File No: NA/702

June 1999

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME**

**FULL PUBLIC REPORT**

**Red DK 2740**

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Director
Chemicals Notification and Assessment

# FULL PUBLIC REPORT

## Red DK 2740

## 1. APPLICANT

Ciba Speciality Chemicals Pty Limited of 235 Settlement Road THOMASTOWN VIC 3074 has submitted a standard notification statement in support of its application for an assessment certificate for Red DK 2740.

## 2. IDENTITY OF THE CHEMICAL

The chemical name, other name, CAS number, molecular and structural formulae, molecular weight, spectral data and purity have been exempted from publication in the Full Public Report and the Summary Report.

| | |
|---|---|
| **Trade Name:** | Red DK 2740 (the notified chemical);<br>Pergasol Red F-2B (containing 8-10% Red DK 2740) |

## 3. PHYSICAL AND CHEMICAL PROPERTIES

| | |
|---|---|
| **Appearance at 20°C and 101.3 kPa:** | The notified chemical is a dark red powder; the imported product is a dark red liquid with an odour of acetic acid. |
| **Melting Point:** | Not available |
| **Boiling Point:** | 750°C |
| **Density:** | 1.36 g/cm$^3$at 20°C |
| **Vapour Pressure:** | 8.3x10$^{-26}$ kPa at 25°C (extrapolated) |
| **Water Solubility:** | > 495 g/L at 22.5°C and pH 7 |
| **Partition Co-efficient (n-octanol/water):** | log $P_{ow} \leq -2$ |
| **Hydrolysis as a Function of pH:** | $T_{1/2}$ at pH 7.0 > 1 year<br>$T_{1/2}$ at pH 9.0 > 1 year |
| **Adsorption/Desorption:** | Not determined |
| **Dissociation Constant:** | Not determined |

| | |
|---|---|
| **Flash Point:** | Not flammable |
| **Flammability Limits:** | Not highly flammable |
| **Autoignition Temperature:** | 367°C |
| **Explosive Properties:** | Not explosive |
| **Reactivity/Stability:** | Considered stable |

**Particle Size:**

| *Range (μm)* | *Mass (%)* |
|---|---|
| < 0.40 | 0.11 |
| 0.40-0.84 | 0.37 |
| 0.84-1.74 | 0.75 |
| 1.74-3.47 | 1.67 |
| 3.47-6.95 | 4.10 |
| 6.95-13.50 | 8.62 |
| 13.50-27.68 | 13.70 |
| 27.68-63 | 24.71 |
| 63-100 | 25.34 |
| 100-200 | 17.47 |
| >200 | 3.15 |

Approximately 7% respirable particles

**Comments on Physico-Chemical Properties**

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

A melting point of the notified chemical was not available. The boiling point of the substance was calculated to be 750°C using the Meissner method (Lyman, 1990). The boiling point of the commercial product, Pergasol Red F-2B (10% aqueous solution) is reported by the notifier to be approximately 100°C.

The maximum water solubility of Red DK 2740 was determined to be 495 g/L at 22.5°C using the flask method (OECD TG 105).

The notified chemical was found to be hydrolytically stable at both pH 7.0 and 9.0 at 25°C determined by OECD TG 111. However, the notifier did not perform the hydrolysis test at pH 4.0 due to the low solubility of the notified chemical at that pH.

The partition coefficient log $P_{OW}$ of Red DK 2740 between n-octanol and water was estimated to be < -2.0 at 20°C by the flask shaking method (OECD TG 107).

Adsorption/desorption data were not provided. The notifier has indicated that given the notified chemical's low environmental release and its low likelihood of entering the soil this test was considered unnecessary. Also, given the notified chemical's low partition coefficient (< -2), it would be expected to bind strongly to silicates in soils since it contains nitrogen

atom substituents, however, it is not expected to bind to organic matter (Dragun, 1988). The adsorption encountered in the Inherent Biodegradability test lends support to this.

A dissociation constant was not provided. The notifier has indicated that it would be difficult to estimate an overall dissociation constant for the notified chemical since it contains secondary and tertiary amine groups as well as phenol (pKa approximately 10) and two sulfonic acids (pKa < 2).

## 4. PURITY OF THE CHEMICAL

| | |
|---|---|
| **Degree of Purity:** | >50% |
| **Toxic or Hazardous Impurities:** | The notifier stated that there are no toxic or hazardous impurities. |
| **Non-Hazardous Impurities (>1% by weight):** | Exempt information |
| **Additives/Adjuvants:** | None |

## 5. USE, VOLUME AND FORMULATION

The notified chemical will not be manufactured in Australia. It will be imported into Australia as a component of an aqueous dye preparation, Pergasol Red F-2B, which will be packed in 600 L HDPE Schutz tanks. Import volumes for the notified chemical will be approximately 850 kg per year for the first 5 years.

The notified chemical will be used solely in the colouration of paper and paper tissue. Coloured paper containing the notified chemical will be used for items such as office stationery, greeting cards, non-food packaging and art supplies. The notifier claimed in the submission that the dye has a fixation performance of 99.8% but test data provided by the notifier suggest a fixation performance of 96.7%.

## 6. OCCUPATIONAL EXPOSURE

Although approximately 7% of the particles of the notified chemical (Red DK 2740) is in the respirable range, the imported product (Pergasol Red F-2B) containing 8-10% of the notified chemical is formulated as an aqueous product. Additionally, the vapour pressure of the notified chemical is very low. Thus, dermal contamination would be the main route of occupational exposure. Workers who will handle the notified chemical include transport and storage workers, dispensing and paper making workers and finishing operators.

***Transport and storage***

The Schutz tanks will be transported from the waterside by road to the notifier's warehouse, where they will be stored in a bunded area. The dye will then be transported to the customer site in its original containers. No repackaging of the dye will be carried out. There will be 10

to 15 transport and storage workers handling the notified chemical. Transport workers and storemen are unlikely to be exposed to the notified chemical unless the package is breached.

***Paper making***

The liquid dye is metered from the Schutz container into the thick paper pulp (a suspension of fibre in water) via an automatic pumping system. The dyed pulp is then piped through a closed system to the paper machine.

Occupational exposure during dispensing and paper making procedures is possible. Workers who connect the metering hose, adjust the pump head and change the dye lines may be exposed to Pergasol Red F-2B, which contains 8-10% the notified chemical. Workers handling wet dyed paper will contact the notified chemical in a diluted form. Assuming the dye product contains 10% notified chemical, the final concentrations of notified chemical in the paper will be 0.1% for medium colours and 0.4% for deep colours. It is expected that up to 25 workers will handle the notified chemical in the dispensing and paper machine operations. The maximum duration of exposure is estimated by the notifier to be 1.5 hours per day and 15 days per year.

Exposure to workers may also occur during plant start-up and breakdown periods. The notifier indicated that reasonable amounts of wet paper may be handled during these periods, which may occur once or twice per shift.

Approximately every 4 months, maintenance on the pumps would be required. The service worker could be contaminated with the notified chemical during the maintenance. However, the residual of the notified chemical in the pumps is expected to be limited.

Ten workers will be involved in the paper finishing operations including reeling, cutting and packaging. They will handle the dry dyed paper for 8 hours per day and 15 days per year. As the dyestuff becomes chemically bonded to the cellulose fibres during fixation, there should be little exposure to the notified chemical in an available form. Some inhalation exposure to fine paper dust may occur during paper cutting.

Control measures are to be adopted by the notifier to minimise occupational exposure, including bulk containers and metering pumps for dispensing the dye, non-drip, quick release couplings for pumps and lines, and automatic dilution. In addition, local ventilation is used to minimise the inhalation exposure. Workers will wear elbow-length PVC gloves and protective clothing during dispensing and paper making procedures. Face visor will be used when workers handle the dye, and operate pumping/storage equipment. During the paper finishing operations, workers will wear protective clothes.

## 7. PUBLIC EXPOSURE

It is expected that during transport, storage, industrial use and disposal, exposure of the general public to the notified chemical will be minimal. The public will come into contact with paper products dyed with the notified chemical, such as office paper, gift cards, non-food packaging and art supplies. The notified chemical dye is strongly bound to the paper, with an average fixation rate for Pergasol Red F-2B of 96.7%. Consequently, potential dermal exposure from touching paper products dyed with the notified chemical is expected to be low.

## 8. ENVIRONMENTAL EXPOSURE

### Release

The bulk of the dye will become chemically fixed to paper, and in this state is not expected to impact on the environment.

The major environmental exposure to dye will come from effluent discharge from mills and their wastewater treatment systems. Other releases will be limited to traces remaining in empty 600 L HDPE transport tanks. The notifier estimates that no more than 1 L of the dye product containing the notified chemical, at a concentration of 8-10%, would remain in the container after use. Thus, a maximum of 100 mL of the notified chemical would be disposed of with each container. All clean up of spills should be carried out according to the instructions given in the material safety data sheet (MSDS).

### Fate

The bulk of the dye will become chemically fixed to the paper fibres with a fixation performance of 96.7%, while the remainder would be rinsed into wastewater. The fate of the majority of the notified substance is linked with the fate of the paper and in this state is not expected to impact on the environment. Eventually the paper will enter the waste disposal stream for either recycling or ultimately for disposal as waste in landfill. Once in the landfill sites, movement of the chemical by leaching is not expected because of its expected high binding affinity to soil.

The dye normally released in water as effluent from the mill is expected to be the major environmental exposure. The dye may either partition to sediment, as expected, or stay in the aqueous compartment. Any dye that binds to the sludge during the waste treatment process would be disposed of through incineration or landfill. Incineration is the preferred option because of the high water solubility and potential mobility of the material. Incineration of the dye will produce oxides of carbon, nitrogen and sulfur, together with sodium salts in the ash. Disposal by landfill will be at a secured site, so the risk of leaching to the water table is substantially reduced.

The mean concentration of dissolved organic carbon (DOC) (Ready Biodegradability: Modified OECD Screening Test TG 301E) in test flasks containing Red DK 2740, varied from 36.4 to 38.5 mg/L over the exposure period of 28 days. The DOC remained practically unchanged in comparison to the initial mean DOC of 33.7 mg/L on day 0. In terms of percentage removal, Red DK 2740 was not biodegradable over the 28 day exposure period to microorganisms from a domestic waste water treatment plant. The dye was eliminated by adsorption to activated sludge to a mean of 40% after 3 hours according to the test procedure OECD TG 302B (Zahn-Wellens/EMPA test).

The potential for bioaccumulation of the dye is low due to the low partition coefficient (log $P_{OW} < -2.0$) and high inherent biodegradation. Hydrophilic dyes with log $P_{OW} < 3$ have been shown not to bioaccumulate (Yen, 1991). Also, biological membranes are not permeable to chemicals of very large molecular size and, since the dye has a molecular weight of around 1 000, this adds further evidence that bioaccumulation of the notified chemical is not expected (Gobas, 1986; Anliker, 1988).

Residues that persist after sewage treatment will enter marine and freshwater environments in solution from city and country wastewater treatment systems, respectively. The concentrations are expected to be very low because of the very high fixation rate in the initial process and the expected movement to sediment/sludge and the high dilution rates in the release processes. A possible route of entry of the dye to the sediment is by the precipitation of its calcium salts, as several calcium salts of sulfonic dyes are known to be insoluble at low concentration (Weber, 1991). Degradation of such dyes in sediment water systems proceeded with a half-life of 2-16 days. Accordingly, no significant increase in dissolved concentration over time is predicted, while residues bound to sediment are expected to undergo reductive degradation.

## 9. EVALUATION OF TOXICOLOGICAL DATA

### 9.1 Acute Toxicity

The acute studies were conducted on the dye substance FAT 40'516/B, which contains 52.3% notified chemical.

**Summary of the acute toxicity of FAT 40'516/B**

| *Test* | *Species* | *Outcome* | *Reference* |
|---|---|---|---|
| acute oral toxicity | rat | $LD_{50}$>2 000 mg/kg | **(Arcelin, 1995b)** |
| acute dermal toxicity | rat | $LD_{50}$>2 000 mg/kg | **(Arcelin, 1995a)** |
| skin irritation | rabbit | Slightly irritating | **(Braun, 1995b)** |
| eye irritation | rabbit | Slightly irritating | **(Braun, 1995a)** |
| skin sensitisation | guinea pig | Not sensitising | **(Arcelin, 1995c)** |

#### 9.1.1 Oral Toxicity (Arcelin, 1995b)

| | |
|---|---|
| *Species/strain:* | Rat/HanIbm: WIST (SPF) |
| *Number/sex of animals:* | 5/sex |
| *Observation period:* | 14 days |
| *Method of administration:* | Oral (gavage), single dose 2 000 mg/kg |
| *Test method:* | Limit test, OECD TG 401 |
| *Clinical observations:* | No clinical signs of toxicity were observed |
| *Mortality:* | None |
| *Morphological findings:* | No organ abnormalities were observed |

| | |
|---|---|
| *Comment:* | Report stated that the rate of bodyweight gain was not affected by the treatment, but no comparison was made |
| *$LD_{50}$:* | > 2 000 mg/kg |
| *Result:* | the notified chemical was of very low acute oral toxicity in rats |

### 9.1.2 Dermal Toxicity (Arcelin, 1995a)

| | |
|---|---|
| *Species/strain:* | Rat/HanIbm:WIST (SPF) |
| *Number/sex of animals:* | 5/sex |
| *Observation period:* | 14 days |
| *Method of administration:* | A dose of 2 000 mg/kg (vehicle: water) was applied evenly on the intact skin under a semi-occlusive dressing for 24 hours. |
| *Clinical observations:* | Slight erythema was observed in all animals at 2-3 days after exposure. No clinical signs of systemic toxicity were observed. |
| *Test method:* | Limit test, OECD TG 402 |
| *Mortality:* | none |
| *Morphological findings:* | none |
| *Comment:* | Report stated that the rate of bodyweight gain was not affected by the treatment, but no comparison was made. Red skin discolouration was observed at the application sites for the first 2 days of observation. |
| *$LD_{50}$:* | > 2 000 mg/kg |
| *Result:* | the notified chemical was of low dermal toxicity in rats |

### 9.1.3 Inhalation Toxicity

An acute inhalation study was not performed as the notified chemical will be imported as a 10% aqueous solution.

### 9.1.4 Skin Irritation (Braun, 1995b)

| | |
|---|---|
| *Species/strain:* | Rabbits/CRL:KBL(NZW)BR |

*Number/sex of animals:* 1 male and 2 females

*Observation period:* 7 days

*Method of administration:* The notified chemical (0.5 g) was applied to the intact skin of the clipped area for 4 hours under a semi-occlusive dressing.

*Test method:* OECD TG 404

*Draize scores (Draize, 1959):*

| | | ***Time after treatment (days)*** | | | |
|---|---|---|---|---|---|
| ***Animal*** | ***1 hour*** | ***1 day*** | ***2 days*** | ***3 days*** | ***7days*** |
| ***Erythema*** | | | | | |
| 1 | - | [a]0 | 1 | 1 | 0 |
| 2 | - | 0 | 0 | 0 | 0 |
| 3 | - | 0 | 0 | 0 | 0 |
| ***Oedema*** | | | | | |
| 1 | 0 | 0 | 0 | 0 | 0 |
| 2 | 0 | 0 | 0 | 0 | 0 |
| 3 | 0 | 0 | 0 | 0 | 0 |

[a] see Attachment 1 for Draize scales

*Comment:* Erythema at 1 hour after treatment could not be assessed due to strong dye staining. Staining of the application site remained for 72 hours but had cleared by 7 days.

*Result:* the notified chemical was slightly irritating to the skin of rabbits

### 9.1.5 Eye Irritation (Braun, 1995a)

*Species/strain:* Rabbit/CRL:KBL(NZW)BR

*Number/sex of animals:* 1 male and 2 females

*Observation period:* 3 days

*Method of administration:* Undiluted the notified chemical (0.1 g) was placed in the conjunctival sac of the left eye, the right eye remained untreated and served as the reference control

*Test method:* OECD TG 405

*Draize scores (Draize, 1959):*

| | Time after instillation | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| ***Animal*** | ***1 hour*** | | ***1 day*** | | ***2 days*** | | ***3 days*** | |
| ***Conjunctiva*** | ***r*** | ***c*** | ***r*** | ***c*** | ***r*** | ***c*** | ***r*** | ***c*** |
| 1 | [1]2 | 2 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2 | 2 | 2 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3 | 2 | 3 | 0 | 0 | 0 | 0 | 0 | 0 |

[1] see Attachment 1 for Draize scales
r = redness c = chemosis

*Draize Scores for cornea and iris:* Draize scores for cornea opacity and iris were all zero at 1, 24, 48 and 72 hours after treatment.

*Comment:* No staining of the cornea or sclera of the treated eyes by the notified chemical was observed. Red staining of the conjunctivae was noted after 1 hour, but had disappeared by 24 hours.

*Result:* the notified chemical was very slightly irritating to the eyes of rabbits

### 9.1.6 Skin Sensitisation (Arcelin, 1995c)

*Species/strain:* Guinea pigs/Ibm:GOHI;SPF

*Number of animals:* 30 females and 6 males in 4 groups:
control group: 10;
test group: 20;
intradermal pretest: 2;
epidermal pretest: 4.

*Induction procedure:*

test group:
day 1 3 pairs of intradermal injections (0.1 mL/site) were made:
1) 1:1 (v/v) mixture of Freund's Complete Adjuvant (FCA) and physiological saline;
2) The notified chemical, diluted to 5% with water;
3) The notified chemical, diluted to 5% by emulsion in a 1:1 (v/v) mixture of FCA and physiological saline.

day 8 A filter paper saturated with the notified chemical (25% aqueous solution) was placed over the injection sites for 48 hours under an occlusive dressing.

control group:
day 1 3 pairs of intradermal injections (0.1 mL/site) were made:

| | |
|---|---|
| day 8 | 1) 1:1 (v/v) mixture of FCA and physiological saline;<br>2) bi-distilled water;<br>3) 1:1 (v/v) mixture of FCA and physiological saline.<br><br>Control group was treated as described above with bi-distilled water only. |
| *Challenge procedure:*<br>day 22 | Two patches of filter paper were saturated with either 15% aqueous notified chemical or bi-distilled water and applied for 24 hours under an occlusive dressing. |
| *Test method:* | Magnusson and Kligman maximisation test, OECD TG 406 |

*Challenge outcome:*

| | ***Test animals*** | | ***Control animals*** | |
|---|---|---|---|---|
| ***Challenge concentration*** | ***24 hours**** | ***48 hours**** | ***24 hours*** | ***48 hours*** |
| 15% | **0/20 | 0/20 | 0/10 | 0/10 |

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

| | |
|---|---|
| *Comment:* | The highest non-irritating concentration (15% aqueous solution) used for challenge application was determined in the epidermal pretest. The sensibility and reliability of the test was demonstrated by the positive control studies with 2-mercaptobenzothiazol and 4-aminobenzoic acid ethyl ester. |
| *Result:* | the notified chemical was not sensitising to the skin of guinea pigs |

## 9.2 Repeated Dose Toxicity (Arcelin et al., 1995)

| | |
|---|---|
| *Test Substance:* | FAT 40'516/B |
| *Species/strain:* | Rat/HanIbm:WIST (SPF) |
| *Number/sex of animals:* | 5/sex/group.<br>Group 1: vehicle (water);<br>Group 2: 50 mg/kg/day;<br>Group 3 : 200 mg/kg/day;<br>Group 4: 1 000 mg/kg/day;<br>Group 5: vehicle with 14 day recovery period;<br>Group 6: 1 000 mg/kg/day with 14 day recovery period. |
| *Method of administration:* | Oral gavage |
| *Dose/Study duration::* | 0, 50, 200 and 1 000 mg/kg/day for 28 days, group 5 and 6 had 14 day recovery period |

*Test method:* OECD TG 407

*Clinical observations:*
One female of group 3 and group 4 had very low food intake during days 15-22 and died spontaneously on day 23 and 24, respectively. The pathology report stated that death may have been trauma due to the gavage technique.

All other animals survived their assigned study periods. No treated related effects were observed in food consumption, bodyweights, ophthalmoscopic examinations and clinical signs.

*Clinical chemistry/Haematology*
Hematological and urinalysis studies showed no changes of toxicological significance at termination of the treatment nor at the end of the treatment-free recovery period.

The only change noticed was urine discolouration in both sexes of group 4 ranging from light orange (1 male) to orange (1/sex), light red (1 male) and red (2 females). At the termination of the recovery period, no discolouration of the urine sample was found.

*Pathology Macroscopic Findings:*
No treatment-related effects were found on organ weights, organ to body weight and organ to brain weight ratios. However, there were a number of unusual macroscopic findings that could not be related to treatment.

*Histopathology:*
No microscopic findings could be attributed to the treatment with the notified chemical. The above lesions were also observed microscopically, but could not be ascribed to treatment.

*Comment:*
The higher incidence of urine discolouration in group 4 is considered to be attributed to passive discolouration by the notified chemical.

*Result:*
The notified chemical has a no observed effect level (NOEL) of 200 mg/kg/day and a no observable adverse effect level (NOAEL) of 1 000 mg/kg/day.

## 9.3 Genotoxicity

### 9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (Wollny, 1995)

| | |
|---|---|
| *Test Substance:* | FAT 40'518/A |
| *Strains:* | *S. typhimurium* TA 1535, TA 1537, TA 98 and TA 100; *E. coli* WP2 and WP2 uvrA. |
| *Concentration range:* | The study consisted of 4 independent experiments both with and without S9 metabolic activation. Each concentration |

including the controls was tested in triplicate:

Exp I: 33.3, 100.0, 333.3, 1 000.0, 2 500.0 and 5 000.0 μg/plate with TA1535, TA1537, TA98, TA100, WP2 and WP2 uvrA;

Exp Ia: 3.3, 10.0, 33.3, 66.6, 100.0 and 333.3 μg/plate with TA1535 and TA1537;

Exp II: 3.3, 10.0, 33.3, 66.6, 100.0 and 333.3 μg/plate with TA1535 and TA 1537; 10.0, 33.3, 100.0, 333.3, 666.6 and 1 000.0 μg/plate with TA98, TA100, WP2 and WP2 uvrA;

Exp IIa: 1.0, 3.3, 6.6, 10.0, 33.3 and 66.6 μg/plate with TA1535 and TA 1537 without S9 mix; 3.3, 10.0, 33.3, 66.6, 100.0 and 333.3 μg/plate with TA100 without S9 mix.

*Test method:* OECD TG 471

*Comment:* Plates incubated with the notified chemical showed reduced background growth in all strains at higher concentrations with and without metabolic activation. Strong toxic effects, evident as a reduction in the number of revertants occurred in all strains used throughout the experiments. Toxicity was observed at 333.3 μg/plate for TA1535 and TA1537 and at higher concentrations for the other strains.

Appropriate reference mutagens were used as positive controls and showed a distinct increase of induced revertant colonies.

*Result:* The notified chemical was not mutagenic under the experimental conditions. However, the assay was hampered by high cytotoxicity in all strains.

### 9.3.2 Chromosome Aberration Assay in Chinese Hamster V79 cells *in vitro* (Czich, 1995)

*Test Substance:* FAT 40'516/B

*Strain:* Chinese hamster V79 cell line

*Concentrations:* Exp I: 125, 500 and 1 000 μg/mL (18 h) and 1 000 μg/mL (28 h) without S9; 50, 125 and 250 μg/mL (18 h) and 250 μg/mL (28 h) with S9;

Exp II: 100, 250 and 1 000 μg/mL (18 h) and 125 μg/mL (28 h) without S9; 25, 125 and 250 μg/mL (18h) and 125

| | |
|---|---|
| | μg/mL (28 h) with S9;<br><br>Vehicle: DMSO. |
| *Test method:* | OECD TG 474 |
| *Comment:* | In the preliminary toxicity test, no toxicity was observed at concentrations up to 2 500 μg/mL. Visible precipitation occurred at concentrations > 125 μg/mL. Due to the low solubility of the test substance in DMSO, the highest concentrations used in the main assay were 1 000 μg/mL without S9 mix, and 250 μg/mL with S9. No cytotoxicity was observed in the two experiments in the main assay.<br><br>Appropriate reference mutagens were used as positive controls and showed distinct increases in cells with structural chromosomal aberrations. |
| *Result:* | The notified chemical did not induce structural chromosomal aberrations under the experimental conditions. However, the assay was hindered by the low solubility of the substance in DMSO, and higher concentrations were not feasible. |

## 9.4 Overall Assessment of Toxicological Data

The notified chemical was of very low acute oral toxicity ($LD_{50}$> 2000 mg/kg) and low acute dermal toxicity ($LD_{50}$>2 000 mg/kg) in rats. It was a very slight skin and eye irritant in rabbits. A Magnusson and Kligman test indicated that the notified chemical was not a skin sensitiser in guinea pigs.

In a 28-day repeat dose oral study, the only effect observed was a higher incidence of urine discolouration in animals of both sexes at 1 000 mg/kg/day. However, no abnormal discolouration was noted after a 14-day recovery period. The NOEL was established as 200 mg/kg/day based on the effects of urine discolouration. The NOAEL was considered to be 1 000 mg/kg/day.

The notified chemical was not mutagenic in stains of *S. typhimurium* and *E. coli* in an Ames test, however, the assay was hindered by cytotoxicity in all strains throughout the experiments. The notified chemical did not induce structural chromosomal aberrations in an *in vitro* assay in Chinese hamster V79 cells, however, the assay was hindered by low solubility of the test substance in the solvent.

Based on the available toxicological studies, the notified chemical is not classified as a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1999).

## 10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The notifier supplied the following ecotoxicity studies. The tests were performed in compliance with OECD/EEC Test Methods and according to OECD Principles of Good Laboratory Practices.

**Ecotoxicity Test Results**

| *Test* | *Species* | *Test concentrations (nominal) mg/L* | *Results (nominal) mg/L* |
|---|---|---|---|
| Acute Toxicity (Static Test) (OECD TG 203) | Rainbow trout *Oncorhynchus mykiss* | 100 | 96 h $LC_{50}$ > 100<br>96 h $LC_0$ > 73.4 |
| Acute Toxicity – Immobilisation (Static Test) (OECD TG 202) | Water Flea (*Daphnia magna*) | 4.6, 10, 21, 46 & 100 | 48 h $EC_{50}$ = 79.6<br>48 h NOEC = 10 |
| Growth Inhibition Growth (μ) & Biomass (b) (Static Test) (OECD TG 201) | Green Algae (*Scenedesmus subspicatus*) | 1, 3.2, 10, 32 & 100 | *Experiment A*<br>E$\mu C_{50}$ > 30.6<br>$E_bC_{50}$ > 3.0<br>LOEC > 2<br>*Experiment B*<br>E$\mu C_{50}$ > 48.1<br>$E_bC_{50}$ > 6.6 |

*Fish*
A limit test, performed in accordance with the test guidelines, demonstrated that the notified substance had no toxic effects on the test fish up to a nominal concentration of 100 mg/L. Therefore, the only concentration tested in the definitive study was 100 mg/L.

In the control and the test nominal concentration of 100 mg/L (measured 70.3 to 76.2 mg/L) all fish survived until the end of the test. The 96 h $LC_{50}$ for Rainbow trout exposed to Red DK 2740 was greater than the nominal concentration of 100 mg/L. The report notes that the test medium was coloured by the test substance.

**Aquatic Invertebrates**
After 48 hours exposure of the dye to *Daphnia magna,* the $EC_{50}$ was calculated to be 79.6 mg/L. The 48 hour NOEC (highest concentration tested without toxic effects) of Red DK 2740 was determined to be 10 mg/L, since no immobilisation and no other signs of intoxication were observed in *Daphnia magna* at that concentration.

A. reproduction test was not supplied. However, based on the low acute toxicity to both fish and daphnia, no reproduction effects on daphnia will be expected.

**Algae**
The influence of Red DK 2740 on the growth of the green algae *Scenedesmus subspicatus* was investigated in a 72 hour static test. The test included two experimental parts:

Part A: the algae grew in test media with suspended dyestuff in Erlenmeyer flasks, each placed in a black cylinder. The cylinders were covered with glass dishes, containing untreated test water

Part B: the glass dishes above the cylinders contained the coloured test media suspensions without algae. In the Erlenmeyer flasks below, the algae grew in test water without dyestuff, however, under changed light conditions due to the filter effect of the coloured test media in the glass dishes above.

The results of both experimental parts A and B are nearly identical which demonstrates that the observed growth inhibition effect of Red DK 2740 on *Scenedesmus subspicatus* was due to the indirect effect of light absorption in the test media. The notifier claims that the real toxic effect of Red DK 2740 on algal cells can be excluded up to the highest tested nominal concentration of 100 mg/L.

However, it should be noted that for environmental purposes, growth inhibition whether due to either chemical or physical factors, is still of relevance. Algistatic effects may still lead to an undesirable environmental impact if exposure is continuous. Therefore, the calculated and determined $EC_{50}$s for algae should not be disregarded, and the notified chemical can be considered as slightly toxic to algae.

**Conclusion**
The ecotoxicity data for the notified substance indicates that it is practically non-toxic to fish and slightly toxic to aquatic invertebrates and algae. Reproductive effects on aquatic invertebrates are not expected.

## 11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The environmental hazard from the dye, when fixed to the cellulose fibre of paper, is rated as negligible.

The notifier has specified that initially only a single paper mill will be using the notified dye. The environmental hazard for that mill has been determined for two dye concentrations used for medium and dark shades.

An estimation of the Predicted Environmental Concentration (PEC) is provided in the following table, modified from that provided by the notifier.

| Process or Dilution Factor | Medium Shades | Deep Shades |
|---|---|---|
| Annual paper production | 140 t | 210 t |
| Concentration of Pergasol red used | 10 kg/t | 40 kg/t |
| Max. equivalent concentration of notified substance (10%) in paper | 1 kg/t | 4 kg/t |
| Daily paper production, based on 15 days operation per year | 9.3 t | 14 t |
| Typical notified substance use expected per day | 9.3 kg | 56 kg |
| Quantity in wash water (at a fixation rate of 96.7%) | 30.7 g | 184.8 g |

| | | |
|---|---|---|
| Quantity in coloured fines after save-all (50% recovery) | 15.4 g | 92.4 g |
| Quantity in coloured fines after clarifier (25% removal) | 11.6 g | 69.3 g |
| Quantity of waste water flow to effluent (100 t/hr*) | 186 000 L | 280 000 L |
| Effluent concentration in dye-specific wash-water | 0.06 mg/L | 0.25 mg/L |
| Dilution factor in waste water holding lagoon | 1:3 | 1:3 |
| Effluent concentration (ex-lagoon) | 0.02 mg/L | 0.08 mg/L |
| Dilution factor in receiving waters (coastal) | 1:10 | 1:10 |
| Predicted environmental concentration in receiving waters | 2 µg/L | 8 µg/L |
| Safety factor ($EC_{50}$/PEC) for exposure to most sensitive aquatic organism, *Daphnia magna* (48 h $EC_{50}$ = 79.6 mg/L) | > 39 000 | > 9 900 |

* Based on paper production rate of 5 tonnes per hour.

These calculations assume that no dye is removed in treatment of the different waste effluents and represent the worst case scenario for dyehouses.

The calculations show that the exposure to fish, daphnia and algae is at levels unlikely to cause any significant effect. At higher release rates, there is still unlikely to be any significant effect on these species. Once in the aquatic environment, the chemical is expected to swiftly dilute to undetectable concentrations, and undergo biotic and abiotic degradation. An adequate safety margin exists for use in country locations, and by implication for any metropolitan sites to be used.

The only other source of environmental contamination is from accidental spills and disposal of packaging. The MSDS contains adequate information to enable users to limit the environmental exposure and, therefore, limit the environmental effects.

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

Red DK 2740 showed very low acute oral toxicity and low acute dermal toxicity in rats. It was a very slight skin and eye irritant in rabbits. A Magnusson and Kligman test indicated that the notified chemical was not a skin sensitiser in guinea pigs. A NOEL was established at 200 mg/kg/day based on the effects of urine discolouration from a 28-day repeat dose oral toxicity study in rats. The NOAEL was the highest dose, 1 000 mg/kg/day. The notified chemical was not mutagenic in the *S. typhimurium* and *E. coli* reverse mutation assay or clastogenic in an *in vitro* chromosomal aberrations analysis in Chinese hamster V79 cells. Red DK 2740 is not classified as a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1999).

***Occupational Health and Safety***

The notified chemical will be imported as a component in a liquid product. The chemical has very low vapour pressure. Consequently, inhalation exposure is expected to be low and skin

contamination will be the main route for occupational exposure. After dyeing, the chemical is fixed to the fibres and essentially unavailable for exposure or absorption.

*Transport and Storage*
The health risk for transport workers and storemen is expected to be negligible unless the package is breached.

*Paper Making*
Dispensing and paper making workers will handle the dye product containing up to 10% the notified chemical and the dyed pulp containing up to 0.4% the notified chemical. Exposure to the notified chemical for the dispensing and paper making workers is expected to be low as the process is largely enclosed and automatic equipment is used. Exposure is limited to procedures such as connecting metering hose, adjusting pump head and changing the dye lines. Exposure may be in creased during starting and breakdown periods. As the notified chemical has low toxicity, the risk of adverse health effects is very low.

Finishing operators will have negligible exposure to the unfixed notified chemical as the dye is strongly fixed to the paper. Therefore, the health risk to these workers is low.

Measures introduced by the notifier to minimise the occupational exposure are considered to be appropriate. Local ventilation is provided in the paper making plant to minimise inhalation hazards such as paper dust. Given that the chemical is a slight eye and skin irritant, workers should wear gloves, eye protection and protective clothing during dispensing and paper making procedures. The notifier indicated that a face visor will be used when workers handle the dye, and operate pumping/storage equipment.

The pump service worker could be contaminated with the notified chemical during maintenance. Although residual notified chemical in the pumps is expected to be small, these workers should wear protective clothing, goggles and gloves to minimise exposure.

***Public Health***
As the potential for public exposure to Red DK 2740 during all phases of its life cycle is considered to be low, it is considered that the notified chemical will not pose a significant hazard to public health when used as described.

## 13. RECOMMENDATIONS

To minimise occupational exposure to Red DK 2740, the following guidelines and precautions should be observed:

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (Standards Australia, 1994) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand, 1992);

- Industrial clothing should conform to the specifications detailed in AS 2919 (Standards Australia, 1987) and AS 3765.1 (Standards Australia, 1990);

- Protective gloves should conform to AS/NZS 2161.2 (Standards Australia/Standards New Zealand, 1998);
- Spillage of the notified chemical should be avoided. Spillages should be cleaned up promptly with absorbents which should be put into containers for disposal;
- Good personal hygiene should be practised to minimise the potential for ingestion;
- A copy of the MSDS should be easily accessible to employees.

## 14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (National Occupational Health and Safety Commission, 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 the Act, secondary notification of the notified chemical shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

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## Attachment 1

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

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

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

***CORNEA***

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

***CONJUNCTIVAE***

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

***IRIS***

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