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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

NARLEX 73-9514

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 Arts, Sport, the Environment and Territories and the assessment of public health is conducted by the Department of Health, Housing and Community Services.

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT**NARLEX 73-9514****1. APPLICANT**

National Starch and Chemical Pty Ltd., 7-9 Stanton Road, Seven Hills, NSW 2147.

2. IDENTITY OF THE CHEMICAL

Based on the data available and the nature of the chemical Narlex 73-9514 is not expected to be hazardous. Therefore the details of chemical name, molecular and structural formula, and spectral data, have been exempted from publication.

Chemical Abstracts Service

(CAS) Registry No.: Not available

Marketing name: Narlex 73-9514

Number-average molecular weight (NAMW): 3,830

The lowest NAMW was determined by gel permeation chromatography.

Weight-average molecular weight: 3500 - 5500

Determined by gel permeation chromatography with infra red detection.

**Maximum percentage of low
molecular weight species**

(molecular weight < 1000): % below 1000 < 6%

% below 500 < 2%

Total cumulative value at any one time is < 6%. These species are unidentified and considered to be closely linked with the notified polymer.

Method of detection and determination:

No specific methodology has been developed. Because of the presence of a wide range of esters, ethers and inorganic materials, the detection and determination of the polymer in complex mixtures is considered extremely difficult. However, it is envisaged physical separation followed by Fourier Transform Infrared Analysis (FTIR) would be the most suitable methodology.

3. PHYSICAL AND CHEMICAL PROPERTIES

The following properties relates to the aqueous solution containing the notified polymer and not to the notified polymer.

**Appearance at 20°C
and 101.3 kPa:**

Opaque, viscous, white to
straw coloured liquid

Odour:

Not identified

Boiling Point:

~100°C (101.3 kPa)

Glass-transition Temperature:

Not determined

Specific Gravity:

1.18 (average)

Vapour Pressure:

2.26 kPa @ 20°C (water)

The vapour pressure is expected to be low. A vapour pressure result would be a function of the presence of water.

Water Solubility:

Water soluble

Fat Solubility:

Not determined

**Partition Co-efficient
(n-octanol/water) log Po/w:**

Not determined

Hydrolysis as a function of pH:

The polymer is already hydrolysed. There is no evidence of any further hydrolysis as a function of pH. The primary polymer chain is highly resistant to hydrolysis.

Adsorption/Desorption:	Some evidence, described in section 11, was provided which suggests the notified substance is moderately adsorbed by sewage solids.
Dissociation Constant pKa:	Not determined
Flash Point:	Not flammable
Flammability Limits:	Not applicable, however, propan- 2-ol which is flammable is present as an impurity associated with the polymer at a concentration of 0.5%. At that concentration propan-2-ol is not likely to contribute to flammability
Combustion Products:	Mainly carbon dioxide and carbon monoxide generated during combustion of the dried polymer
Pyrolysis Products:	Not determined
Decomposition Temperature:	Not determined
Decomposition Products:	Not determined
Autoignition Temperature:	Not determined
Explosive Properties:	The polymer is not explosive
Reactivity/Stability:	The polymer solution is not reactive. Contact with strong oxidizing agents should be avoided
Particle size distribution:	Not applicable

4. PURITY OF THE CHEMICAL

Degree of purity of the notified polymer:

- 99.5%

Even though the total cumulative value of the low molecular weight species (< 1000 molecular weight) is approximately 6%, this species is closely linked to the polymer and is considered that part of the composition mixture of the notified polymer which is unidentified.

Residual monomers are not present in hazardous amounts, therefore therefore exempted from this report.

Maximum content of residual monomers(s): < 0.1%

Additive(s) /Adjuvant(s):

Chemical name:	Water
Synonym:	Dihydrogen oxide
CAS No.:	773 2- 18 - 5
Weight percentage:	70-40%

5. INDUSTRIAL USE

Narlex 73-9514 is a polymer for use in laundry detergent. The polymer will be manufactured overseas and imported into Australia by the applicant to be formulated into an end use product with other ingredients. The final concentration of the notified polymer in laundry detergent will be in the order of 1% or less.

The notified polymer will be imported at a concentration of 30 - 60% in water in sealed 1000 litre tanks. The projected import volume is > 5 tonnes/year.

It is proposed by limiting the handling of the notified polymer notified polymer has been used in the United Kingdom and Europe both in industrial and in domestic laundry detergents for approximately five years.

6. **OCCUPATIONAL EXPOSURE**

Occupational exposure to Narlex 73-9514 is possible as part of the following main activities:

- during importation, transport and storage of Narlex 73- 9514 if containers leak or spills occur. Risk is minimised by importation of the polymer in sealed 1000 litre tanks;
- during transfer of the polymer from sealed tanks to dosing tank which includes connecting and disconnecting of the drain hose, opening of the outlet valves (in case of a loose connection) and vent valves of the sealed tanks;
- packaging of the product containing the polymer from mixing tank and during quality control operations.

The proposed technique of limiting the handling of the polymer to a single location, addition of the polymer via gravity feed from 1000 litre tanks to a closed compounding vessel, cold mixing with other ingredients and transfer of the detergent to a nearly automatic dosing system to fill the retail detergent containers will minimise the risk of worker exposure to the polymer.

During routine operations skin and eye contact are the main routes of exposure to the polymer.

Inhalation is not expected to be a significant route of exposure:

- as the polymer has a low vapour pressure;
- as the possibility of aerosol formation is low; and
- due to the polymer being compounded at low levels in a closed mixing vessel.

Under normal use conditions, the potential for occupational exposure to the polymer appears to be very low. The most likely route of exposure is skin and eye contact during use in formulation of the laundry detergent. Exposure by inhalation may also occur in operations involving vapour or mist formation where there is inadequate local exhaust ventilation and respiratory protection.

7. **PUBLIC EXPOSURE**

The public is unlikely to be exposed to the chemical during importation and formulation. The chemical is imported in sealed 1000 litre tanks, and formulated at a single site. Formulation entails cold mixing of the chemical, and residues from the mixing tank are reclaimed and 100% recycled.

The public may be exposed to the chemical at a concentration of approximately 1% or less in laundry detergents.

8. ENVIRONMENTAL EXPOSURE

Release

The polymer will be added, via gravity feed from the 1000 litre tanks, and cold mixed with other ingredients in a closed compounding vessel. The detergent is then transferred to a nearly automatic dosing system to fill the retail detergent containers.

The notifier indicates that there will be no release of the notified substance during these processes as:

all 1000 litre International Bulk Container tanks will be washed out with water and discharged into subsequent detergent production batches; and

all compounding vessel washings are reclaimed and discharged into subsequent detergent production batches.

In the case of accidental spillage, the material should be absorbed into vermiculite, sand or sawdust and disposed of at a suitable waste disposal facility in accordance with NSW EPA guidelines.

The bulk of the notified substance will ultimately be released to the aquatic compartment through domestic use of the laundry detergent. As a result of this significant Australia-wide environmental exposure, closer scrutiny of the environmental hazard is required and appears below.

Fate

The notifier states that by nature of the application, the polymer is required to be stable under a wide range of conditions. The polymer will form water vapour and oxides of carbon and nitrogen on combustion.

Statements in the dossier indicate the notified polymer, at low concentrations ie 0.1 ppm, will adsorb to sewage sludge during primary settling treatment and/or chelate with available metal cations and precipitate into the sludge compartment. The literature records that the partition ratio between treated effluent and sludge favours the latter as the concentration of polycarboxylate decreases (1). At likely concentrations of notified substance in Australian effluents, the notifier indicates 94% of polycarboxylate will be adsorbed on sludge in sewage treatment plants.

The notifier suggests that, like other polymers, the notified substance will not be readily biodegradable. This assertion is supported by the literature which, more specifically, states that polycarboxylate detergent builders like the notified substance are known to resist significant biodegradation during sewage treatment (1).

9. EVALUATION OF TOXICOLOGICAL DATA

No toxicology data is required under the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) for polymers > 1000 molecular weight. However, the following studies have been carried out and reported.

9.1 Acute Toxicity

Table 1 Summary of the acute toxicity of Narlex 73-9514

Test	Species	Outcome	Reference
Skin Irritation	Rabbit	Moderately irritating	(4)
Eye Irritation	Rabbit	Moderately irritating	(6)
Skin Sensitisation	Guinea Pig	Non sensitising	(8)

9.1.1 Absorption from the gastrointestinal tract (2)

Narlex 73-9514 was tested for gastrointestinal absorption in ten Colworth Wistar rats (five/sex). Each rat was gavaged with 1.0 ml of the test substance (containing 0.5% notified polymer with labelled C-14 in aqueous solution). Two rats (one/sex) were killed at intervals of 2, 4, 8, 24 and 48 hours after dosing. Expired air, urine and faeces were analysed for the presence of the test substance. The frozen carcasses were examined using whole body autoradiography.

Following administration of the test substance in rats, approximately 98% was excreted in the faeces, mainly during the initial 24 hours of the 48 hour test period. Trace amounts, 1% or less, were measured in expired air and urine. Whole body autoradiography of rat sections showed that detectable amounts were confined to the digestive tract.

The study indicates that Narlex 73-9514 is largely unabsorbed from the gut.

9.1.2 Dermal Absorption (3)

Narlex 73-9514 was tested for dermal absorption in four Colworth Wistar rats (four/sex). An area of 10 cm² of the dorsal area of each animal was shaved and 0.1 ml of the test solution (containing 5% notified polymer with labelled carbon in aqueous solution) was applied. The treatment site was protected with an occlusive bandage for forty eight hours. Urine and faeces were collected at intervals of 2, 24 and 48 hours, which together with exhaled air were analysed for the presence of the test substance. After 48 hours all animals were killed. Each bandage, the excised area of treated skin and carcasses were also analysed for the presence of the test substance.

The results showed that almost all of the applied material remained associated with the treated area of the skin and the protective occlusive bandage. In the male rats 0.14% of the applied dose was expired, 0.22% was excreted in the urine and 0.16% in the faeces. A total penetration of 0.76% was observed in the males. For females a total penetration of 0.32% was measured.

The results of this study indicate that the notified polymer is poorly absorbed via the dermal route.

9.1.3 Skin Irritation (4)

Narlex 73-9514 was tested for skin irritation (5) in three male New Zealand white rabbits. The test substance (0.5 ml of liquid) was applied to eighteen clipped (6 sites/animal) areas of the dorsal region of the trunk of each animal using a semi- occlusive bandage for four hours. Skin reactions at the sites of application were evaluated at 1, 24, 48 and 72 hours after removal of the bandage and scored according to the OECD guideline scoring system for redness (erythema) and swelling (oedema).

Very slight redness was observed in all three animals (in all six applications in one animal) at one hour. This erythema persisted in two animals up to 72 hours, in the other animal at 24 hours this erythema (very slight redness) developed into a well defined erythema which persisted up to 72 hours. In two animals very slight oedema appeared at one hour, and disappeared at 48 hours in one animal and persisted in the other animal up to 72 hours . In the third animal the same oedema appeared at 24 hours which persisted up to 72 hours. Results of this study indicate that Narlex 73-9514 is a moderate skin irritant. The pH of the notified chemical in solution was not stated.

9.1.4 Eye Irritation (6)

Narlex 73-9514 was tested for eye irritation/corrosion potential (7) in four male New Zealand white rabbits in two groups (group A, one rabbit and group B, three rabbits). The undiluted test substance 10 p1 (for group A) and 100 p1 (for group B) was instilled into the conjunctival sac of one eye of each rabbit with the other untreated eye acting as the control. Eye reactions were evaluated at 15 minutes, 24, 48 and 72 hours post exposure and scored according to the OECD guide-line scoring system for conjunctival redness and chemosis, damage to the iris, and corneal

opacity.

The rabbit in group A showed slight conjunctival erythema shortly after treatment. This erythema had diminished by day 2. Two animals in group B showed slight loss of corneal epithelium and slight conjunctival erythema and one of the animals also showed slight corneal swelling. The third animal showed slight conjunctival erythema. The eye reactions were fully reversible by day 3. Results of this study indicate that Narlex 73-9514 is a moderate eye irritant.

9.1.5 Skin Sensitisation (8)

Narlex 73-9514 was assessed for skin sensitisation potential in guinea pigs using the maximisation test (9). Initially, a dose ranging study with Narlex 73-9514 established the required doses for induction (0.1% and 50% in saline) and challenge (25% in saline). Six males and 4 females were used in the test. Induction was made in two phases, the first in which intradermal injections (0.1% in saline) were made, the second 6-7 days later when the test chemical (in 50% saline) was applied superficially to shoulder injection site under an occluded dressing for 48 hours. Challenge doses were administered 12-14 days later, at 25% in saline under an occluded dressing. Further challenge was made after 7 days. Negative (adjuvant/vehicle) treated controls were used (8 guinea pigs, 4/sex). Positive controls were not used, and no mention is made of the strain used in the study having been recently tested with known sensitisers in the test laboratory.

Skin reactions were evaluated at 24 and 48 hours after removal of the dressing after the challenge. At no stage was skin redness (erythema) or swelling (oedema) observed. Narlex 73-9514 was not found to be a skin sensitiser in guinea pigs.

9.2 Repeated Dose Toxicity (10)

Narlex 73-9514 was tested in rats (SPF-bred KFM-Han. Wistar rats), for repeated dose toxicity in a 28 day study (11). The study population comprised five treatment groups with 10 male and 10 female rats in each group. The test article intake and corresponding dietary concentrations were reported as follows:

Group	Dietary Concentration (ppm)	Test Article Intake mg/kg/day	
		Males	Females
1	0	0	0
2	50	5.37	5.29
3	500	52.4	53.27
4	5000	536.98	528.62
5	50000	5300	5159.83

The substance was administered for a period of four weeks.

There were no treatment-related deaths during the study and no significant differences in food consumption. No treatment-related effects were reported for: body weight, clinical signs, ophthalmoscopy parameters, urinalysis, macroscopic and microscopic histopathological analysis in both males and females; clinical biochemistry parameters and organ weights of females.

One female receiving 50000 ppm of Narlex 73-9514 showed uncoordinated movements, ruffled fur and loss of body weight, and appeared in poor condition during the second week.

In all male groups total serum protein was statistically significantly higher than in the control group. But the differences between individual groups and controls were not dose related.

Males receiving the test substance gained body weight slightly faster than the controls. This could be attributed to the slightly higher food consumption noted.

The following treatment related effects were observed:

- in haematology studies; both sexes that received the highest dietary concentration, 50000 ppm, of Narlex 73-9514 exhibited statistically significantly lower prothrombin time than the controls;
- in blood chemistry studies; males in all test groups showed higher blood urea than the controls. The differences were statistically significant at dietary concentrations of 50, 500, and 50000 ppm Narlex 73-9514.
- in pathological examination; kidney weight in males receiving dietary concentration of 50000 ppm Narlex 73-9514 showed an increase.

9.3 Gonotoxicity

9.3.1 Salmonella typhimurium Reverse Mutation Assay (12)

Narlex 73-9514 was tested in the bacterial species *Salmonella typhimurium*, strains TA 98, TA 100, TA 1535 and TA 1537, with or without metabolic activation with S-9 mix (13). In the preliminary dose range finding study, with dose levels up to 5000 µg/plate, toxicity was observed towards TA 98 and TA 100 strains in the absence of metabolic activation. For the test 50, 150, 500, 1500 and 5000 µg/plate were used. There was no evidence of an increase in the number of revertants in any strain of bacteria at any concentration of the test substance with or without S-9 fraction. Water was used as the negative control. 9-aminoacridine, N-ethyl-N' -nitro-N-nitrosoguanidine and 2-nitrofluorene without S-9 fraction, and 2-Aminoanthracene, with S-9 fraction were used as positive controls which produced the expected increase in the number of revertant colonies.

No evidence of mutagenic activity was observed at any dose level of the notified polymer with or without the S-9 mix.

9.3.2 In vitro Mammalian Cytogenetic Test (14, 15)

Narlex 73-9514 was tested for its ability to induce chromosomal aberrations *in vitro* in cultured human lymphocytes. Concentrations of the test substance for the assay were established by prior treatment of the test substance with the cultured cells. Cultured human lymphocytes were treated with 625, 1250, 2500 and 5000 µg/ml of the test substance in the presence and absence of metabolic activation with S-9 fraction. No concentration of the test substance caused statistically significant increase in the chromosomal aberrations, in either the presence or absence of metabolic activation when tested against the negative control groups. Both positive controls, ethyl methane sulphonate (without S-9 fraction), and cyclophosphamide (with S-9 fraction) produced the expected increase in chromosomal damage in the cultured cells demonstrating the sensitivity of the test system and the efficacy of the S-9 mix used for metabolic activation.

Narlex 73-9514 did not appear to have any clastogenic activity against cultured human lymphocytes.

9.4 Overall Assessment of Toxicological Data

Narlex 73-9514 showed low oral and skin absorption. It is moderately irritating to the skin and the eye, and a likely respiratory irritant. The notified polymer is not a skin sensitiser.

Repeated oral administration in rats for 28 days showed:

- an increase in the kidney weight in male rats at a dose of 50000 ppm;
- changes in some haematology parameters (prothombin time) in both sexes (receiving dietary concentrations of 50,000 ppm Narlex 73-9514) and in some clinical biochemistry parameters (blood urea) in males. However, there was no conclusive evidence from macroscopic or microscopic pathological evidence to attribute these changes to toxicity of Narlex 73-9514.

Narlex 73-9514 was not genotoxic when tested in *Salmonella typhimurium* or cultured human lymphocytes.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Although not a requirement for polymers of NAMW > 1000 according to the Act, ecotoxicological data were provided. Tests were performed in accordance with OECD Guidelines 201, 202 and 203.

Test	Species	Result
Acute toxicity (96h)	Rainbow trout	LC ₅₀ > 100 mg L ⁻¹
Acute toxicity (48h)	Daphnia magna	EC ₅₀ > 100 mg L ⁻¹
Algal growth inhibition (96h)	Selenastrum capricornutum	EC ~ 39 mg L ⁻¹

The results indicate the notified polymer to be practically non-toxic to fish and aquatic invertebrates and slightly toxic to green algae.

The literature suggests that similar derivatives are moderately toxic to green algae, similar to the notified chemical in its ability to chelate nutrient elements (16). This provides an indirect mode of toxicity in removing the nutrient elements required for algal growth. However, this paper further indicates that the presence of additional nutrients significantly ameliorates the toxic effect. Nutrient levels in sewage treatment plants and to a lesser extent in effluent to receiving waters are likely to be sufficient to quell the indirect toxic effect of the notified substance to green algae.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Given its stated use as deflocculating dispersant and component in domestic laundry detergent, most of the notified polymer can be expected to ultimately be released to the aquatic compartment Australia wide. As a result the environmental hazard of the notified polymer require close scrutiny.

If the polymer remains suspended, a predicted environmental concentration (PEC) for the substance in sewage water throughout Australia can be estimated from the following assumptions: 100 tonne maximum annual use, an Australian population of 17 million and daily per capita water usage volume of 150 L. This provides a PEC of 100 ppb in sewage water which would be swiftly reduced to insignificant levels (likely to be in the ppt range) by precipitation and dilution in rivers, lakes and oceans which act as receiving waters to nearly all sewage treatment plants in Australia.

In addition, as alluded to in the environmental fate section, at the expected concentrations of notified substance, the studies provided in the dossier indicate that an average 94% of polycarboxylate will be adsorbed on sludge in the sewage treatment plant. This would result in effluent concentrations in the range of 1 to 10 ppb substance being released to receiving waters. At likely environmental concentrations of notified polymer, a safety factor of at least 3 orders of magnitude may be afforded to aquatic organisms.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Since, the notified polymer is non flammable, non explosive and not reactive under normal use conditions (other than contact with strong oxidising agents) it will not pose a flammable, explosive, or a reactive hazard during formulation of the polymer.

The notified polymer reacts with strong oxidising agents and should not be allowed to come in contact with these agents.

The polymer is imported in sealed 1000 litre tanks. The greatest risk during import, transport or storage is from a leak or spill.

The notified polymer is a moderate skin and eye irritant and a probable respiratory irritant with low oral and skin absorption. Under normal use conditions and correct handling procedures Narlex 73-9514 is not expected to pose a significant health and safety hazard to the workers. Some degree of exposure could be expected in operations involving closed system mixing which involve closing and opening of the mixing tank during addition and emptying of the polymer product.

The public is unlikely to be exposed to the chemical during importation and formulation. The

public may be exposed to the chemical at concentrations of less than approximately 1% in laundry detergents. The chemical in laundry detergents is unlikely to present a hazard to the public, due to its low concentration, low oral and dermal absorption.

13. RECOMMENDATIONS

To minimise public and worker exposure to Narlex 73-9514 the following guide-lines and precautions should be observed:

- Good work practices should be implemented to avoid spillages;
- Good housekeeping and maintenance should be practised. Spillages should be dealt with promptly;
- Where there is a possibility of exposure to the polymer, personal protective equipment which complies with Australian Standards should be worn such as splash proof goggles (AS 1336-1982 (17), AS 1337-1984 (18)), gloves (AS 2161-1978 (19)) and overalls (AS 3765.1-1990 (20));
- In operations where vapour and mist formation may occur local exhaust ventilation should be used or personal protective equipment which complies with Australian Standards should be worn such as respiratory protection devices (AS 1716-1991 (21), AS 1715-1992 (22)); and
- A copy of the Material Safety Data Sheet (MSDS) should be easily accessible to all employees.

14. MATERIAL SAFETY DATA SHEET

The Material Safety Data Sheet (MSDS) for Narlex 73-9514 (Attachment 1) was provided in Worksafe Australia format (23). This MSDS was provided by National Starch and Chemical Pty 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 National Starch and Chemical Pty Ltd.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989 (the Act)*, secondary notification of Narlex 73-9514 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**

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