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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

EXP-2126 POLYMER

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

EXP-2126 POLYMER

1. APPLICANT

National Starch and Chemical Pty Ltd., 7 Stanton Road, Seven Hills, NSW 2147.

2. IDENTITY OF THE CHEMICAL

Trade name: EXP-2126 Polymer

Method of detection and determination:

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

Spectral data:

Major characteristic peaks were observed at: 640, 800, 850, 1150, 1350 1410, 1450 and 1570 cm^{-1}

3. PHYSICAL AND CHEMICAL PROPERTIES

The notified polymer at a concentration of 35% will be imported as an aqueous solution known as EXP-2126. All properties listed below are those of the aqueous solution unless otherwise specified.

Appearance at 20°C and 101.3 kPa:	Syrupy, clear, solution
Boiling Point:	100°C
Density:	Not determined, approximate range expected to be 1050-1115 kg/m^3
Water solubility:	Soluble in water (extent of solubility not quantified)
Hydrolysis as a function of pH:	Not determined
Partition coefficient:	Not determined
Adsorption/desorption:	Not determined
Decomposition Temperature:	Not applicable
Dissociation constant:	Not determined
Reactivity/Stability:	Stable, hazardous polymerisation is not expected to occur

Flash point:	Not flammable
Autoignition temperature:	Not applicable
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 polyacrylate, the vapour pressure would be expected to be low. Any vapour pressure result would be a function of the presence of water. The polymer contains no groups 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. Some evidence, described in more detail below, suggests the notified substance is adsorbed by sewage solids.

4. PURITY OF THE CHEMICAL

Degree of purity: > 96%

5. INDUSTRIAL USE

EXP-2126 POLYMER is to be used as an additive in detergents to prevent the redeposition of calcium salts (scale inhibitor) during wash cycles. It is also used as a modifier of rheology stability in liquid formulations. The expected concentration of EXP-2126 polymer in the finished laundry detergent is 1-10%.

EXP-2126 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 EXP-2126 or as a component of a finished laundry detergent. 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 following which cold mixed with other ingredients to produce finished liquid detergent. The liquid detergent is then transfered 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

The major public exposure to the notified polymer will result from the use of the finished laundry detergent and contact with washing machine water. The notifier estimated that dilution in washing machine water is likely to decrease the concentration of the polymer by at least two orders of magnitude. Minor public exposure may result from accidental spillage during transport, storage (of the polymer or finished product) and reformulation.

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 liquid 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 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). Further, 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 pigment 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 Assessemnt) Act 1989* for polymers with a number-average molecular weight(NAMW)> 1000. However, the following studies were carried out on the product EXP-2126 containing the polymer and are reported here.

9.1 Acute Toxicity

Table 1 **Summary of the acute toxicity of EXP-2126**

Test	Species	Outcome	Reference
Acute oral toxicity	rat	LD_{50} >5000 mg/kg	(4)
Skin irritation	rabbit	non-irritant	(6)
Eye irritation	rabbit	slight-irritant	(9)
Skin sensitisation	guinea-pig	non-sensitiser	(11)

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 EXP-2126 in double distilled water was administered by gavage to Sprague-Dawley rats (6/sex). The animals were observed at 1 and 4 hours after dosing and subsequently once daily for 14 days. No deaths were noted during the study. All animals showed the expected gain in body weight over the study period. No abnormalities were noted at necropsy.

The results of this study indicate an oral LD_{50} of >5000 mg/kg for EXP-2126 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 EXP-2126 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 EXP-2126 is a non-irritant to the skin of rabbit.

9.1.4 Eye Irritation (9)

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

Six New Zealand Albino male rabbits were used in the study. Initially, a single dose of 0.1 ml of EXP-2126 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.

Slight conjunctival redness were observed in five animals one hour post-treatment which persisted up to day 1. On day 2 all treated eyes appeared normal.

The results of this study indicate that EXP-2126 is a slight-irritant in rabbits.

9.1.5 Skin Sensitisation (11)

This study was carried out according to the OECD Guidelines for Testing of Chemicals No:406 (12).

The maximisation test was used to assess skin sensitisation potential of EXP-2126. Skin reactions were assessed according to a four-point scale.

The following concentrations for induction and the challenge were selected from a preliminary study.

Intradermal induction: 20 % EXP-2126 in saline (w/v) with or without Freund's adjuvant.

Percutaneous induction: 100% EXP-2126

1st challenge: 20% EXP-2126 in saline (w/v)

Induction

Thirty Hartley, guinea pigs (20 test and 10 control) were used.

Three duplicate intradermal injections each of: 1) 0.1 ml of 50% Freund's Complete Adjuvant 2) 0.1 ml of EXP-2126 or 0.1 ml of saline; and 3) 0.1 ml of EXP-2126 emulsified in 50% complete Freund's Adjuvant solution or 0.1 ml of the saline solution in 50% complete Freund's adjuvant was made on each side of the mid-line of the test animals. One week later, a single dose of 100% w/w of EXP-2126 was administered by occlusive application to the shoulder area of each test animal for 48 hours. Twenty-four hours after the removal of the dressing, the application sites were examined for reactions. Control animals were similarly treated but without the test substance.

Challenge

Two weeks after the topical induction the test and the control group animals were challenged with a single dose of 20% w/v of EXP-2126 in saline by occlusive application for 24 hours on the shoulder area of the intradermal application.

No adverse skin reactions were noted in the twenty test animals or in the control group.

The results of this study indicate that EXP-2126 non-sensitiser in guinea pigs at the

9.3 Genotoxicity

9.3.1 Salmonella typhimurium Reverse Mutation Assay (13)

This study was carried out according to OECD Guidelines for Testing of Chemicals No: 471 (14).

EXP-2126 at dose levels of 5000, 1670, 500, 167, 50 or 16.7 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 N-methyl-N'-nitro-N-nitrosoguanidine, 9-aminoacridine, 4-nitro-O-phenylenediamine (without S-9 mix) and 2-aminoanthracene (with S-9 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 S-9 mix. The positive controls induced the expected increases in all strains tested.

The results of this study indicate that EXP-2126 is not mutagenic in *Salmonella typhimurium.*

9.4 Overall Assessment of Toxicological Data

EXP-2126 has low acute oral toxicity in rats. It not a skin irritant but a slight eye irritant. It is not a skin sensitiser in guinea pigs. EXP-2126 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 classsified as hazardous in accordance with *Approved Criteria for Classifying Hazardous Substances* (15) in relation to acute lethal effects (oral, dermal); irritant effects (skin, eye) and sensitisng effects (skin).

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 (16). The toxicity is considered moderate with 96 h EC_{50} 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 (< 500 = 6.7% and <1000 = 20.4%). 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 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 an modified approach of calculating the PEC was used. 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. Low levels of residual monomers also make it unlikely that the notified polymer will present a health hazard.

The notified polymer is non-flammable, non-explosive and stable. Under normal use coditions it will not pose a flammable, explosive or a reactive hazard as a component in EXP-2126 or in detergent.

There is a relatively high level (20.4%) of species with a 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 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 to be low given the containment procedure in use and engineering controls in place.

Widespread public exposure will result from use of laundry detergent containing the polymer. Additional minor exposure may result during reformulation, transport, disposal of unused product, or in waste water.

12. RECOMMENDATIONS

To minimise occupational exposure to EXP-2126 POLYMER the following guidelines and precautions should be observed:

. if engineering controls and work practices are insufficient to reduce exposure to EXP-2126 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) (17,18), impermeable gloves (AS 2161) (19) and overalls should be worn;

. good personal hygiene should be observed;

. good work practices should be implemented to avoid spills which 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 EXP-2126 was provided in Worksafe Australia format (20).

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 EXP-2126 polymer shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

15. REFERENCES

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

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