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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Orange JOG-365 AS

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

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Orange JOG-365 AS

1. APPLICANT

Ciba Geigy Australia Ltd of 235 Settlement Rd THOMASTOWN VIC 3074 has submitted a standard notification statement in support of their application for an assessment certificate for Orange JOG-365 AS.

2. IDENTITY OF THE CHEMICAL

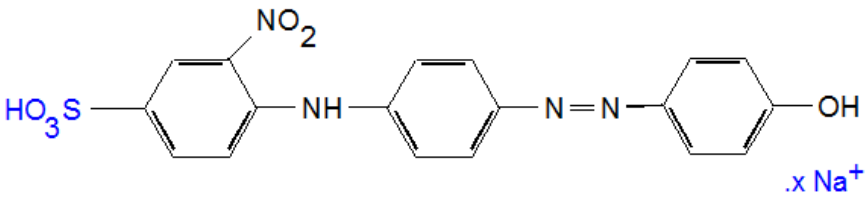
Chemical name: 4-[4-(4-hydroxyphenylazo)-phenylamino]-3-nitrobenzenesulphonic acid, sodium salt

Chemical Abstracts Service (CAS) Registry No.: 156738-27-1

Trade name: Orange JOG-365 AS, FAT 40'514/A
The commercial products to be imported will be known as Sellacid Orange PF, Sellacid Black PF Tectilon Orange 4G containing up to 40% of the notified chemical

Molecular formula: $C_{18}H_{14}N_4O_6S.xNa$

Structural formula:



Molecular weight: 414

Methods of detection and determination: ultraviolet/ visible, infrared and nuclear magnetic resonance spectroscopy; high performance liquid chromatography with visible detection; detection of sodium content by atomic absorption spectroscopy

Spectral data: uv/visible: major peaks were observed at 252, 370 and 441 nm in neutral solution; 254 and 463 nm in alkaline (0.1 M NaOH) solution and 252, 370 and 442 nm in acid (0.4 M HCl) solution

infrared: 50 peaks were observed as follows where % refers to the transmission at the band maximum

cm^{-1}	%	cm^{-1}	%	cm^{-1}	%	cm^{-1}	%
3903.5	70.38	3870.4	75.55	3853.7	74.24	3838.9	78.19
3821.2	81.01	3802.1	83.36	3769.6	88.62	3750.4	86.27
3734.8	90.18	3723.6	94.22	3711.4	92.04	3689.9	93.01
3675.9	91.12	3648.5	84.68	3628.2	76.61	3566.1	55.40
3446.7	38.92	2362.4	61.48	2343.5	62.16	1734.1	74.46
1717.9	73.67	1699.9	72.55	1684.1	67.33	1653.7	53.71
1621.8	28.84	1596.9	29.42	1569.5	35.16	1508.3	27.18
1437.8	59.03	1406.4	61.95	1351.8	45.82	1260.3	21.56
1221.0	30.06	1138.3	31.92	1073.3	66.47	1039.4	40.40
908.3	83.52	837.5	65.86	820.6	69.99	762.2	78.46
748.3	79.68	723.7	81.51	701.0	80.66	675.8	56.11
658.8	61.25	632.1	73.18	607.9	58.26	583.4	56.37
549.7	47.63	430.2	63.17				

nuclear magnetic resonance: a ^{1}H spectrum was provided

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa: dark yellow powder

Melting Point: > 400°C (at 760 mm Hg)

Density: 848 kg/m^3 at 23°C

Vapour Pressure: 4 X 10^{-13} kPa at 25°C

Water Solubility: 1.28 g/L at 20°C

Surface Tension: 72 mN/m at 1.00 g/L and 24.7°C

Fat Solubility: < 0.1 mg/100g of standard fat at 37°C

Partition co-efficient (n-octanol/water): log P_{ow} = -0.9 at 21°C

Hydrolysis as a function of pH: $T_{1/2}$ estimated at > 1 year at pH 4.0, 7.0 and 9.0 at 25°C

Adsorption/desorption: not determined

Dissociation constant: AR-SO_3H: pK_a = -3.6

	Phenol: pK_a = 8.3
Flash point:	not determined
Flammability limits:	not highly flammable
Autoignition temperature:	287.7°C
Explosive properties:	not explosive
Reactivity/stability:	not an oxidising substance; themal stability in air: no peak up to 150°C with or without air

Particle Size:

< 0.37 μm	0.04% w/w
0.37-0.78 μm	0.14% w/w
0.78-1.60 μm	0.35% w/w
1.60-3.19 μm	0.72% w/w
3.19-6.39 μm	1.59% w/w
6.39-12.41 μm	3.43% w/w
12.41-25.46 μm	8.48% w/w
25.46-63.00 μm	18.42% w/w
> 63.00 μm	73% w/w

Comments on Physico-Chemical Properties

Adsorption/desorption data were not provided. High water solubility and low partition coefficient would normally indicate a low affinity for soil or sediment.

The dye is not surface active and has a very low fat solubility.

4. PURITY OF THE CHEMICAL

Degree of purity:	75% (typical concentration) comprising the main component at 68.4% with identified organic by-products at 0.1% and unidentified organic by-products at 4.2%
Non-hazardous impurities (> 1% by weight):	sodium ion, 9.6%; chloride ion, 12.7%; acetate ion, 1.0% and water, 2.5%
Additives/Adjuvants:	none

5. USE, VOLUME AND FORMULATION

The notified chemical is a dye designed to replace the more toxic acid orange 3G for colouring leather and woolly sheepskins. It is to be imported as a component of dyestuffs at a maximum concentration of 40% at a rate of 2-4 tonnes per year for the first year rising to 7-9 tonnes per year by the fifth year. The formulations contain other dyes, inorganic salts, dispersing and buffering agents as the main ingredients.

6. OCCUPATIONAL EXPOSURE

The dyestuffs are to be imported in 30 kg cardboard containers with internal polythene liners. The notifier describes the packaging as ‘substantial’ and suggests

that occupational exposure is unlikely even in the event of transport or handling accidents.

The packages to be imported are ready-to-sell but some minor repackaging may occur at the notifier's warehouse in which case weighing out is conducted under local exhaust ventilation to minimise inhalational exposure. It is estimated by the notifier that a maximum of 100 kg would need to be repacked on 10 days per year for 15-20 minutes per day.

The dyestuffs are formulated to be non-dusting so that dust generation is expected to be minimal. Nevertheless, dyehouses typically perform weighing out and dissolution of dyestuffs under local exhaust ventilation to minimise the likelihood of formation of invisible dust clouds in the workplace given the known hazards of azo dyes as a chemical class. The dyestuff is pasted in a small quantity of cold water and then added to warm water in a blending vessel. The resulting stock solution is normally gravity fed to the dyeing paddle.

The notifier has submitted a model exposure calculation for weighing and dissolution. For dyehouses using 450 kg per year, weighing is estimated to occur on 100 days of the year and the dose received is estimated as 1.3 μg/kg/day.

Once the dye solution is in the dyeing vat, leather or skins are fed thereto but the operator will not come in contact with the dye. Leather is fat-liquored as a final step in the process and the leather or skins are washed to remove unfixed dye. As 98% of the dye is fixed to the substrate, the liquor should contain 2% dye following exhaustion. After washing, the leather or skins are oven-dryed.

7. PUBLIC EXPOSURE

There is negligible potential for public exposure to the notified chemical to arise from leather treatment processes. There may be widespread public contact with the notified chemical on the surface of treated leathergoods, but its strong fixation to the substrate and physico-chemical properties will be sufficient to preclude absorption across the skin or other biological membranes.

8. ENVIRONMENTAL EXPOSURE

Release

The bulk of the dye will become fixed to the leather and woolly sheepskins, and in this state is not expected to impact on the environment. The result of fastness performance tests shows that a high order of fastness rating is achieved in all cases.

The major release of the dye will come from the discharge of dyehouse effluent and waste water treatment systems. Other releases will be limited to traces remaining from any clean-up of any spills, repacking operations and trace residues in empty packaging.

All clean up of spills and disposal of empty packaging should be carried out according to the Material Safety Data Sheet (MSDS). Information relating to the proper emptying of drums before disposal will be highlighted in the MSDS for the commercial form of the substance.

Fate

The unfixed dye normally released in water as effluent from the dyehouse is

expected to be the major environmental release. The dye may either partition to sediment 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 disposal route of choice because of the high water solubility of the material. Incineration of the dye will produce oxides of carbon, nitrogen and sulfur. Disposal by landfill should be done at a secured site, so the risk of leaching to the water table is significantly reduced.

The dye was found to degrade only partially (25% after 28 days) in the OECD 301A test for ready biodegradability and also (2 - 28% after 28 days) in the modified Zahn-Wellens test (OECD 302B) for inherent biodegradablility. There was no significant (> 10%) inhibition in respiration of bacteria. Although the dye is not readily biodegradable, the potential for bioaccumulation is low due to the low partition coefficient (log P_{ow} < -0.9) and low lipid solubility (< 0.1 mg.100 g^{-1} at 37°C) of the substance.

Residues that survive sewage treatment will enter freshwater or marine environments in solution. The low biodegradability and stability to hydrolysis coupled with the high water solubility suggest the compound may persist for long periods in the aquatic compartment. However, the dye would quickly become diluted to levels well below that likely to be toxic to aquatic organisms. Significant sorption to soils/sediments is not expected as reactive dyes show poor binding and are not absorbed (1).

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of Orange JOG-365 AS

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 2000 mg/kg	2
acute dermal toxicity	rat	LD_{50} > 2000 mg/kg	3
skin irritation	rabbit	slight irritant	4
eye irritation	rabbit	slight to moderate irritant	5
skin sensitisation	guinea pig	sensitiser	6

9.1.1 Oral Toxicity (2)

Species/strain:	rat/ HanIbm: WIST (SPF)
Number/sex of animals:	5 males, 5 females
Observation period:	14 days
Method of administration:	gavage; vehicle: corn oil
Clinical observations:	none
Mortality:	none
Morphological findings:	none

Test method:	OECD Guidelines (7)
LD_{50}:	> 2000 mg/kg
Result:	the notified chemical was of low acute oral toxicity in rats

9.1.2 Dermal Toxicity (3)

Species/strain:	rat/ HanIbm: WIST (SPF)
Number/sex of animals:	5 males, 5 females
Observation period:	14 days
Method of administration:	under semi-occlusive dressing with corn oil as the vehicle; 24 hour duration
Clinical observations:	skin discolouration; reduction in body weight gain in females due to dressing; scales were noted in 5 animals between test days 3-13
Mortality:	none
Morphological findings:	none
LD_{50}:	> 2000 mg/kg
Test method:	OECD Guidelines (7)
Result:	the notified chemical was of low acute dermal toxicity in rats

9.1.3 Skin Irritation (4)

Species/strain:	rabbit/ New Zealand White
Number/sex of animals:	1 male, 2 females
Observation period:	14 days
Method of administration:	0.5 g moistened with distilled water under semi-occlusive dressing for 4 hours
Test method:	OECD Guidelines (7)
Result:	the notified chemical was a slight skin irritant in rabbits; no oedema was observed; very slight erythema was observed in 1 male at 24 hours, in all animals at 48 and 72 hours, in the 2 females at 7 days and in no animals at 14 days post-treatment

9.1.5 Eye Irritation (5)

Species/strain:	rabbit/ New Zealand White
Number/sex of animals:	1 male, 2 females
Observation period:	3 days
Method of administration:	0.1 g of the notified chemical into the cupped conjunctival sac of one eye of each animal
Draize scores (8) of unirrigated eyes:	no iridal effects were seen and slight corneal opacity was observed in the male at 24 and 48 hours post-treatment; no conjunctival redness or chemosis was observed at 48 or 72 hours post-treatment and slight conjunctival redness was observed in all animals at 24 hours; at 1 hour post-treatment severe redness and chemosis were observed in the male and moderate redness and chemosis were observed in the females
Test method:	OECD Guidelines (7)
Result:	the notified chemical was a slight to moderate eye irritant in rabbits

9.1.6 Skin Sensitisation (6)

Species/strain:	guinea pig/ Ibm: GOHI Himalayan spotted
Number of animals:	10 control, 20 test females
Induction procedure:	pairs of 0.1 mL injections in the dorsal scapular region comprised Freund's complete adjuvant (FCA) 1:1 in physiological saline; distilled waster plus 5% notified chemical; 5% dilution of the notified chemical in FCA 1:1 in physiological saline on test day 8 topical induction was performed after the dorsal scapular region had been pretreated with 10% sodium lauryl sulfate for 19 hours; induction was with 50% notified chemical in vaseline under occlusive dressing for 48 hours
Challenge procedure:	14 days after topical induction, challenge was performed with the highest non-irritating concentration of the notified chemical (25%) in vaseline under occlusive dressing on the flank for 24 hours

Challenge outcome:

	Test animals		Control animals	
Challenge concentration	**24 hrs***	**48 hrs***	**24 hrs**	**48 hrs**
25%	14/20**	16/20	0/9	0/9

* time after patch removal

** number of animals exhibiting positive response

Test method: OECD Guidelines (7)

Result: the notified chemical was a strong skin sensitiser in guinea pigs

9.2 Repeated Dose Toxicity (9)

Species/strain: rat/ Wistar

Number/sex of animals: 5 males and females per dose with an extra 5 males and females in the control and high dose groups given a 14-day recovery period

Method of administration: gavage, vehicle: distilled water

Dose/Study duration:: 0, 50, 200 and 1000 mg/kg/day for 28 days

Clinical observations: none

Clinical chemistry/Haematology slight statistically significant changes were noted only in the high dose group; slightly increased mean corpuscular volume and reticulocyte count and a slight shift in the reticulocyte fluorescence ratios were noted in males; a slightly higher methaemoglobin concentration was noted in females; slightly increased total bilirubin levels were observed in both males and females and slightly increased alanine aminotransferase activity, phosphorus, chloride, albumin and total protein levels were observed males; no changes of toxicological significance were noted in urinalysis

Histopathology: a number of histopathological lesions were diagnosed in all groups; their incidence and severity were similar in treated and control groups

Test method: OECD Guidelines (7)

Result: the observed minor haematological and biochemical changes in the 1000 mg/kg/day dose group were considered to be related to treatment but a target organ was not identified

9.3 Genotoxicity

9.3.1 Bacterial Reverse Mutation Assay (10)

Strains:	*Salmonella typhimurium* TA 1535, TA 1537, TA 98 and TA 100; *Escherichia coli* WP2 and WP2 *uvrA*
Concentration range:	33.3 - 5000 μg/plate
Test method:	OECD Guidelines (7)
Result:	the notified chemical did not induce a dose-related increase in numbers of prototrophic back mutants in any strain tested in either the presence or absence of metabolic activation provided by rat liver S9

9.3.2 Chromosomal Aberration Assay in Chinese Hamster V79 Cells (11)

Dosing schedule:	chromosomes were prepared 18 h and 28 h after start of treatment; for the 18 h treatment time the concentration of notified chemical was 10-100 μg/mL without metabolic activation provided by rat liver S9 and 10-200 μg/mL with S9; for the 28 h treatment time the concentration was 100 μg/mL without S9 and 200 μg/mL with S9
Test method:	OECD Guidelines (7)
Result:	the notified chemical did not induce structural chromosomal aberrations in chinese hamster V79 in either the presence or absence of metabolic activation

9.4 Overall Assessment of Toxicological Data

The notified chemical exhibited low acute oral and dermal toxicity in rats (both LD_{50}s > 2000 mg/kg) and produced only minor changes to haematological and clinical chemistry parameters in a 28-day oral repeat dose subchronic toxicity study at a dose of 1000 mg/kg/day.

The notified chemical was a slight skin irritant and a slight to moderate eye irritant in rabbits. It was a strong skin sensitiser in guinea pigs and was not genotoxic in *in vitro* tests for mutagenicity and clastogenicity.

The notified chemical would be classified as hazardous according to Worksafe Australia's *Approved Criteria for Classifying Hazardous Substances* (12) (Approved Criteria) in relation to skin sensitisation but would not be classified as hazardous in relation to the other toxicological endpoints.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following ecotoxicity studies have been provided by the notifier. The tests were carried out according to OECD Test Methods.

Test	*Species*	*Result*
Acute Toxicity	Rainbow Trout	96h LC_{50} = 67.8 mg/L
Acute Toxicity	*Daphnia magna*	48h EC_{50} = >100 mg/L
Growth Inhibition	Green algae *Scenedesmus subspicatus*	72h EbC_{50} = 150 mg/L * NOEC = 0.32 mg/L
Respiration Inhibition	Bacteria from activated sludge	3h IC_{50} = > 100 mg/L

* See comments below

The ecotoxicity data for the notified substance show that the dye is slightly toxic to fish, and practically non-toxic to daphnia. It shows a moderate toxicity to growth of algae. Since the test solution is intensely coloured, algistatic effects can be caused by interception of light (shading effect) necessary for algae growth.

Each of the toxicity test reports were based on nominal values. The analytically determined test substance concentrations all varied within the range of 100.6% and 89.1% of the nominal value.

The 96h LC_{50} data for rainbow trout indicates a steep increase in effect on fish as concentration increases between 46 mg/L and 100 mg/L. This may be due physical factors such as intense colouring of the water medium.

The 72h EbC_{50} of 150 mg/L determined for green algae is an adjusted figure through Probit Analysis to take into consideration the pure light filter effect the dye exhibits. The 72h EbC_{50} before adjustment was 7.5 mg/L. The Environment Protection Agency believes the 72h EbC_{50} should not be adjusted, as the light shading effect of the notified substance is an important consideration.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The environmental hazard from the dye, when fixed to leather and woolly sheepskins, is rated as low.

The notifier has specified that a limited number of dyehouses in city and country NSW and Victoria will be using the notified dye. The environmental hazard has been determined for dyehouses located in two general locations, one metropolitan based dyehouse and the other country based. The Predicted Environmental Concentration (PEC) is estimated below. These calculations assume that no dye is removed in treatment of the different waste effluents.

Predicted Environmental Concentration (PEC) Table.

Calculation Factor	***City Dyehouse***	***Country Dyehouse***
Typical Use of Dye Expected Per Day	0.85 kg	0.576 kg
Conc. in Washwater (Fixation Rate of 98%)	0.017 kg	0.0116 kg
Quantity of Water Used Including Wash-off Water (at 100 L/kg)	20,000 L	20,000 L
Effluent Concentration in Dye-specific Wash-water	0.85 mg/L	0.58 mg/L
Dilution Factor in Dyehouse by Other Wash-waters	7:1 (160,000 L/day effluent)	7:1 (160,000 L/day effluent)
Influent Concentration	0.106 mg/L	0.0725 mg/L
Dilution Factor in Sewage Treatment Plant	1:100	1:100 (Min Flow = 16 Megalitres/day
Conc. Balance in Effluent From Sewage Treatment Plant	0.0011 mg/L	0.0007 mg/L
Dilution Factor in Receiving Waters	3:1 to 10:1	1.25:1 Flow rate worst case = 19 megalitres/day
Conc. (PEC) in Receiving Waters	0.11 ppb to 0.36 ppb	0.56 ppb

The safety factor for exposure of the most sensitive aquatic organism, algae (growth inhibition at 0.32 mg/L) for receiving waters of the city and rural areas are both 3 orders of magnitude.

It has also been assumed in the calculations that no removal of the dye would take place during the wastewater treatment process. Some of the dye would probably be removed due to the adsorption of the dye to the organic sludge and possible complexation of the dye (13). Therefore the actual concentration to receiving waters is likely to be lower than that calculated.

These calculations show that the exposure to fish and daphnia is at levels unlikely to cause any significant hazard. Dye concentrations > 1 ppm can give rise to intensely coloured effluent which inhibit algae growth due to the shadow effect rather than its toxicity. Concentrations are not expected to reach this level and therefore unlikely to have any significant effect on algae.

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

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified chemical is likely to exhibit low acute toxicity and is not likely to exhibit toxic effects on repeated or prolonged exposure. It is likely to be a slight skin irritant and a slight to moderate eye irritant but is not likely to be genotoxic. However, the notified chemical is likely to be a strong skin sensitiser and also will probably be a respiratory sensitiser.

Exposure during transport and handling of the imported cardboard cartons containing the notified chemical is only likely to occur in the event of an accident. In this case the notifier states that the substantial packaging may still preclude exposure.

The imported dyestuffs contain the notified chemical at a maximum concentration of 40% and are formulated to be non-dusting. In addition, weighing out for either repackaging at the notifier's warehouse or prior to dissolution in water for actual dyeing is conducted under local exhaust ventilation. The notifier has provided information that the maximum dose to dyestuff weighers is likely to be 1.3 μg/kg/day by the inhalational route. Following dissolution of the dyestuff containing the notified chemical in water and addition to the dyebath, workers will not come in contact with it so that the above dose level is likely to be the maximum achieved. In addition the fixation rate of 98% means there is a low concentration of dye remaining through the washing cycle.

Although the notified chemical is a strong skin sensitiser in experimental animals, the risk to workers or the public of either skin or respiratory sensitisation is considered to be low due to likely low exposure levels. The widespread public contact with the notified chemical on the surface of treated leather goods is not expected to result in adverse health effects due its strong fixation to the substrate and physico-chemical properties.

13. RECOMMENDATIONS

To minimise occupational exposure to the notified chemical following guidelines and precautions should be observed:

- Local exhaust ventilation should be employed during repacking, weighing out and dissolution of dyestuffs in water;
- The workplace should be well ventilated;
- During repacking, use or disposal of dyestuffs personal protective equipment as described in Australian (AS) or Australian/New Zealand (AS/NZS) Standards as follows should be worn:
    - Eye protection should be selected and fitted in accordance with AS 1336 (14) and meet the requirements of AS/NZS 1337 (15);
    - Impermeable gloves should conform to AS 2161 (16);
    - Protective clothing should conform to AS 2919 (17);
    - Protective footwear should conform to AS/NZS 2210 (18).
- If there is a possibility of dust inhalation respiratory protection conforming to AS/NZS 1715 and 1716 (19,20) should be employed;

- Good work practices should be implemented to avoid spillages and splashing;
- Good work practices should be implemented to minimise mists and aerosols;
- Good housekeeping and maintenance should be practised. Spillages should be cleaned up promptly with absorbents which should then be put into containers for disposal in accordance with Local or State government regulations;
- Good personal hygiene should be observed; and
- A copy of the relevant MSDS should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (21).

This MSDS was provided by the applicant as part of the notification statement. 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.

16. REFERENCES

1. Hobbs, S 1988, *Industry Category Document: UK Dye Production and Use in the Textile Industry*, UK Department of the Environment (CR36/38).
2. Crouch C N 1994, *Acute Oral Toxicity Study with FAT 40'514/A in Rats*, Project No. 378843, RCC, Research and Consulting Co. Ltd, Itingen, Switzerland.
3. Crouch C N 1994, *Acute Dermal Toxicity Study with FAT 40'514/A in Rats*, Project No. 378854, RCC, Research and Consulting Co. Ltd, Itingen, Switzerland.
4. Arcelin G 1994, *Primary Skin Irritation Study with FAT 40'514/A in Rabbits (4-Hour Semi-Occlusive Application)*, Project No. 378865, RCC, Research and Consulting Co. Ltd, Itingen, Switzerland.
5. Arcelin G 1994, *Primary Eye Irritation Study with FAT 40'514/A in Rabbits*, Project No. 378876, RCC, Research and Consulting Co. Ltd, Itingen, Switzerland.
6. Arcelin G 1994, *Contact Hypersensitivity to FAT 40'514/A in Albino Guinea Pigs Maximisation-Test*, Project No. 378887, RCC, Research and Consulting Co. Ltd, Itingen, Switzerland.
7. Organisation for Economic Co-operation and Development, *OECD Guidelines for Testing of Chemicals*, OECD, Paris, France.

8. Draize J H, 1959, 'Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics', *Association of Food and Drug Officials of the US,* **49**.

9. Pfister T *et. al* 1995, *Subacute 28-Day Oral Toxicity (Gavage) Study with FAT 40'514/A in the Rat*, Project No. 378898, RCC, Research and Consulting Co. Ltd, Itingen, Switzerland.

10. Wollny E 1994, *Salmonella typhimurium and Escherichia coli Reverse Mutation Assay with FAT 40'514/A*, Project No. 378911, RCC, Research and Consulting Co. Ltd, Itingen, Switzerland.

11. Volkner W 1995, *Chromosome Aberration Assay in Chinese Hamster V79 Cells in vitro with FAT 40'514/A*, Project No. 378922, RCC, Research and Consulting Co. Ltd, Itingen, Switzerland.

12. National Occupational Health and Safety Commission 1994, *Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1994)]*, Australian Government Publishing Service, Canberra.

13. Weber E J 1991, *Environmental Toxicology & Chemistry*, **10**, 609-618.

14. Standards Australia, 1994, *Australian Standard 1336-1994, Recommended Practices for Eye Protection in the Industrial Environment*, Standards Association of Australia Publ., Sydney, Australia.

15. Standards Australia, Standards New Zealand 1992, *Australian/ New Zealand Standard 1337-1992, Eye Protectors for Industrial Applications*, Standards Association of Australia Publ., Sydney, Australia, Standards Association of New Zealand Publ. Wellington, New Zealand.

16. Standards Australia 1978, *Australian Standard 2161-1978, Industrial Safety Gloves and Mittens (excluding Electrical and Medical Gloves*), Standards Association of Australia Publ., Sydney, Australia.

17. Standards Australia, 1987, *Australian Standard 2919 - 1987 Industrial Clothing,* Standards Association of Australia Publ., Sydney, Australia.

18. Standards Australia, Standards New Zealand 1994, *Australian/ New Zealand Standard 2210 - 1994 Occupational Protective Footwear, Part 1: Guide to Selection, Care and Use. Part 2: Specifications,* Standards Association of Australia Publ., Sydney, Australia, Standards Association of New Zealand Publ. Wellington, New Zealand.

19. Standards Australia, Standards New Zealand, 1994, *Australian/New Zealand Standard 1715 - 1994 Selection, Use and Maintenance of Respiratory Protective Devices*, Standards Association of Australia Publ., Sydney, Australia, Standards Association of New Zealand Publ., Wellington, New Zealand.

20. Standards Australia, Standards New Zealand,1991, *Australian/New Zealand Standard 1716 - 1991 Respiratory Protective Devices,* Standards Association of Australia Publ., Sydney, Australia, Standards Association of New Zealand Publ., Wellington, New Zealand.

21. National Occupational Health and Safety Commission 1994, *National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)]*, AGPS, Canberra.

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.
Diffuse beefy red	3 severe	Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	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