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NATIONAL INDUSTRIAL CHEMICALS
NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Disazo Red DK 618

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Disazo Red DK 618

1. APPLICANT

Ciba-Geigy Australia Ltd, 140 Bungaree Road, Pendle Hill, NSW, 2145.

2. IDENTITY OF THE CHEMICAL

The notifier has requested the chemical name, CAS No., molecular formula, structural formula, molecular weight and spectral data to be exempt from publication.

Other name(s): F.A.T 40'350/B
Direct Red 262

Trade name(s): Pergasol Red 3B

Methods of detection and determination:

High Pressure liquid chromatography (HPLC), thin-layer chromatography (TLC), Gas chromatography (GC), atomic absorption spectroscopy and volumetry (barium acetate). Method details were not submitted.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20 °C and 101.3 kPa:	Disazo Red DK 618 is a dark-red, honey-like viscous material. It may also appear green, depending on the illumination.
Odour	Not provided
Glass-transition temperature:	-36.2^{0}C
Specific Gravity/Density:	1219 kg/in^3 at 60C
Dynamic Viscosity:	53,800 - 56,000 mPa.s at 40^{0}C at shear rate D=8.35-47.1 s 8,100 - 8,600 mPa.s at 60^{0}C at shear rate D=11.1-359 s

Surface tension:	50.6 - 49.4 mN/rn (aqueous solution of dye at a concentration of 10 g/L at 20^0C)
Vapour Pressure:	< 1.2 x 10^{-3} Pa at 25^0C
Water Solubility:	280 g/L at 20^0C
Fat Solubility:	Lower than 0.05 mg/l00 g fat at 37^0C
Partition Co-efficient: (n-octanol/water)	log $P_{o/w}$ = -2.24 at pH 6.4, 25^0C

Hydrolysis as a function of pH: Disazo red DK 618 undergoes slow hydrolysis, with a half-life greater than one year at 25^0C and pH values of 4, 7 or 9. At 50^0C and after 2.4 hours only around 1% of the sample was hydrolysed at pH 4, 7 or 9.

Adsorption/Desorption:	Not determined
Flash Point:	> 105^0C
Flammability Limits:	Not determined
Pyrolysis products:	Not determined
Autoignition Temperature:	460^0C
Explosive Properties:	Disazo Red DK 618 was found not to be explosive.
Reactivity/Stability:	The dye was found to be thermally. stable with no exothermic peak between room temperature and 150^0C.

Comments on physicochemical properties:

Soil adsorption/desorption was not determined for the reasons that the substance has a low level of entry into soil, it has improved fixation properties and this test was not required for notification to the EEC. However, as discussed below, strong adsorption to sediments may be expected.

The dissociation constant was not measured as this was not required for notification to the EEC. The high water solubility of the dye, and the presence of a counter ion and two sulfonated groups

indicate a high degree of dissociation.

4. PURITY OF THE CHEMICAL

Product	CAS No.	% Weight
Active material	Confidential	60-90
Uncoloured by-products	Not known	<10
Coloured by-products	Not known	<10
Desmophen (excess)	124605-85-2	<10
Water	7732-18-5	10-20
Unsulphonated aromatic amines	Not known	0.01

5. INDUSTRIAL USES

Disazo Red DK 618 will be manufactured overseas and imported into Australia. The chemical will be used solely in the colouration of paper and tissue products. Disazo Red DK 618 is a non-reactive dye which becomes trapped within the fibrous matrix of paper (1-3). It is anticipated that this dye, as a result of its higher affinity for pulp, will largely replace an existing product, Direct Red 254. The import volume is estimated to be >1 tonne per year for the first 5 years.

6. PUBLIC AND OCCUPATIONAL EXPOSURE

From the point of entry Disazo Red DK 618 will be transported by road or ship (to Tasmania) in 800 litre containers (type not specified). Under normal conditions, spillage from these containers will be unlikely.

The dye will be used in the paper industry at several sites situated at major cities and regional town centres. Under normal conditions, worker exposure may occur during dispensing of the dye, handling of paper products during paper making, and during finishing operations, such as reeling, cutting and packaging. Significant exposure may also occur during cleanup and repair operations as a result of spillage from tanks or leakage from pumps and distribution lines. The main route of exposure is expected to be dermal. Formation of an aerosol of the dye is also possible.

The total number of workers exposed and the duration of exposure is presented in Table 1.

Table 1: Worker exposure

Operation	Max. No. of Workers	Route of Exposure	Max. Duration h/day	Days/Year
Repacking	4	Dermal	1	12
Dispensing	35	Dermal	0.5	24
Paper Making	63	Dermal	1	25
	14	Inhalational (aerosol)	Not significant	
Clean-up/Repair	3-7	Dermal	0.5	12
Finishing	70	Dermal	Not significant	
		Inhalational (paper dust)		

Disposal of dyestuff will be by incineration or by deposition in a secure landfill. Disposal of coloured paper will be by landfill or in water treatment sediments.

Disazo Red DK 618 will not be made available for home dyeing or paper-making.

7. ENVIRONMENTAL EXPOSURE

7.1 Release

Disazo Red DK 618 will be imported in containers (size not stated) and transported from point of entry to sites in Victoria and NSW where it will be diluted with water (32% dye, 68% water) and repackaged in 800 litre containers as the sale product, Pergasol Red 3B. The product will be transported by road to all sites, except those in Tasmania where transport will be by ship. Bearing in mind the unlikely event of a major transport accident, spillages during product distribution is not expected. An estimate of disposal quantities was not provided, but it was not expected that significant quantities would need to be disposed. Disposal of unused dyestuff (container residues and spillages) will be by incineration or secure landfill.

7.2 Fate

Disazo Red DK 618 has a higher affinity (99% fixation) for pulp compared to Direct Red 254 and lower quantities of unfixed dyestuff will pass to paper mill effluent. Therefore, Disazo Red DK 618 will be expected to have a lower impact than Direct Red 254 on the environment. The dye is used in two processes, light and dark paper colouration, in which the dye is almost entirely exhausted. The notifier indicates that an average of 2% of unfixed dyestuff, which makes

allowances for late-dyeing and losses in startup and clean-up stages, passes to the paper mill effluent for recovery by “save-all” and “clarifier” processes. It is estimated that at least 50% of unfixed dye is recovered as a precipitate with treatment chemicals or attached to paper fines. The recovered dye is recycled to the paper machine or disposed off to landfill as solid waste. One processing site will be involved in dark colouration of paper on 25 days of the year and would be expected to discharge a higher concentration of unfixed residues since a higher quantity (10 kg dye/tonne pulp compared to 1 kg dye/tonne pulp) of dye is used.

Unfixed residues from dyeing operations will enter the aquatic environment following three scenarios dependent upon the site of the paper mill. Unfixed residues will be pumped directly to the sea or to a lake, be filtered and clarified before discharge to the sea or to a river, or be subject to primary treatment at the site and secondary treatment at a sewage plant before discharge in a lake (4). The mode of release from Sydney and Melbourne paper mill sites is unclear.

Discharge of unfixed and unrecovered dye directly or via clarification to sea will result in dilution to insignificant levels. Discharge of dye to a coastal lagoon will result in increasing levels of dye with time, moderated only by periodic flushing to open sea (4). In a largely stagnant lagoon, binding of discharged dye to sediment may allow anaerobic degradation to occur. Azo dyes are generally stable under aerobic conditions, but are susceptible to reductive degradation under anaerobic conditions characteristic of sediment (5). Although hydrophilic, Disazo Red DK 618 and its sulfonated metabolites can be expected to partition to sediment as other highly sulfonated bis(azo) dyes have been shown to sorb to sediment (6). Degradation of such dyes in sediment water systems proceeded with a half-life of 2-16 days. Accordingly, no significant increase in dissolved concentrations over time is predicted, while residues bound to sediment are expected to undergo reductive degradation. The bulk effluent from one of the sites will receive primary treatment at the mill site before secondary treatment at Latrobe Water and Sewerage Authority’s Dutson Downs plant and ultimate discharge to Lake Cameron (4). Unfixed dye discharged into the sewage system is likely to undergo chemical or biological degradation or be bound to sludge. A study of adsorption of dyes, similar to Disazo Red DK 618, to biomass in activated sludge showed high adsorption to sludge where anaerobic degradation is likely to occur (3). Residues which survive treatment will enter freshwater or marine environments in solution form.

Environmental exposure from the extraction of the substance during the paper recycling processes is likely to be insignificant given the widespread use of coloured paper and the current low levels of paper recycling in Australia.

Hydrolysis

Hydrolytic degradation is unlikely given that tests indicate the lack of hydrolysis under any conditions.

Biodegradation

Ready biodegradation was not observed when the dye was tested using effluent from a domestic sewage plant according to OECD Guideline 301A (0.0% loss of dissolved organic carbon in 28 days). Testing of biological oxygen demand confirmed this resistance to degradation ($BOD_5 = 0$ mg/g 02) but the dye was susceptible to chemical oxidation ($COD_5 = 1523$ mg/g 02). Highly sulfonated dyes are known to degrade slowly under aerobic conditions (7).

Bioaccumulation

The bioaccumulation potential of Disazo Red DK 618 was not investigated because of the low partition coefficient. Hydrophilic dyes with log $P_{o/w}$ <3 have been shown not to bioaccumulate (8).

8. EVALUATION OF TOXICOLOGICAL DATA

8.1 Acute Toxicity

Table 2: Summary of acute toxicity of Disazo Red DK 618

Test	Species	Dose	Outcome	Reference
Oral	Rat	2000 mg/kg	LD5O>2000 mg/kg	9
Dermal	Rat	2000 mg/kg	LD5O>2000 mg/kg	11
Skin Irritation	Rabbit	0.5 g	Non-irritating	13
Eye Irritation	Rabbit	0.1 g	Non-irritating	15
Skin Sensitisation	Guinea Pig	1% induction 25% challenge	Non-sensitising	17

8.1.1 Oral Toxicity (9)

This study was carried out in accordance with the OECD Guidelines for Testing of Chemicals No: 401 (10)

Wistar KFM-Han rats (5/sex) were administered with a single oral dose of Disazo Red DK 618 in water at a dose of 2000 mg/kg body weight by gavage. The animals were observed for 15 days. There were no deaths and no clinical signs. Necropsy did not reveal any treatment-related findings. The test chemical has an oral $LD_{50} > 2000$ mg/kg. Under the conditions of this

experiment, the test substance appears to have low acute oral toxicity.

8.1.2 Dermal Toxicity (11)

This study was carried out in accordance with the OECD Guidelines for Testing of Chemicals No: 402 (12)

Disazo Red DK 618 was applied neat at a dose of 2000 mg/kg under a semi-occlusive dressing for 24 hours to the shaved skin surface of wistar KFM-Han rats (5/sex). The animals were observed for 15 days. There were no deaths. All animals had red skin in the area to which the test substance was applied. This was probably due to staining of the skin with the dye and may have masked any erythema. Necropsy did not reveal any treatment-related findings. The rat dermal LD_{50} was >2000 mg/kg. Under the conditions of this experiment the test substance appears to have low acute dermal toxicity.

8.1.3 Skin Irritation (13)

This study was carried out in accordance with the OECD Guidelines for Testing of Chemicals No: 404 (14)

Disazo Red DK 618 (0.5 g) was tested for skin irritation potential in New Zealand white rabbits (1 male and 2 females). The test substance was applied to intact skin under semi- occlusive dressing f or a period of 4 hours. The animals were observed f or up to 72 hours. There was violet staining of the skin in the application area. Erythema or oedema were not observed at the application site. However, it should be pointed out that any erythema may have been masked by staining of the skin with the dye. Nonetheless, the test substance does not appear to cause significant skin irritation under the conditions of this experiment.

8.1.4 Eye Irritation (15)

This study was carried out in accordance with the OECD Guidelines for Testing of Chemicals No: 405 (16).

Disazo Red DK 618 (0.1 g) was applied to the conjunctival sac of the left eye of each of three New Zealand white rabbits (2 male and 1 female). The right eye served as the control. The eyes were examined at 1, 24, 48 and 72 hours after administration. There were no observable effects on the cornea, iris or the conjunctivae. The eyelashes around the site of application were stained violet from the dye. The results of this study indicate that Disazo Red DK 618 is not irritating to the rabbit eye.

8.1.5 Skin Sensitisation (17)

This study was carried out in accordance with the OECD Guidelines for Testing of Chemicals No: 406 (18)

Disazo Red DK 618 was tested for allergenic potential in female albino guinea pigs in the maximisation-test. The strain of guinea pig used in this laboratory is regularly tested for positive skin sensitisation to formaldehyde.

Pretest

A pretest study was used to determine a skin irritant dose level. For intradermal application, sample concentrations of 0.1% to 5% were used and there was a dose-dependent increase in the extent of oedema formation, ranging from weak to moderate. Erythema could not be detected due to staining of the skin with the dye solution. A concentration of 5% was chosen for the intradermal injections during the induction phase. For epidermal application (24 hour exposure period), concentrations of the test substance of up to 25% did no cause any skin irritation after 24 hours. At a concentration of 50% there was only a slight degree of erythema in 2/4 animals. A concentration of 50% was chosen as the epidermal application dose during the induction phase and a 25% dose during the challenge phase.

Induction Phase

Intradermal injections of Disazo Red DK 618 at 1% both with and without Freunds' complete adjuvant were given to 20 female albino guinea pigs. After one week, the injection sites were covered with filter paper, saturated with the test article at 50% concentration, and aluminium foil. The dressing was left in place for 48 hours. Slight oedema was observed in the treated animals immediately after the removal of the dressing, and at 24 hours and 48 hours after removal of the dressing.

Challenge Phase

Two weeks after the epidermal induction application, the animals received a challenge epidermal application of the test substance at a concentration of 25%. The dressing was left in place for 24 hours. There were no signs of erythema or oedema immediately, 24 hours or 48 hours after removal of the dressing.

Under the conditions of this experiment Disazo Red DK 618 does not appear to be a skin sensitiser.

8.2 Repeated Dose Toxicity

8.2.1 Twenty Eight Day Oral Toxicity Study in Rats (19)

This study was carried out in accordance with the OECD Guidelines for Testing of *Chemicals No: 407 (20)*

The 28-day study was preceded by a 5-day range-finding study (21). In the range-finding study groups of Wistar KFM-Han rats (3/sex) were treated by gavage with Disazo Red DK 618 at doses of 0 (vehicle), 200 or 1000 mg/kg/day. There were no deaths during the study. Treatment-related clinical signs were not observed. There was no effect on food consumption or body weight. Ophthalmoscopy did not reveal any treatment-related effects. There were no macroscopic findings. Absolute and relative spleen weights were slightly increased in the treated males, but these changes did not reach statistical significance. Histology was not conducted.

In the 28-day study, groups of Wistar KFM-Han rats (10/sex in G1 and G4, 5/sex in G2 and G3) were treated by oral gavage with Disazo Red DK 618 at doses of 0 (G1), 50 (G2), 200 (G3) or 1000 mg/kg/day (G4). Following the treatment period, five animals of each sex from the control and the high dose groups were used in a 15-day recovery study. There were no deaths during the study. Clinical signs included red to black discoloration of the faces in all high-dose animals after day 10 of treatment and extended to day 5 of recovery period. Food consumption and body weight gain were not affected by the treatment. There was no effect on haematological parameters. Serum calcium and chloride levels were increased in both males and females of the high dose group. Urinalysis showed a
slight increase in specific gravity in the mid and high dose groups which was mainly due an increase in protein levels. Ophthalmoscopy did not show any treatment-related effects. Macroscopic findings included discolouration of the gastrointestinal tract in all the high dose animals, but this was not observed in the recovery group. There were increases in the absolute and relative spleen weights in the low and mid dose groups. In the high dose group, 2/5 males also had increased spleen weights. Histology did not detect any findings related to the discolouration of the gastrointestinal tract or the increase in spleen weight. One high dose recovery male showed a small focus of ulceration of the stomach but this was not considered to be treatment-related. Another high dose male showed haemosiderin deposition in the renal lymph node and this also was not considered to be related to the treatment.

8.3 Genotoxicity

8.3.1 Reverse Mutation Assay in Salmonella typhimurium (22)

This study was carried out in accordance with the OECD Guidelines for Testing of Chemicals No: 471 (23)

Disazo Red DK 618 was tested for potential mutagenic activity in *Salmonella typhimurium* (Ames

test) strains TA 98, TA 100, TA 1535, TA 1537 and TA 1538. A pre-test trial with strains TA 98 and TA 100 showed normal spontaneous reversion frequencies up to dye concentrations of 5000 µg/plate both in the presence and absence of rat liver S9 mix. In the main test there were no significant increases in the revertant frequencies in any of the strains both in the presence and the absence of rat liver S9 mix with dye levels of up to 5000 µg/plate. Appropriate positive controls were used. Cytotoxicity was evidenced in strain TA 1537 at 5000 µg/plate.

Under the conditions of this experiment Disazo Red DK 618 doses not appear to have mutagenic activity in bacteria.

8.3.2 Chromosome Aberration Assay in Chinese Hamster V79 Cells (24)

This study was carried out in accordance with the OECD Guidelines for Testing of Chemicals No: 473 (25)

Disazo Red DK 618 was assessed for its potential to induce chromosomal aberrations in Chinese hamster V79 cells in vitro. Chromosomes were examined (100 metaphase cells per culture) at 7, 18, and 28 hours after the start of treatment. The concentration of test article used were selected on the basis of a pre-test run in which the highest dose selected (5 mg/mL) reduced the plating efficiency by 36% without metabolic activation and 82% with activation. At the high dose the mitotic index was reduced by 14% and 33%, with and without activation, respectively. The concentrations tested at the various fixation intervals were as follows:

Fixation interval (hours)	Concentration (mg/mL)
7	1.0
18	0.5, 2.5, 5.0
28	1.0

The test article both in the presence or absence of metabolic activation did not cause an increase in the frequency of chromosomal aberrations. Appropriate positive controls were used.

Under the experimental conditions described Disazo Red DK 618 did not appear to have any clastogenic activity.

8.3.3 Mouse Micronucleus Assay (26)

This study was carried out in accordance with the OECD Guidelines for Testing of Chemicals No: 474 (27)

Disazo Red DK 618 was investigated for its potential to induce micronuclei in polychromatic erythrocytes in mouse bone marrow. NMRI mice (5/sex/group) were given the test substance (in 1% carboxymethylcellulose) as a single oral dose at 5000 mg/kg. Bone marrow samples were scored for polychromatic erythrocytes containing micronuclei at 24, 48 and 72 hours post-dosing. The ratio of polychromatic to normochromatic erythrocytes indicated some cytotoxicity at the dose level used. However, the number of cells with micronuclei in the tested animals was similar that in control animals. Cyclophosphamide was used as a positive control.

Under these experimental conditions Disazo Red DK 618 did not appear to induce micronuclei.

8.4 Overall Assessment of Toxicological Data

Disazo Red DK 618 was found to exhibit low oral (LD5O>2000 mg/kg) and dermal (LD5O>2000 mg/kg) acute toxicity in the rat. The dye did not possess any skin or eye irritation properties in the rabbit and was not a skin sensitiser in the guinea pig. Repeat-dose toxicity studies conducted with the dye consisted of a 5-day oral range-finding study (doses up to 1000 mg/kg/day) and a 28-day oral study (doses up to 1000 mg/kg/day). In both studies findings included red staining of the gastrointestinal tract and an increase in the spleen weight in the males. There were no histological changes in these organs and the toxicological significance of these findings is not clear. Disazo Red DK 618 was also tested for genotoxicity in the *Salmonella typhimurium* reverse mutation assay, chromosome aberration assay in Chinese hamster V79 cells, and the mouse micronucleus assay. The dye was negative in these assays, indicating low genotoxicity potential.

9. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following tests were carried out in accordance with the OECD Guidelines for Testing of Chemicals No: 203 (28) and 202 (29).

Test	Species	Result
96 h toxicity	Zebrafish	LC5O>1000 mg/L
Acute immobilisation	*Daphnia magna*	24 h EC5O>1000 mg/L

The results indicate that Disazo Red DK 618 is practically nontoxic to aquatic fauna. While reproduction tests for daphnids were not conducted, the lack of acute toxicity and the probability that the dye, given its relatively high molecular weight, will not undergo cellular absorption indicate that reproduction effects are unlikely to be observed.

Respiratory inhibition of microorganisms in activated sewage sludge was tested according to OECD Guideline 209 (30). The IC_{50} exceeded the highest concentration tested (100 mg/L), indicating that the dye is practically nontoxic to microbes, and should not affect sewage microorganisms.

No data were provided for algal growth inhibition on the grounds that "the substance will colour alga strongly, and any growth changes will be masked by this effect and render the test unreliable". Algal growth inhibition tests on 56 dyestuffs showed close parallels with fish toxicity, apart from some acid dyes highly toxic to fish which did not affect algae (31). Accordingly it appears unlikely that the notified substance will be toxic to algae and a test will not be required.

10. ASSESSMENT OF ENVIRONMENTAL HAZARDS

The main hazard associated with the use of Disazo Red DK 618 is involved with direct discharge from paper mill sites or release from sewage treatment works of unfixed dye residues into the aquatic environment. If released to the ocean or to a river (unless low flow conditions prevail), dilution would be expected to swiftly reduce the environmental concentration to undetectable levels. In the longer term, residues would be expected-to bind to sediment and undergo reductive degradation, with amine metabolites being released to the water column where they can undergo further degradation through aerobic processes.

The notifier has provided two scenarios, light and dark paper colouration, which require closer scrutiny. In addition, consideration should be given to the mode of discharge of effluent from paper mill sites, whether it is directly to a lake, or release to sewage treatment works.

The worst case envisaged by the notifier would occur at the one unidentified site producing dark coloured paper on 25 days of the year. Given the daily quantity of Disazo Red DK 618 used at each site, 2% average unfixed dye from the process and 50% recovery in the "save-all" and clarification procedures, the daily discharge to water bodies or release to sewage treatment works would be 0.15 kg of the technical mixture.

If mill effluent release is to sewage treatment works, an assumed daily rate of 2 ML would result in a Disazo Red DK 618 concentration of 75 ppb to receiving waters, which compares to 14 ppb for light colouration. This daily flow estimate is very conservative, considering that all sites are located in metropolitan or major country town regions. In addition, a paper mill is likely to have other different processes running simultaneously, resulting in a greater dilution of the substance before reaching the sewage treatment works. It is more likely that the predicted environmental concentration to receiving waters after sewage treatment will be below 10 ppb.

If mill effluent is pumped directly to a lake (estimated volume 96,000 ML), the predicted environmental concentration, assuming even distribution throughout the lake and 3.75 kg release of unfixed dye per annum, will be approximately 0.04 ppb. The concentration will not exceed 1 ppb, in the event that mill effluent is concentrated in a 4% section of the lake.

In both scenarios, the concentration of the dye in receiving water is more than 4 orders of magnitude lower than concentrations causing acute effects in aquatic fauna, indicating that adverse environmental effects should not occur.

11. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY

Acute toxicity studies, including skin and eye irritation and skin sensitisation studies, and repeat-dose toxicity studies in animals with this dye have not revealed any significant adverse findings. In addition, this dye was negative in three genotoxicity assays. The relatively high molecular weight of the dye (646 g/mol) and the low lipid solubility tend to indicate low dermal absorption. The most likely route of exposure is dermal, but some inhalational exposure of an aerosol form of the chemical, or dust from paper dyed with the chemical is also possible. However, under normal conditions, public and worker exposure to Disazo Red DK 618 is expected to be low. This dye is not expected to pose a significant hazard to the public and workers.

12. RECOMMENDATIONS FOR THE CONTROL OF PUBLIC AND WORKER EXPOSURE

To minimise worker exposure to Disazo Red DK 618 the following guidelines and precautions should be observed:

- Engineering control measures such as local exhaust ventilation, should be employed in areas where an aerosol of the dye solution may form and in areas where paper dust may form.

- Workers who are likely to be exposed to the dye should wear impervious gloves, face shield, and appropriate protective clothing, complying with the appropriate Australian Standards (32, 33).

- The generation of an aerosol of the dyestuff or dust from paper dyed with the chemical should be avoided.

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

To minimise public exposure to Disazo Red DC 618 it is recommended that paper products coloured with the dye should not be allowed to come into contact with food.

13. MATERIAL SAFETY DATA SHEET(S)

The Material Safety Data Sheet (MSDS) for Disazo Red DK 618 (Attachment 1) was provided in Worksafe format (34). This MSDS was provided by CIBA GEIGY Ltd as part of their notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of CIBA GEIGY Ltd.

14. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act), secondary notification of Disazo Red DK 618 shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise.

A secondary notification will be required if the use pattern for this dye indicates that there may be significant contact with food.

15. REFERENCES

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9. Acute oral toxicity study with FAT 40'350/B in rats. Research & Consulting Company AG, Itingen, Switzerland. RCC project 247296, 1989.

10. *OECD Guidelines for Testing of Chemicals,* "Acute Oral Toxicity" No: 401, 1981.

11. Acute dermal toxicity study with FAT 40'350/B in rats. Research & Consulting Company AG, Itingen, Switzerland. RCC project 247307, 1989.

12. *OECD Guidelines for Testing of Chemicals,* "Acute Dermal Toxicity" No: 402, 1987.

13. Primary skin irritation study with FAT 40'350/B in rabbits. Research & Consulting Company AG, Itingen, Switzerland. RCC project 247320, 1989.

14. *OECD Guidelines for Testing of Chemicals,* "Acute Dermal Irritation/Corrosion" No: 404, 1981.

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18. *OECD Guidelines for Testing of Chemicals,* "Skin Sensitisation" No: 406, 1981.

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20. *OECD Guidelines for Testing of Chemicals,* "Repeated Dose Oral Toxicity Rodent: 28-day or 14-day Study" No: 407, 1981.

21. 5-Day oral toxicity (range-finding) study with FAT 40'350/B in rats. Research & Consulting Company AG, Itingen, Switzerland. RCC project 247364, 1989.

22. Salmonella typhimurium reverse mutation assay with FAT 40'350/B. Research & Consulting Company AG, Itingen, Switzerland. RCC project 159118, 1989.

23. *OECD Guidelines for Testing of Chemicals,* "Genetic Toxicology *Salmonella typhimurium,* Reverse Mutation Assay" No: 471, 1983.

24. Chromosome aberration assay in Chinese hamster V79 cells *in vitro* with FAT 40'350/B. Research & Consulting Company AG, Itingen, Switzerland. RCC project 159120, 1989.

25. *OECD Guidelines for Testing of Chemicals,* "Genetic Toxicology: *in vitro* mammalian cytogenetic test" No: 473, 1983.

26. Micronucleus assay in bone marrow cells of the mouse with FAT 40'350/B. Research & Consulting Company AG, Itingen, Switzerland. RCC project 159131, 1989.

27. *OECD Guidelines for Testing of Chemicals,* "Genetic Toxicology micronucleus test" No: 474, 1983.

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