File No: NA/209

Date: 17 November 1994

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

SANDOGEN CN

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

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

For Enquiries please contact the Administration Coordinator at:

Street Address: 92 Parramatta Rd Camperdown, NSW 2050, AUSTRALIA
Postal Address: GPO Box 58, Sydney 2001, AUSTRALIA
Telephone: (61) (02) 565-9466 **FAX (61) (02) 565-9465**

Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

SANDOGEN CN

1. APPLICANT

Sandoz Australia Pty Ltd, 675 Warrigal Rd, Chadstone, Victoria, 3148

2. IDENTITY OF THE CHEMICAL

Chemical name: Reaction product of a mixture of isomeric oxo bis(methylbenzenes) with sulphuric acid, ammonium salts

Chemical Abstracts Service (CAS) Registry No.: 75314-26-0

Trade name: Sandogen CN Liquid (the notified substance comprises 52% of Sandogen CN Liquid)

Molecular formula: $C_{28}H_{29}NO_7S_2$ (major component - monosulphonated dimer)

Molecular weight: 555 (major component)

Method of detection and determination:

Gel Permeation Chromatography

Spectral data:

No data available. Characterisation was limited to GPC.

3. PHYSICAL AND CHEMICAL PROPERTIES

The notified substance will be imported as a component (52%) of Sandogen CN Liquid and is never isolated. The properties listed below are those of the imported formulation which is an aqueous solution of the notified substance.

Appearance at 20°C and 101.3 kPa: Dark brown, viscous liquid

Boiling Point: ~100°C

Density: 1200 kg/m^3

Vapour Pressure: similar to water

Water Solubility: completely miscible with water

Partition Co-efficient (n-octanol/water)
log P_{OW}: Not applicable as the substance dissociates in water

Hydrolysis as a function of pH: The notified substance is not expected to undergo hydrolysis

Dissociation Constant pKa: The notified substance is expected to fully dissociate in water

Explosive Properties: Not explosive

Reactivity/Stability: The notified substance is stable and will not decompose under normal storage and handling conditions

Comments on physico-chemical properties

Thermal properties and particle size are not applicable for an aqueous solution.

4. PURITY OF THE CHEMICAL

Degree of purity: 97%

Toxic impurity:

. **Chemical name:** 1,1'-Oxybis(methylbenzenes)
Synonym: Ditolyl ether
Weight percentage: 3%
Toxic properties: Oral administration in rats and mice results in salivation, sedation and palmospasms. In mice, histopathological changes in the liver, lungs and gastrointestinal tract were observed. Ditolyl ether was strongly irritating to rabbit skin but was not an eye irritant. It was shown not to be mutagenic in the Ames and mouse micronucleus tests and was not teratogenic in rats (1).

Other impurities (> 1% by weight): None

Additives/Adjuvants: None

5. INDUSTRIAL USE

The notified substance will be used as a levelling agent in the dyeing of nylon.

6. OCCUPATIONAL EXPOSURE

Sandogen CN Liquid will be imported in 60 L plastic drums at a rate of < 1 tonne per year for the first 5 years. The product will be sold in these drums or repacked by manual decanting by one storeman into smaller quantities if necessary.

It is expected that the product will be sold to 12 dyehouses. At each dyehouse a total of 5 workers may be exposed to the notified substance.

About 0.5 to 6 L of Sandogen CN Liquid (0.25 - 3 kg of the notified substance) will be drawn from the drum and diluted with water to 0.25%. It is estimated that one hour per day will be spent diluting the Sandogen CN Liquid and adding it to the dyebath for each dyehouse. The dyeing process itself is usually carried out in a closed system.

Because of the low volumes involved, no special engineering controls are expected to be used during mixing or for addition to the dyebath.

7. PUBLIC EXPOSURE

No public exposure to the notified chemical is expected during repackaging, distribution, use or storage.

Public exposure to the notified chemical resulting from use or contact with treated fabrics may be extensive. However, the notified chemical is claimed to be 'chemically bonded to the fibers, in a similar manner to a dyestuff'. Therefore, exposure levels are expected to be negligible.

8. ENVIRONMENTAL EXPOSURE

. Fate

The notifier has provided evidence that half of the chemical (50%) will become chemically bound to fibres and in this state is not expected to adversely impact on the environment.

The unfixed residues from dyeing operations will enter the aquatic environment after discharge from the textile mills and subsequent treatment at sewage treatment plants. As a result of the chemical's expected low Kow, and hydrolytic stability, it is likely that significant quantities will remain in the aquatic phase.

The chemical was tested for its ready biodegradability using an old OECD (l/1/1974) method, and was found to be not readily biodegradable. Even though it did not meet the criteria for ready biodegradation, it did show significant degradation in the test (28 and 52% elimination at a concentration of 1500 mg/L and 425 mg/L respectively), indicating that it is inherently biodegradable and likely to degrade relatively rapidly in the environment.

The bioaccumulation potential of the chemical was not investigated due to its expected low partition coefficient, as allowed by the Act. This, together with the high water solubility and likely biodegradation, indicate that bioaccumulation should not occur.

9. EVALUATION OF TOXICOLOGICAL DATA

Under the *Industrial Chemicals (Notification and Assessment) Act, 1989,* toxicity data are not required for new chemicals intended to be manufactured or imported at a rate of less than 1 tonne per year. However, summaries of various studies on Sandogen CN liquid were available and were submitted as part of the notification statement.

Sandogen CN liquid was found to be of low oral (LD_{50} > 5000 mg/kg) and dermal (LD_{50} > 4000 mg/kg) toxicity in rats, a slight skin irritant and a slight to moderate eye irritant in rabbits.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

As there is ≤ 1 tonne imported ecotoxicity tests are not required. However, the following ecotoxicity tests were provided by the notifier, as required by the Act. The fish test provided was completed in 1976, before standard test methods were agreed, and only a summary was presented.

Table 1 Ecotoxicity test results

Species	Test	Result
Rainbow Trout, *Salmo gairdneri*	48 hour acute	NOEC = 100 mg/L LC_{50} = 160 mg/L
Waste water bacteria	48 hour Respiration OECD TG 209	IC_{50} > 100 mg/L

The above results show that the notified compound is practically non-toxic to fish. Based on these results, effects on daphnia would not be expected at the estimated environmental concentrations.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

As indicated above, 50% of Sandogen CN liquid is fixed in the dyeing process. The notifier has calculated the concentration of discharge per kilogram of nylon The notifier has indicated that the chemical is likely to be used in < 5 dyehouses in Australia, all city based. The calculations presented by the notifier are as follows:

Nylon to be dyed	1 kg
Amount of Sandogen liquid (~2% on weight of fabric)	20 gm
Content of notified chemical	52%
Fixaton rate	50%
Volume of water used	20 L per kg of fabnc
Concentration of notified chemical remaining in bath	260 mg/L
Dilution in waste water assumed at 1:10	26 mg/L

The EPA has used these calculations for a typical city based dyehouse, dyeing 100 kg of nylon per batch.

Amount of Sandogen used per batch (52% pure)	= 1.04 kg
Fixation rate of 50%, quantity passing to effluent	= 0.52 kg
Total volume of dyehouse wash waters	= 3,000,000 L
Effluent concentration	= 170 ppb
Dilution in sewage treatment plant:	
290 ML per day	= 1.8 ppb (l00% discharged)
Ocean discharge (10:1 dilution)	= 0.2 ppb

These calculations are based on no removal of the notified chemical in the sewage treatment plant either by degradation or absorption to sludge. The calculations give an expected environmental concentration significantly below the NOEL for fish (100 mg/L). These calculations should be considered worst case, as there is expected to be some biodegradation in the sewage treatment works; however it is not possible to estimate the amount.

The notified chemical is not expected bioaccumulate.

Spills of the chemical should not present an environmental hazard when cleaned up in accordance with the recommendations contained in the MSDS.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The toxicity data submitted were generated using Sandogen CN Liquid, an aqueous solution of the notified substance. It can be assumed that any effects observed were due to the notified substance itself. Thus, it is likely to be a slight skin irritant and a slight to moderate eye irritant.

The maximum volume of Sandogen CN Liquid handled at any one time will be 6 litres and its high viscosity is likely to reduce the potential for splashing although this may be possible on dilution. Because such small volumes are handled at any one time, engineering controls are unlikely to be used. Nevertheless, occupational exposure to the notified substance is expected to be low under normal conditions of use.

It can be concluded that there is some risk of skin or eye irritation resulting from use of the chemical by workers.

There is negligible risk of adverse public health effects resulting from transport, storage, distribution or use of the chemical or from use of the fabrics containing chemical residues.

13. RECOMMENDATIONS

To minimise occupational exposure to Sandogen CN the following guidelines and precautions should be observed:

. if work practices are insufficient to reduce exposure to the notified substance to a safe level, then personal protective devices which conform to and are used in accordance with Australian Standards (AS) for eye protection (AS 1336, AS 1337) (2,3) and impermeable gloves (AS 2161) (4) should be worn in addition to overalls;

. good work practices should be employed to avoid spillage and splashing;

. good personal hygeine should be practised;

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

14. MATERIAL SAFETY DATA SHEET

The Material Safety Data Sheet (MSDS) for Sandogen CN Liquid containing the notified substance was provided in Worksafe Australia format (5).

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

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989*, secondary notification of Sandogen CN 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. Riskline - National Chemicals Inspectorate (Sweden) (1991 - 1994), Source: Beratergremium fuer unweltrelevante Altstoffe (BUA); pp 18 - 21, 1987.

2. Australian Standard 1336-1982, *Recommended Practices for Eye Protection in the Industrial Environment*, Standards Association of Australia Publ., Sydney, 1982.

3. Australian Standard 1337-1984, *Eye Protectors for Industrial Applications*, Standards Association of Australia Publ., Sydney, 1984.

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

5. National Occupational Health and Safety Commission, *Guidance Note for the Completion of a Material Safety Data Sheet*, 2nd. edition, AGPS, Canberra, 1990.