, details of the chemical formulation, exact import volume details and customers have been exempted from publication in the Full Public Report and the Summary Report.

**Marketing Names:** DS-3175A-E
3175 H.P. Naphthol Red, Transparent

## 3. PHYSICAL AND CHEMICAL PROPERTIES

The following data are for the notified chemical.

| | |
|---|---|
| **Appearance at 20°C & 101.3 kPa:** | Dark red powder. |
| **Melting Point:** | Decomposes at 314°C (EC Method A1 of 92/69/EEC). |
| **Specific Gravity:** | 1.45 at 21.5°C (EC Method A3 of 92/69/EEC). |
| **Vapour Pressure:** | Not determined (Predicted to be 3.65 x $10^{-22}$ Pa). |
| **Water Solubility:** | Less than 0.129 mg/L at 20°C (see comments below). |
| **Partition Co-efficient (n-octanol/water):** | Log $P_{ow}$ = 4.74 (see comments below). |
| **Hydrolysis as a Function of pH:** | Not determined (see comments below). |
| **Adsorption/Desorption:** | Not measured experimentally.<br>Log Koc estimated at 3.94 (QSAR) and 4.47 (PCKOCWIN). |
| **Dissociation Constant:** | Not measured due to low water solubility. $pK_a$ for the phenol group is predicted to be 10.62 using the Hammet |

| | |
|---|---|
| | computer model. |
| **Particle size:** | 76.8% substance is less than 100 µm (Sieve method).<br>4.93% substance is less than 10 µm (Cascade impactor method). |
| **Flash Point:** | Not applicable for a high melting solid. |
| **Flammability Limits:** | Not highly flammable (EC Method A10). Combustible; Will burn in fire, evolving noxious fumes. |
| **Autoignition Temperature:** | No self-ignition below 400°C (EC Method A16). |
| **Explosive Properties:** | Not explosive. |
| **Reactivity/Stability:** | Stable. |

**Comments on Physico-Chemical Properties**

Full test reports were provided. Tests were performed according to EEC/OECD test guidelines at facilities complying with OECD Principles of Good Laboratory (Woolley and Mullee, 2000).

Vapour pressure was not determined, though the notifier expects that it will be negligible.

The flask method with HPLC analysis, based on EC Method A6 of 92/69/EEC, was used to determine the water solubility of the notified chemical. The column elution method could not be used, as it was not possible to properly coat the notified substance onto the glass beads. However, the solubility value was very low and below the limit of detection for the method.

Partition coefficient determination was performed using the HPLC method of EC Method A8 in 92/69/EEC. Six reference standards were used having Log Pow between 2.1 to 6.2. The result (Log Pow=4.74) indicates that the chemical is hydrophobic and associated with the n-octanol phase.

Hydrolysis as a function of pH was not determined due to the low water solubility of the notified chemical. The chemical does not contain any groups likely to hydrolyse under environmental conditions, though the two amide groups may do so under much more forcing conditions.

The Adsorption/Desorption laboratory test was not performed. However, QSAR calculations were used to estimate the Log Koc at 3.94. An alternative estimate of 4.47 was calculated using PCKOCWIN version 1.66 software. The notified chemical exhibits low water solubility and therefore entry into and through the soil profile is expected to be low. The notified chemical is expected to associate with the organic fraction of soil and sediments.

## 4. PURITY OF THE CHEMICAL

**Degree of Purity:** More than 90% pure.

**Hazardous Impurities:** None.

**Non-hazardous Impurities (>1% by weight):** Exempt information.

**Additives/Adjuvants:**

| | |
|---|---|
| *Chemical name:* | Sulfated castor oil |
| *Synonyms:* | Sulfonated castor oil |
| *CAS No.:* | 8002-33-3 |
| *Weight percentage:* | 4-8 % |

## 5. USE, VOLUME AND FORMULATION

The notified chemical is a pigment and will be used to colour plastic articles, not including containers that come in contact with food. It will be imported as a 5% component of a pigment mix and used to manufacture coloured masterbatch, which will be sold to plastic moulders for plastic articles manufacture. The final concentration of the notified chemical in the plastic articles will be <1%. The pigment mix substance is a dry powder and will be imported in 11.3 kg paper bags with inner plastic lining. The notifier estimates that less than 1 tonne of the pigment will be imported each year for the first five years.

## 6. OCCUPATIONAL EXPOSURE

*Transport and storage*

The imported product contained in 11.3 kg bag will be unloaded at the docks and transported by road to a warehouse for storage until required. The notifier estimates that, due to low volumes of the substance being imported into Australia, only three workers (one driver and two storemen) will be involved in its transportation and warehousing. The total time for handling the substance has been estimated to be one workweek per year. The masterbatch produced from the pigment mix will be bagged in 25 kg woven polypropylene bags. Larger orders may be packed in 110-190 L fibre or steel drums as well as supper sacks. Normal transportation mode for the masterbatch within Australia is by road. The final plastic articles are generally not packed as chemical substances, but a crate or cardboard container will be used to transport plastic parts/units. Larger plastic units may be palletised and shrink-wrapped for transportation without the use of a container per se. Finished articles will be transported by truck and/or rail within Australia. The number of workers involved in the packing, storage and transportation of the masterbatch or the finished articles is not provided.

*Masterbatch production*

At the production site, a weighing operator (one worker) will open the bags of new material and weigh out the pigment mix and polymer required for a given batch (10 batches per year). The estimated exposure time for the weighing operator to the notified chemical is 15 minutes

per day, 30 days per year. Dermal and ocular exposure is possible during these tasks. As the particle size of the pigment is within the inspirable range, with approximately 10% in the respirable range, inhalation exposure is also possible. An operator (one worker) will add the weighed out substances to a blender for mixing. The blend is then fed to an extruder to produce dust-free pellets of polymer masterbatch (colour concentrate). Extrusion is carried out in a closed system. At this point, the notified chemical will be embedded within the polymer matrix of the masterbatch pellets. The concentration of the pigment mix in the masterbatch will be 30% (1.5% notified chemical). It is estimated that the extruder operator will be exposed to the substance for 6 hours per day, 30 days per year. Dermal and inhalation exposure may occur when adding the pigment mix to the mixing vessel.

The final steps, packaging and transportation of the masterbatch, are stated to be carried out in a dust free environment. One package operator and one shipping operator will be potentially exposed to the masterbatch product for 30 and 45 days/year, respectively, for up to half hour per day.

*Plastic article production*
At the plastic article production site, the pelletized masterbatch will be weighed and mixed with additional polymer then extruded or moulded into the final plastic article. The concentration of the pigment mix in the final article will be 1-2% (0.05-0.1% notified chemical). The finished articles will be packaged for shipment.

There will be no more than one employee in each of the production steps. The moulder and packaging operators may be exposed to the masterbatch and the finished articles for up to 7 hours per day, 15 to 40 days per year. The shipping operator may be exposed to the finished product for 7 hours per day, 5-20 days per year. Dermal exposure to the masterbatch and the finished product is possible. However, the concentration of the notified polymer is very low and it is embedded in the plastic moiety.

The notifier states that engineering controls, such as dust collection systems, would be utilised at the weighing and blending operations (masterbatch production) and in some cases at the moulding phase (article production). Workers involved in the weighing and blending steps will be wearing protective clothing, eye protection and respiratory protection equipment. Moulder and extruder operators and packers do not wear respiratory protection, as no dust or vapours are expected during these operations.

*Use of plastic articles*
The notified chemical will be used primarily to colour plastic articles, where the chemical is bound within the polymer matrix. The notified chemical is not volatile and will not exude under normal process or use conditions. Exposure of workers or end users to the notified chemical is therefore expected to be minimal.

## 7. PUBLIC EXPOSURE

Exposure of the general public to the notified chemical during transport, formulation, storage and use is expected to be very low. There will be limited public contact with finished plastic products containing the notified chemical, as these will not be sold to the public.

## 8. ENVIRONMENTAL EXPOSURE

### Release

*Masterbatch Formulation*
The notifier has not provided any estimates for the amount of the notified chemical (as powdered pigment) that is expected to be spilled during weighing, blending and extrusion stages of the masterbatch formulating process. However on past experience in assessment of this type of pigment powder, it is expected that this figure would be <1% (up to 4 kg/annum). This waste may presumably be reused in future batches if uncontaminated, or disposed of to landfill.

The equipment will be cleaned by purging with resin, which will then be incorporated into future batches. Solid, spilled, contaminated masterbatch granules will be swept up and reprocessed into less critical products.

The notifier estimates that less than 0.1% (<0.4 kg/year) of the pigment will be disposed of to landfill as residue in empty packaging.

*Plastic Processing*
The notifier states that most off-spec material and plastic sprue will be reprocessed into lower quality articles. Contaminated floor sweepings and over heated plastic scraps estimated at up to 0.25% (1.5 kg chemical/year) would be deposited into landfill.

Release may also occur as a result of spills during road or rail transport. The small package sizes and particulate nature of the product means that any spills will be expected to be minor and may be cleaned up easily.

Ultimately the majority of the notified chemical contained within plastic articles will be deposited to landfill or incinerated at the end of their useful life. Some plastic articles may be recycled but the statistics for recycling have not been determined and the recycling percentage is likely to be very low at present.

**Fate**

*Fate of Pigment in Powdered Form*
Negligible release of the notified chemical into sewer is expected to occur during reformulation and processing.

The notified chemical has low water solubility (<0.129 mg/L), and is not expected to be readily biodegradable (Clark and Anliker, 1980) or hydrolyse at environmental pH. The log $P_{OW}$ of 4.74 suggests that the notified chemical will adsorb to aquatic sediment.

The notified chemical has the potential to bioaccumulate due to its relatively low molecular weight and log $P_{OW}$ of 4.74. However Anliker and Moser (1987) found that organic pigments do not bioaccumulate in fish and attributed this to the very limited lipid storage potential of the pigments. The low n-octanol solubility (<11.6 mg/L) reported in the submission and anticipated the low exposure to the aquatic compartment indicate low potential for bioaccumulation.

Pigment released into landfill, as residue would be expected to sorb to soil organic matter and remain immobile. The notified chemical is expected to slowly degrade via biotic and abiotic processes.

*Fate of Pigment in Polymer and Plastic Form*
In either masterbatch or plastic form, the notified chemical will be firmly encapsulated by the polymer. It is not expected to be mobile in landfill but to slowly degrade from biotic and abiotic processes. Incineration of products containing the notified chemical will produce water and oxides of carbon and nitrogen.

## 9. EVALUATION OF TOXICOLOGICAL DATA

Toxicological data for DS-3175A-E is not available. The notifier has submitted toxicological data on a structural analogue (DS-2920A-E) of the notified chemical.

The data is accepted as a surrogate data for DS-3175A-E, based on the similarity of structural formulae of the two chemicals.

### 9.1 Acute Toxicity

**Summary of the acute toxicity of DS-2920A-E**

| *Test* | *Species* | *Outcome* | *Reference* |
|---|---|---|---|
| Acute oral toxicity | Rat | $LD_{50}$ >2000 mg/kg bw. | Safepharm Laboratories Ltd, 1988a |
| Skin sensitisation | Guinea pig | Not a skin sensitiser | Safepharm Laboratories Ltd, 1988b |

#### 9.1.1 Acute oral Toxicity (Safepharm Laboratories Limited, 1998a)

*Species/strain:* Sprague-Dawley CD strain rats.

| | |
|---|---|
| *Number/sex of animals:* | 5/sex |
| *Observation period:* | 14 days |
| *Method of administration:* | Oral (gavage); 2000 mg/kg bw DS-2920A-E in 10 mL/kg bw. |
| *Test method:* | OECD TG 401 (limit test) |
| *Mortality:* | There were no deaths. |
| *Clinical observations:* | No signs of systemic toxicity were noted. All animals showed normal body weight gains. Faeces of all animals were stained orange one or two days after treatment. The urine of all females was stained orange during this period. |
| *Morphological findings:* | No abnormalities were noted at necropsy. |
| *$LD_{50}$:* | >2000 mg/kg bw. |
| *Result:* | DS-2920A-E was of very low acute oral toxicity in rats |

### 9.1.2 Skin Sensitisation (Safepharm Laboratories Limited, 1998b)

| | |
|---|---|
| *Species/strain:* | Dunkin Hartley guinea pigs |
| *Number of animals:* | 30 (female, 20 test animals and 10 control animals) |
| *Induction procedure:* | |
| Test group: Day 0 | Three intradermal injections (0.1 mL) were made on each side of the mid-line. The injections were:<br><br>FCA diluted 1:1 with distilled water<br>25% w/v DS-2920A-E in distilled water<br>25% w/v DS-2920A-E in a 1:1 mixture of FCA and water. |
| Day 7 | A 2x4 cm filter paper patch was saturated with 50% DS-2920A-E in distilled water and placed over the shaved area and covered by an overlapping layer of aluminium foil. The occlusive dressing was kept in place for 48 hours. |
| Control group: Day 0 | Treated controls: During the induction phase control animals (10 female) were treated in the same way as test animals except that the test substance was omitted from the intradermal injections and topical applications. |
| *Challenge procedure:* | |

Day 21 — The test and control animals were challenged topically two weeks after topical induction using 50% DS-2920A-E in distilled water. Patches of filter paper were saturated with 50% DS-2920A-E solution and placed on shaved right flanks for 24 hours.

To ensure that maximum non-irritant concentration was used at challenge, the test material at a concentration of 25% w/w in distilled water was similarly applied on the left shorn flank.

*Test method:* OECD TG 406, Magnusson and Kligman Maximisation Test.

*Challenge outcome:*

| ***Challenge concentration*** | ***Test animals*** | | ***Control animals*** | |
|---|---|---|---|---|
| | ***24 hours**** | ***48 hours**** | ***24 hours*** | ***48 hours*** |
| 25% | 0/20** | 0/20 | 0/10 | 0/10 |
| 50% | 0/20 | 0/20 | 0/10 | 0/10 |

* Time after patch removal
** number of animals exhibiting positive response (Draize score ≥1).

*Result:* DS-2920A-E was non-sensitising to the skin of guinea pigs

## 9.2 Genotoxicity

### 9.2.1 Reverse Mutation Assay (Safepharm Laboratories Limited, 1998c)

*Strains:* *Salmonella typhimurium* TA1535, TA1537, TA98 and TA100
*Escherichia Coli* WP2uvrA$^-$

*Metabolic activation:* Microsomal fraction from liver homogenates of Aroclor-induced male Sprague-Dawley rats (S9 fraction).

*Concentration range:* 0-5000 μg/plate DS-2920A-E

*Test method:* OECD TG 471 and 472

*Comment:* The plate incorporation assay was used. Positive controls were 9-aminoacridine, 4-nitroquinoline-1-oxide, N-ethyl-N'-nitro-N-nitrosoguanidine, 2-Aminoanthracene and benzo(a)pyrene. The positive control substances confirmed the reversion properties and specificity of the strains and were within historical ranges. The negative controls were within the historical ranges.

The test material up to 5000 µg/plate was non-toxic to strains of bacteria tested (TA100 and WP2uvrA$^-$). A dark orange colour was observed at 500 µg/plate, becoming intense at 5000 µg/plate but did not affect scoring.

No increase in the number of revertant colonies was observed at concentrations up to 5000 µg/plate, with and without metabolic activation.

*Result:* DS-2920A-E was non mutagenic under the conditions of the test

### 9.2.2 Chromosomal Aberration Assay in Human Lymphocytes *In Vitro* (Safepharm Laboratories Ltd, 1999)

*Cells:* Human lymphocyte culture

*Metabolic activation system:* Liver fraction (S9 mix) from Sprague-Dawley rats pre-treated with Aroclor 1254.

*Dosing schedule:* The test substance was dissolved in DMSO and tested in duplicate cultures in 2 experiments with or without metabolic activation.

| Metabolic Activation | Experiment/ Study Number | Test concentration (μg/mL) | Controls |
|---|---|---|---|
| -S9 | First<br><br><br><br>Second | Treatment/recovery time = 4/16 hours<br>39.06, 78.13, 156.25, 312.5, 625*, 1250*, 2500* and 5000 μg/mL.<br><br>Treatment time=20 hours<br>39.06, 78.13, 156.25, 312.5, 625*, 1250*, 2500* and 5000 μg/mL. | Positive: EMS (750 and 500 μg/mL in first and second experiments, respectively).<br><br>Negative: DMSO. |
| +S9 | First<br><br>1% S9 mix<br><br>Second<br>2% S9 mix | Treatment/recovery time = 4/16 hours<br>39.06, 78.13, 156.25, 312.5, 625*, 1250*, 2500* and 5000 μg/mL.<br><br>Treatment/recovery time = 4/16 hours<br>39.06, 78.13, 156.25, 312.5, 625*, 1250*, 2500* and 5000 μg/mL. | Positive: Cyclophosphamide (25 μg/mL).<br><br>Negative: Phosphate buffered saline. |

EMS - ethyl methanesulphonate; DMSO – dimethylsulphoxide; CP - Cyclophosphamide
* - Cultures selected for metaphase analysis

*Test method:* OECD TG 473

*Comment:* The chemical showed toxicity at 2500 and 5000 μg/mL without S9 and 2500 μg/mL with S9 in the first experiment, and showed toxicity at 1250 μg/mL with and without S9 in the second experiment.

Precipitates were observed in the first experiment at and above 1250 μg/mL in culture medium in both treatments. Precipitates were observed in the second experiment at and above 312.5 μg/mL in the culture medium in the without-activation group and at and above 1250 μg/mL in the with-activation group.

The chemical did not induce chromosomal aberrations in the absence or presence of metabolic activation in this *in vitro* cytogenetic test system.

Both positive control compounds caused large, statistically significant increases in the proportion of aberrant cells.

*Result:* DS-2920A-E was non-clastogenic under the conditions of the test.

### 9.3 Overall Assessment of Toxicological Data

No toxicological data for the notified chemical were available. However, limited data were

available for a structural analogue, DS-2920A-E.

DS-2920A-E was of very low acute oral toxicity ($LD_{50}$ >2000 mg/kg). It was not a skin sensitiser in the guinea pig.

Two *in vitro* genotoxicity studies were provided. DS-2920A-E was not mutagenic in bacteria or in human lymphocyte cultures.

Analogue data was not available on dermal toxicity, skin and eye irritation effects or subacute oral toxicity.

Toxicological data on the notified chemical or its analogue is not sufficient to classify the notified chemical as a hazardous substance according to NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1999).

## 10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicological data has been supplied by the notifier.

## 11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The majority of the notified chemical will ultimately be released to landfill or incinerated either as processing waste, sprue or plastic products at the end of their useful life. The notified chemical has low water-solubility and, when bound within a polymer matrix, either as a masterbatch or plastic articles, little release is expected to occur. Except in the case of accidental release during transport, the primary source of release of the pigment will be associated with the slow degradation of plastic and masterbatch granules into which the pigment is incorporated. This release will be widespread and diffuse, and unlikely to lead to toxic concentrations of the chemical.

Only a small percentage (1%) of the notified chemical is expected to be released into the environment in its powder form, unbound into the plastic matrix. The chemical has very low water solubility and should remain bound to the soils and sediments of the landfill and not be mobile in the aquatic compartment. Information from the published literature supports the position that pigment discharged into waterways should not present a significant bioaccumulation hazard to fish.

When used as indicated in the submission, the new chemical is unlikely to present a hazard to the environment.

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

No toxicological data for the notified chemical were available. Extrapolating from the limited toxicological data on a structural analogue, the notified chemical is likely to be of very low acute oral toxicity; not a skin sensitiser and not genotoxic. There are no data on the

irritant or repeat dose effects of the analogue.

Toxicological data on the analogue is not sufficient to classify the notified chemical as a hazardous substance according to NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1999).

*Occupational health and safety*
The notified chemical will be imported at a low concentration (5%) within the pigment preparation. Transport and storage workers will handle packaged product or the masterbatch infrequently and will be exposed to the notified chemical only if packaging were breached or spillage occurred. The likelihood of exposure and the risk of adverse health effects in these workers are low.

During the manufacture of masterbatch, weighing operators may be exposed to the notified chemical when opening the pigment mix bag and weighing out the pigment. Workers involved in the formulation of masterbatch may be exposed to the notified chemical when adding the weighed substance to the blender/extruder equipment (extruders). Skin and eye contact may occur, and inhalation of product dust is also possible due to the small size (10% respirable). Since dermal and inhalation toxicity of the notified chemical is not known, care should be taken to avoid dermal or inhalation exposure.

At the plastic article production site, workers will handle the coloured masterbatch in pellet form. These pellets are stated to be dust-free and will also contain considerably less amount of the notified chemical, which at this stage is embedded in the polymer matrix. Extrusion and moulding will be carried out in closed system. Dermal and eye contact is expected to be minimal and inhalation of product dust is not likely.

Workers involved in the mixing and blending steps (masterbatch production) should wear protective clothing, gloves, eye protection and respiratory protection equipment. Moulder operators and packers should wear protective clothing, eye protection and gloves. These measures, combined with engineering controls, such as dust collection systems at the mixing and blending sites, are needed to minimise worker exposure to the notified chemical and therefore reduce the risk of adverse health effects.

*Public health*
The potential for public exposure to the notified chemical is limited, as finished plastic products containing the notified chemical will not be sold to the public. Consequently, the potential for public exposure to the notified polymer throughout all phases of its life cycle is considered to be low. Based on this information and the available toxicological information, it is considered that the notified chemical is unlikely to pose a significant hazard to public health when used in the proposed manner.

## 13. RECOMMENDATIONS

To minimise occupational exposure to DS-3175A-E, the following guidelines and precautions should be observed:

- Workplaces handling the notified chemical in powder form should be fitted with local exhaust ventilation to ensure respiratory exposure to workers does not occur;

- Eye/face protection, dust mask, chemical resistant industrial clothing and footwear and impermeable gloves should be used when handling the notified chemical in powder form;

- Spillages of the notified chemical should be avoided. Spillages should be cleaned up promptly with absorbents which should be put into containers for disposal;

- A copy of the MSDS should be easily accessible to employees.

If products containing the notified chemical are hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999b), workplace practices and control procedures consistent with State and Territory hazardous substances regulations must be in operation.

Guidance in selection of goggles may be obtained from Australian Standard (AS) 1336 (Standards Australia, 1994) and Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand, 1992); for industrial clothing, guidance may be found in AS 3765.2 (Standards Australia, 1990); for impermeable gloves or mittens, in AS 2161.2 (Standards Australia/Standards New Zealand, 1998); for occupational footwear, in AS/NZS 2210 (Standards Australia/Standards New Zealand, 1994).

## 14. MATERIAL SAFETY DATA SHEET

The MSDS for the imported product containing the notified chemical was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994).

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 Subsection 64(1) of the Act, secondary notification may be required if the notified chemical is used in other applications such as paints and inks, or if the import volume exceeds 1 tonne.

Under Subsection 64(2) of the Act, secondary notification of the notified chemical may be required if any of the circumstances stipulated under the subsection arise.

The Director must be notified in writing within 28 days if these circumstances occur.

## 16. REFERENCES

Anliker R. and Moser P. (1987). "Bioaccumulation of Organic Pigments in Fish: Their Relation to the Partition Coefficient and the Solubility in Water and Octanol", *Ecotoxicology and the Environment Safety,* Vol 13.

Clarke E. A. and Anliker R. (1980). "Organic dyes and pigments", *The Handbook of Environmental Chemistry,* Vol 3, Part A. Springer-Vertag Berlin/Heidelberg.

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.

Magnusson B and Kligman AM (1970) Allergic contact dermatitis in the guinea pig: Identification of contact allergens. C. C. Thomas, Springfield, Illinois, USA.

National Occupational Health and Safety Commission (1994) National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)]. Australian Government Publishing Service, Canberra.

National Occupational Health and Safety Commission (1999) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1999)]. Canberra, Australian Government Publishing Service.

Safepharm Laboratories Limited (1998a) DS-2920A-E: Acute Oral Toxicity (limit Test) in Rat, SPL Project Number: 1235/003. UK.

Safepharm Laboratories Ltd (1998b) DS-2920A-E: Magnusson and Kligman Maximisation Study in the guinea pig, SPL Project Number: 1235/006. UK.

Safepharm Laboratories Ltd (1998c) DS-2920A-E: Reverse Mutation Assay 'Ames' Using Salmonella *Typhimurium* and Escherichia *Coli*, SPL Project Number: 1235/007. UK.

Safepharm Laboratories Ltd (1999) DS-2920A-E: Chromosome Aberration Test in Human Lymphocytes *In Vitro*, SPL Project Number: 1235/055. UK.

Standards Australia (1987) Australian Standard 2919-1987, Industrial Clothing. Standards Association of Australia, Sydney.

Standards Australia (1990) Australian Standard 3765.2-1990, Clothing for Protection against Hazardous Chemicals Part 2 Limited protection against specific chemicals. Standards Association of Australia.

Standards Australia (1994) Australian Standard 1336-1994, Eye protection in the Industrial Environment. Standards Association of Australia.

Standards Australia/Standards New Zealand (1992) Australian/New Zealand Standard 1337-1992, Eye Protectors for Industrial Applications. Standards Association of Australia/ Standards Association of New Zealand.

Standards Australia/Standards New Zealand (1994) Australian/New Zealand Standard 2210-1994, Occupational Protective Footwear. Standards Association of Australia/Standards Association of New Zealand.

Standards Australia/Standards New Zealand (1998) Australian/New Zealand Standard 2161.2-1998, Occupational protective gloves, Part 2: General requirements. Standards Association of Australia/Standards Association of New Zealand.

Woolley S. M. and Mullee D. M. (2000). "Determination of General Physico-Chemical Properties" SPL Project No. 1235/133. Safepharm Laboratories Ltd. January 2000.

## Attachment 1

The Draize Scale (Draize, 1959) 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 (Draize *et al*., 1944) 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. |
| | | Swelling with lids half-closed | 3 mod. | | |
| Diffuse beefy red | 3 severe | Swelling with lids half-closed to completely closed | 4 severe | Discharge with moistening of lids and hairs and considerable area around eye | 3 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 |