

File No: NA/224

Date:

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

ALCOSPERSER 408-D POLYMER

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**ALCOSPERSE 408-D****1. APPLICANT**

National Starch and Chemical Pty Ltd of 7 Stanton Road, Seven Hills, NSW 2147 has submitted a limited notification statement with their application for an assessment certificate for Alcosperse 408-D.

2. IDENTITY OF THE CHEMICAL

Based on the nature of the chemical and the data provided, Substance H112793, is considered to be non-hazardous. Therefore, the chemical name, CAS number, molecular formula, structural formula, molecular weight and spectral data have been exempted from publication in the Full Public Report and the Summary Report

Trade name: Alcosperse 408-D

NAMW: > 1000

Method of detection and determination:

The notified polymer is separated by Gel Permeation Chromatography and identified by Infra-red spectroscopy.

3. PHYSICAL AND CHEMICAL PROPERTIES

The notified polymer is imported as Alcosperse 408-D is a spray dried polymer comprising approximately 90% sodium salt and 10% water. All properties listed below are those of Alcosperse 408-D unless otherwise specified.

Appearance at 20°C and 101.3 kPa: Off-white powder

Melting Point: 100°C

Density: 500 kg/m³ (Approximately)

Water solubility: Soluble in water (extent of solubility not quantified)

Hydrolysis as a function of pH: 5.0 - 6.5 (40% solution Alcosperse 408-D)

Vapour pressure: Not determined

Partition coefficient: Not determined

Adsorption/desorption: Not determined

Decomposition Temperature: Not determined

Dissociation constant: Not determined

Reactivity/Stability:	Stable, hazardous polymerisation is not expected to occur
Flash point:	Not flammable
Autoignition temperature:	Not determined
Explosive properties:	Not explosive
Pyrolysis products:	Not determined
Combustion products:	Not determined

. **Comments on Physico-Chemical Properties**

An aqueous solution of the polymer is expected to show characteristic acidity because of the free carboxylic acid. As the salt of a polycarboxylic acid, the vapour pressure is expected to be low. Any vapour pressure result would be a function of the presence of water. The polymer contains an amide functionality, but this is not normally accepted as subject to hydrolysis under environmental conditions. Due to the substance's surface active nature, a partition co-efficient result would be difficult to obtain. Evidence suggests the notified substance is adsorbed by sewage solids.

4. PURITY OF THE CHEMICAL

Degree of purity: > 96%

5. INDUSTRIAL USE

Alcosperse 408-D polymer is to be used as a deflocculant/rheology modifier in commercial and domestic laundry detergent formulations. The expected concentration of Alcosperse 408-D polymer in the finished laundry detergent is less than 2%.

Alcosperse 408-D polymer will be imported at the rate of 100 tonnes per year for the next five years.

6. OCCUPATIONAL EXPOSURE

The notified polymer will be imported as Alcosperse 408-D in cardboard kegs or as a component of a finished laundry detergent in multiple types of containers (bottles, boxes). Six workers will be involved in transporting and warehousing the shipped notified polymer. Twelve workers will be involved in reformulation, quality control inspections and filling out operations. Reformulation consists of addition of the notified polymer by gravity through a pipe system to a closed compounding vessel. It is mixed with other ingredients to produce the finished liquid detergent. The liquid detergent is then transferred by means of an automatic dosing system to retail detergent containers. Reformulation and packaging of the notified polymer is carried out under local exhaust ventilation.

7. **PUBLIC EXPOSURE**

Public exposure to Alcosperse 408-D is likely to be widespread since it will be formulated into domestic laundry detergents for the public market. However, exposure will be limited given the expected low concentration of Alcosperse 408-D in finished products (< 2%).

8. **ENVIRONMENTAL EXPOSURE**

. Release

The notifier provided additional information on likely release in the formulation of finished laundry detergents. The process is likely to consist of the addition of the polymer by gravity feed to a closed compounding vessel and cold mixed with other ingredients. The detergent would then be transferred to a nearly automatic dosing system to fill the retail detergent containers. It is claimed that there will be no release of the notified substance during formulation.

The majority of the polymer will be released through the use of the laundry detergent. This has the potential of significant Australia-wide exposure, as the annual import volume of greater than 100 tonnes is likely to be close to the amount released to the Australian environment.

. Fate

The polymer is used to scavenge calcium and other metal ions, and as such, is likely to partition to the sewage sludge. Any free polymer entering the sewage system is likely to adsorb to effluent, sludge or any free metal ion and then to sludge. Literature suggests that the partition ratio between treated effluent and sludge favours sludge as the concentration of polycarboxylate decreases (1). The notifier indicates that the majority of the polycarboxylate would be absorbed on sludge in sewage treatment plants.

By analogy with other polymers of the polycarboxylic acid class, the polymer is not expected to readily biodegrade (1). However, any lower molecular weight species are expected to be increasingly biodegradable as their molecular weight decreases and become more susceptible to bacterial action.

Also, no bioaccumulation of the polymer is expected due to its high water solubility and since its large molecular size is likely to inhibit membrane permeability and prevent uptake during exposure (2,3).

9. **EVALUATION OF TOXICOLOGICAL DATA**

No toxicology data are required under the *Industrial Chemicals (Notification and Assessment) Act 1989* as amended, for polymers with a number-average molecular weight (NAMW) > 1000. However, the following studies were carried out on the product Alcosperse 408-D containing the polymer and are reported here.

9.1 Acute Toxicity

Table 1 Summary of the acute toxicity of Alcosperse 408-D

TEST	SPECIES	OUTCOME	REFERENCE
Acute oral toxicity	Rabbit	Non-irritant	(4)
Skin irritation	rabbit	non-irritant	(6)
Eye irritation	rabbit	non-irritant	(9)

9.1.1 Oral Toxicity (4)

This study was carried out according to OECD Guidelines for Testing of Chemicals No: 401 (5).

A single dose of 5000 mg/kg of Alcosperse 408-D was administered by gavage to Sprague-Dawley rats (5/sex). The animals were observed at 1 and 4 hours after dosing and subsequently once daily for 14 days. One animal was found dead 24 hours after dosing. The death was attributed to a mis-dose. All animals exhibited watery faeces. One male and a female were found to be lethargic and the same female convulsive following dosing. One female exhibited hemorrhage in the thymic area, pleural adhesions and distended stomach and duodenum with a clear yellow fluid at necropsy. There was no body weight recorded during the study.

The results of this study indicate an oral LD₅₀ of >5000 mg/kg for Alcosperse 408-D in male and female rats.

9.1.2 Skin Irritation (6)

This study was carried out in accordance with OECD Guidelines for Testing of Chemicals No: 404 (7).

A single dose of 0.5 ml of Alcosperse 408-D was administered by occlusive application to intact and abraded skin of six male New Zealand White rabbits for four hours. The site of application was examined approximately 60 minutes and 1, 2 and 3 days after removal of the dressing. Skin reactions were assessed according to Draize (8). There were no signs of erythema or oedema in any of the animals.

The results of this study indicate that Alcosperse 408-D is a non-irritant to the skin of rabbits.

9.1.4 Eye Irritation (9)

This study was carried out in accordance with OECD Guidelines for Testing of Chemicals No: 405 (10).

Three New Zealand White Albino male rabbits were used in the study. Initially, a single dose of 0.1 ml of Alcosperse 408-D was instilled into the conjunctival sac of the right eye of each rabbit. The other eye which remained untreated, served as the control. Ocular reactions were assessed according to Draize (8) after 1 hour and 1, 2 and 3 days post-treatment.

All treated eyes appeared normal during the study period.

The results of this study indicate that Alcosperse 408-D is a non-irritant to the eye of rabbits.

9.3 Genotoxicity

9.3.1 Salmonella typhimurium Reverse Mutation Assay (11)

This study was carried out according to OECD Guidelines for Testing of Chemicals No: 471 (12).

Alcosperse 408-D at dose levels of 10000, 7500, 5000, 1670, 500 or 167 µg/plate was tested for gene mutation using *Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537 and TA 1538 either in the presence or absence of metabolic activation (S9-mix). Positive controls used were 9-aminoacridine, sodium azide and 2-nitrofluorene (without

S9 mix) and 2-anthramine (with S9 mix). Distilled water was used as the diluent for the test substance and as the negative control.

The test substance did not induce statistically significant dose-related increases in the number of revertant colonies in *Salmonella typhimurium* strains either in the presence or absence of S9 mix. The positive controls induced the expected increases in all strains tested.

The results of this study indicate that Alcosperse 408-D is not mutagenic in *Salmonella typhimurium*.

9.4 Overall Assessment of Toxicological Data

Alcosperse 408-D has low acute oral toxicity in rats. It not a skin or eye irritant in rabbits. Alcosperse 408-D was found to be non-mutagenic in the *Salmonella typhimurium* reverse mutation assay.

On the basis of submitted data, the notified chemical would not be classified as hazardous in accordance with *Approved Criteria for Classifying Hazardous Substances* (13) in relation to acute lethal effects (oral) and irritant effects (skin, eye).

9. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicological data were provided, which is acceptable for polymers of NAMW > 1000 according to the Act.

Due to its high NAMW the polymer is not expected to cross biological membranes.

However, because of its chelating properties, this polymer class is considered potentially toxic to green algae (14). The toxicity is considered moderate with 96 h EC₅₀ values for growth inhibition ranging from 1 to 100 mg/L. The effect, however, is mitigated when enough calcium is added to satisfy its anionic charge.

The polymer also has a substantial amount of lower molecular weight species (NAMW < 500 = 5% and <1000 = 25%). These species should have similar ecotoxic properties to the polymer.

10. ASSESSMENT OF ENVIRONMENTAL HAZARD

It is expected that the polymer will have wide distribution in the aquatic environment throughout Australia because of its widespread use and high volume of use as a component in laundry detergent. This, together with its property of chelating metal ions which are nutrients for algal growth, implies that the polymer might pose some hazard to aquatic organisms.

Given this, the notifier has provided a predicted environmental concentration (PEC) of the polymer after treatment at a metropolitan sewage plant. It is calculated that an average wash would use 160 g of detergent (containing 1% of the polymer) and 130 L of water. This would give 12 mg/L of polymer per wash load. Assuming that all of this was passed through the sewage treatment plant which serviced 1.3 million households, and each household had one wash per day, then the amount of polymer entering receiving waters would be diluted with about 1100 ML to give a concentration of 1.8 mg/L.

The PEC is relatively high when compared to the toxicity of polycarboxylic acids reported in the literature. However, it is likely to be the extreme worst case as it assumes every household uses only the finished product containing the notified polymer, every day.

Therefore, the EPA has modified the approach of calculating the PEC. For instance, if all of the annual import volume was used equally on a daily basis (i.e. 100 t per 365 d), but

only in a large city, then a rough calculation assuming all the polymer enters and leaves the sewage treatment plant in the 1100 ML for the large metropolitan city, gives a concentration of only 0.25 mg/L. This does not account for the product's use in other cities. Also, several other factors will reduce the actual concentration of polymer released to the environment compared to the above PEC's, and consequently reduce the hazard the polymer may pose to the environment:

- Further dilution will be achieved in receiving waters;
- Any sewage effluent is likely to be nutrient rich and would tend to mitigate any loss of metal ions; and
- Because of its general chelating properties, it would complex with any metal ions when the effluent stream mixes with receiving waters.

It is expected that the molecular weight species below 1000 will also complex metals, but otherwise not be toxic. Further, the smaller the species, the more likely it will be biodegradable. This, together with the likely dilution, suggests that this fraction does not represent a significant hazard to the environment.

11. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

As the notified chemical is a polymer of high number-average molecular weight (> 1000), it is not expected to be able to cross biological membranes and should not be considered a health hazard for this reason.

The notified polymer is non-flammable, non-explosive and stable. Under normal use conditions it will not pose a flammable, explosive or a reactive hazard in Alcosperse 408-D or in detergent.

There is a relatively high level (25%) of species with number-average molecular weight < 1000 of unknown toxicity. However, it is expected that any toxic effects would be dependent on leaching of the low molecular weight species from the polymer.

Exposure of formulating and packaging personnel is largely controlled by automated systems and local exhaust ventilation and is limited to a maximum of 12 workers. Automated systems used during formulating and packaging of the notified polymer would be expected to minimise exposure to the low molecular weight species of unknown toxicity.

It is expected that the risk of adverse health effects from exposure to the polymer during formulation and packaging would be low given the containment procedure in use and engineering controls in place.

Public exposure to Alcosperse 408-D is likely to be widespread since it will be formulated into domestic laundry detergents for the public market. However, exposure will be limited given the expected low concentration of Alcosperse 408-D in finished products ($< 2\%$).

This is minimised by the recommended practices for storage and transportation. Emergency procedures for the containment and clean up of accidental spills are available with the notifier and should be followed.

12. RECOMMENDATIONS

To minimise occupational exposure to Alcosperse 408-D polymer the following guidelines and precautions should be observed:

- . if engineering controls and work practices are insufficient to reduce exposure to Alcosperse 408-D 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) (15,16), impermeable gloves (AS 2161) (17) and overalls should be worn;
- . the workplace should be well ventilated and engineering controls such as local exhaust ventilation should be employed where the powder is handled and where formulation takes place. The dust level should be maintained below Worksafe Australia's exposure standard for nuisance particulates of 10 mg/m³.
- . good personal hygiene should be observed;
- . good work practices should be implemented to avoid spills. If spills occur, they should be cleaned up promptly and disposed of in accordance with recommendations contained in the Material Safety Data Sheet (MSDS); and
- . a copy of the MSDS should be easily accessible to employees.

13. MATERIAL SAFETY DATA SHEET

The attached MSDS for Alcosperse 408-D was provided in a suitable format (18).

These MSDS were provided by National Starch and Chemical Pty Ltd as part of their notification statement. The accuracy of this information remains the responsibility of National Starch and Chemical Pty Ltd.

14. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989*, secondary notification of Alcosperse 408-D polymer shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise.

15. REFERENCES

1. UK Department of the Environment. 1991 Final Report. *Pollutants in Cleaning Agents*.
2. Anliker *et al.* 1988. *Chemosphere*, **17**, 1631-1644.
3. Gobas *et al.* 1986. *Environmental Toxicology and Chemistry*, **5**, 637-646.
4. White Eagle Toxicology Laboratories, Pennsylvania, USA., "Alcosperse 408-D: Acute Dermal Toxicity to the Rat". Data on file, Report No 93403, August, 1993.
5. OECD Guidelines for Testing of Chemicals, "Acute Oral Toxicity" No: 401, 1981.
6. White Eagle Toxicology Laboratories, Pennsylvania, USA., "Alcosperse 408-D: Skin Irritation to the Rabbit". Data on file, Report No 93404, August, 1993..

7. OECD Guidelines for Testing of Chemicals, "Acute Dermal Irritation/Corrosion" No: 404, 1981.
8. Draize, J.H., et. al., "The Appraisal of Chemicals in Food, Drugs and Cosmetics", Association of Food and Drug Officials of the United States, Austin, Texas, 1959.
9. White Eagle Toxicology Laboratories, Pennsylvania, USA., " Alcosperse 408-D: Eye Irritation to the Rabbit". Data on file, Report No: 93405, August, 1993.
10. OECD Guidelines for Testing of Chemicals, "Acute Eye Irritation/Corrosion" No: 405, 1987.
11. Pharmakon USA, Pennsylvania, USA., " Alcosperse 408-D: An Evaluation of Mutagenic Potential Using Salmonella typhimurium". Data on file, Report No: PH 301-NS-001-93, August, 1993.
12. OECD Guidelines for Testing of Chemicals, "Genetic Toxicology: Salmonella typhimurium, Reverse Mutation Assay" No: 471, 1983.
13. Guidance Note for Determining and Classifying a Hazardous Substance, [NOHSC:3011(1991)], AGPS, Canberra, June 1991.
14. Nabholz JV, Miller P, Zeeman M 1993. Environmental Risk Assessment of New Chemicals Under the Toxic Substances Control Act (TSCA) Section Five. In *Environmental Toxicology and Risk Assessment*. ASTM STP 1179. G Landis, JS Hughes, MA Lewis (eds). American Society for Testing and Materials, Philadelphia. pp 40-45.
15. Australian Standard 1336-1982, *Recommended Practices for Eye Protection in the Industrial Environment*, Standards Association of Australia Publ., Sydney, 1982.
16. Australian Standard 1337-1984, *Eye Protectors for Industrial Applications*, Standards Association of Australia Publ., Sydney, 1984.
17. Australian Standard 2161-1978, *Industrial Safety Gloves and Mittens (excluding Electrical and Medical Gloves)*, Standards Association of Australia Publ., Sydney, 1978.
18. National Occupational Health and Safety Commission, *National Code of Practice for the Preparation of Material Safety Data Sheets*, [NOHSC:2011(1994)] AGPS, Canberra, March 1994.