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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

28-4961

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Director
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FULL PUBLIC REPORT**28-4961****1. APPLICANT**

National Starch and Chemical Pty Ltd of 7 Stanton Road, Seven Hills, NSW 2147 (ABN 37 000 351 806) has submitted a limited notification statement in support of their application for an assessment certificate for 28-4961.

2. IDENTITY OF THE CHEMICAL

Marketing Name: 28-4961

**Number-Average
Molecular Weight (NAMW):** 18860

**Weight-Average
Molecular Weight:** 191615

**Maximum Percentage of Low
Molecular Weight Species**

Molecular Weight < 500: 2.83 %

Molecular Weight < 1 000: 3.89 %

Method of Detection and Determination: gel permeation chromatography, infrared spectroscopy

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa: fine white free flowing powder with virtually no odour

Melting Point: decomposition is expected above 200°C

Specific Gravity: 1.16

Vapour Pressure: not determined

Water Solubility:

pH 4	310 mg/L at 25°C
pH 7	215 mg/L at 25°C
pH 9	270 mg/L at 25°C

Particle Size:	Range (µm)	Mass (%)
	< 5	0.0
	5 – 10	0.7
	10 – 20	0.0
	20 – 30	1.6
	30 – 39	25.1
	39 – 51	51.2
	51 – 59	12.9
	59 – 68	5.5
	68 – 89	2.7
	> 89	0.3
	< 7 – 10 µm respirable < 180 µm inspirable	
Autoignition Temperature:	not flammable	
Explosive Properties:	not expected to be explosive	
Reactivity/Stability:	the notified polymer contains no reactive functional groups; it is expected to be stable to depolymerisation	

3.1. Comments on Physico-Chemical Properties

Water solubility testing was conducted in buffered solutions by applying high shear mixing for one hour. The mix was then filtered to remove the undissolved material and mass concentration was determined. These results for water solubility are high compared to the results in the ecotoxicity testing and probably reflect differences in methodology.

No data were provided for hydrolysis, partition coefficient, adsorption/desorption and dissociation constant on the grounds of high polymer molecular weight and the known low susceptibility of amide ester and acid groups to hydrolyse. The low potential for exposure of the polymer to soil is given as a reason for not conducting the adsorption/desorption test. If it did reach the soil compartment, the notified substance would be expected to adsorb strongly. The polymer may dissociate as it contains carboxylic acid functional groups, but this is not expected to be of concern.

4. PURITY OF THE CHEMICAL

Degree of Purity: > 97 %

Toxic or Hazardous Impurities: none

Non-hazardous Impurities (> 1% by weight):

<i>Chemical name:</i>	water
<i>Weight percentage:</i>	≤ 3 %
<i>CAS No.:</i>	7732-18-5

Maximum of Residual Monomers:	Content all are present at below the relevant cutoffs for the notified polymer to be classified as a hazardous substance
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5. USE, VOLUME AND FORMULATION

The notified polymer will be used as a component in hair care products such as hair sprays and gels in both pressure pack and non-aerosol formulations. The concentrations of notified polymer in the currently identified finished products are 2.8 % (w/v) in aerosol hairsprays and 2.28 % (w/v) in non-aerosol hair sprays.

The polymer will not be produced in Australia. The notifier estimates that the import volume will eventually be 10 000 kg per year. The polymer will be imported in pure form and mixed with other ingredients at one formulation site to produce the finished hair care products.

6. OCCUPATIONAL EXPOSURE

Routes of Exposure

The notified polymer is a solid of low water solubility. Direct dermal contact may occur, however substantial dermal absorption is not expected due to the high molecular weight of the polymer. The solid is a fine, free-flowing powder, with all particles being below 100 µm diameter, which will readily form atmospheric dust. Although only 0.3 % of the particles are in the respirable size range, one main route of exposure may be through respiratory and eye contact with nuisance dust. Skin contact with solutions of the polymer may also occur.

As the hair care products are in both pressure pack and non-pressure pack forms, skin contamination and inhalation may occur.

Transport and Storage

The notified polymer will be imported in 90 kg kegs. The notifier states that the number of waterside, transport and warehousing personnel who will be involved in handling the polymer will be small. It is likely that workers will only have to handle the kegs for short and infrequent periods. It is unlikely that any substantial exposure will occur except in the case of an accident involving a breach of the packaging.

Transport and warehouse workers will also be involved in distributing the consumer products following formulation. The degree of handling is likely to be widespread, but exposure should not occur unless the packaging is breached.

Formulation

The polymer powder is poured from the import containers into the mixing vessels. The notifier states that the manufacturing process from this point is mechanised. The pouring of the powder is done either under extraction ventilation or by workers wearing a dust mask. Wetted spills of the notified polymer are stated to represent a slip hazard.

The filling process is automated, however, if overfilling and spillage occurs, skin contamination with the liquid products containing the notified polymer may occur.

The notifier indicates that the mixing vessels where the powdered material is dissolved are fitted with ventilation. Workers handling the polymer will wear overalls and safety boots, and, if it is in powder form, gloves and eye protection. Respiratory protection will be used in the case of exposure to the powder in the absence of exhaust ventilation.

Hairdressing Industry

There is also potential for both dermal and inhalational exposure to the notified polymer through use of products containing this polymer by commercial hairdressers. The frequency of exposure for hairdressing workers will be much greater than that for the general public.

A higher than normal incidence of respiratory complaints (lung disease and respiratory irritation and asthma) is found among workers in the hairdressing industry. The exact chemical cause cannot be determined in all cases, however the inhalation of aerosol droplets from hair sprays is believed to be a contributing factor (Dahl, 1990; Winder, 1993). The exposure pattern for the notified polymer by inhalation would be expected to be the same as for existing hair sprays. The same risk would not be associated with gels and mousses.

7. PUBLIC EXPOSURE

Little public exposure to the notified chemical is expected during the importation, transport and reformulation of the notified chemical. The polymer will be expected to be widespread in the environment as detailed below.

There is great potential for direct exposure of the public to the notified polymer, as it is available for retail sale to the general public and the hairdressing industry in hair care products. The types of products that the notified polymer is to be used in are hair sprays, and possibly styling gels and mousses. Exposure will therefore be predominantly dermal and inhalational.

8. ENVIRONMENTAL EXPOSURE

8.1. Release

Transport from wharf to storage and from storage to factory site involves a risk of spillage through accident. The Material Safety Data Sheet (MSDS) contains adequate detail on methods of collection and cleanup in such an event.

Residue in the kegs used to import the notified substance is estimated to be less than 10 g per keg (1.1 kg per annum) which would be disposed of to landfill by a licensed waste contractor. Equipment clean down water containing low concentrations of the polymer will be kept and used in the next batch.

The notified substance is intended solely for use in hairspray or gel products and, as such, would be expected to be released to the environment via consumer use through washing the residual polymer (assumed to be 100 % of that applied) out of the hair and into the sewerage system. It is envisaged that the substance will replace existing hair spray polymers which have similar properties resulting in no net environmental effect. Due to its structural properties, the notified substance is likely to be associated with the sludge/solids

compartment of sewage. This would be incinerated or spread onto agricultural land. If the polymer were to remain suspended in sewage water, a predicted environmental concentration (PEC) for the substance in sewage water throughout Australia can be estimated from the assumptions, 10 tonnes maximum annual import, an Australian population of 18 million and a daily per capita water usage volume of 150 L. This provides a PEC of 10 ppb in sewage water which would be swiftly reduced to insignificant levels by precipitation or dilution in rivers, lakes and oceans which act as receiving waters to nearly all sewage treatment plants in Australia.

The notifier estimates that 10 mL of solution containing up to 2.3% of the notified substance will remain as a residue in aerosol hairspray cans or gel bottles.

8.2. 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 on combustion.

Residues of the notified substance remaining in the cans and bottles disposed of with household garbage to landfill are unlikely to be mobile in the landfill given the polymer's limited solubility, stated chemical stability and expected adsorption to organic matter and clay.

9. EVALUATION OF TOXICOLOGICAL DATA

A limited notification statement for 28-4961 was submitted. For polymers with number average molecular weight > 1000, toxicological data are not required. The only toxicological study included in the submission was an acute oral toxicity test.

9.1 Acute Toxicity

Summary of the acute toxicity of 28-4961.

<i>Test</i>	<i>Species</i>	<i>Outcome</i>	<i>Reference</i>
acute oral toxicity	rat	LD ₅₀ > 5000 mg/kg	(Tufnell, 1990)

9.1.1 Oral Toxicity (Tufnell, 1990)

<i>Species/strain:</i>	rat/Sprague-Dawley
<i>Number/sex of animals:</i>	5/sex
<i>Observation period:</i>	15 days
<i>Method of administration/dose:</i>	gavage, test material suspended in arachis oil 500 mg/ml; dose 5000 mg/kg bodyweight
<i>Test method:</i>	limit test, OECD TG 401 (ref)

<i>Mortality:</i>	no deaths were recorded during the study
<i>Clinical observations:</i>	no clinical signs of systemic toxicity were recorded during the study
<i>Morphological findings:</i>	no macroscopic abnormalities were observed at necropsy
<i>LD₅₀:</i>	> 5000 mg/kg
<i>Result:</i>	the notified chemical was of very low acute oral toxicity in rats

9.2 Overall Assessment of Toxicological Data

Only one toxicological study was presented with the submission for the polymer, which is acceptable for a limited notification for a polymer of molecular weight greater than 1000. The polymer is of a class which is generally assessed under the “synthetic polymer of low concern” category, without any toxicological data being required. The notified polymer does not fit into this category as the water solubility is comparatively high, and the solid is in the form of a fine powder.

The acute oral toxicity of the notified polymer is very low (LD₅₀ > 5000 mg/kg), as would be expected for an acrylic polymer containing monomers with no reactive functional groups.

The levels of unreacted monomers in the notified polymer are low. This is important as acrylate monomers are known skin and respiratory sensitisers. In the absence of unreacted monomer, the polymer is not likely to be hazardous to health. The MSDS does mention the possibility of eye and respiratory irritation as a nuisance dust.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following ecotoxicity studies have been supplied by the notifier. The tests used OECD Test Guidelines or equivalent.

<i>Test</i>	<i>Species</i>	<i>Results</i>
96 h acute toxicity (Handley, 1990)	Golden orfe (<i>Leuciscus idus</i>)	LC ₅₀ > 1 mg/L NOEC ≥ 1 mg/L
18 h inhibition (Clubb, 1990)	Bacteria (<i>Pseudomonas putida</i>)	NOEC ≥ 8 mg/L

* NOEC - no observable effect concentration

Fish

A limit test, performed in accordance with the test guidelines, demonstrated that the notified substance had no toxic effects on the test fish at nominal concentrations of 1 mg/L. In the control and the test concentration of 1 mg/L, all fish survived until the end of the test and no signs of intoxication were observed. The report notes that a co-solvent was used and a solvent control was included.

Microorganisms

The inhibitory effect of the notified substance on aerobic waste water bacteria (activated sludge from a domestic waste water treatment plant) was investigated in a respiration test. The notified substance showed practically no toxic effects, with the respiration rate not inhibited when exposed to test concentrations at the limit of solubility (8 mg/L) over the exposure period of 18 hours.

Conclusions

The ecotoxicity data for the notified polymer indicate that at the limit of solubility the notified substance is non-toxic to fish and waste water bacteria.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The environmental hazard presented by the importation and use of the polymer is expected to be low. The products containing the notified substance will be used throughout Australia. The major environmental exposure to the substance will come from discharge of domestic wash waters to waste water treatment systems. The theoretical PEC shows that the exposure to fish and waste water treatment microorganisms is at levels unlikely to cause any significant effects. In addition, the chemical is non-toxic up to the limit of its solubility (8 mg/L). Adsorption to sludge, soil and sediment as well as swift dilution in receiving waters should reduce environmental concentrations to negligible levels. The chemical is not expected to persist in the environment, being removed through a combination of sorption to particulates and eventual chemical degradation.

The notified polymer is not likely to present a hazard to the environment when it is stored, transported and used in the proposed manner.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Occupational Health and Safety

Occupational exposure to the notified polymer will occur in the form of the pure powder and the 2 – 3 % solution in hair care products. For both forms of the polymer, the most probable routes of exposure are dermal, ocular and inhalational.

Dermal exposure should result in negligible health risk as the absorption of any polymer with NAMW of approximately 19000 across the skin and other biological membranes would not be expected. However, the polymer powder has a size distribution in the inspirable range, so it will act as a nuisance dust and may cause eye and respiratory irritation.

The risk of adverse health effects arising from inhalation exposure to the polymer in powder form is moderated by the enclosed nature of the formulation process and the provision of exhaust ventilation. The NOHSC exposure standard for nuisance (inspirable) dust of 10 mg/m³ should be observed. Safety glasses should be worn to prevent eye irritation. To prevent inspiration of the dry powder, respiratory protection should be worn when handling the powder if exhaust ventilation is not present.

Exposure to the polymer in the finished product by skin contact will not be expected to pose

any health risk due to the high molecular weight and low final concentration of the polymer. Occupational use of the finished products in the hairdressing industry may result in inhalational exposure to the notified polymer; inhalation of hair spray droplets is believed to be a contributing factor in producing a higher than normal incidence of respiratory complaints in these workers. Hair dressing industry workers would be expected to have much more frequent exposure than members of the general public using the same formulation.

Employers in the hairdressing industry should take precautions to minimise inhalation of spray products, e.g. by providing adequate ventilation for workers and the public. The relevant State or Territory industry guidelines or codes of practice should be observed.

Public Health

There will be widespread public contact with the notified polymer when it is incorporated in hair care products, but the high NAMW should preclude absorption across biological membranes. The exposure will also be intermittent and the concentration of polymer in the hair care products is low. Therefore there is expected to be negligible hazard posed to the general public due to the introduction of the new polymer. The notifier states that the notified polymer has been used in the US for over 15 years in a similar manner to the proposed use here, with no adverse health effects recorded from the use of the finished product by consumers.

Based on the toxicity profile and use pattern of the notified polymer, it is considered that the notified polymer will not pose a significant hazard to public health.

13. RECOMMENDATIONS

To minimise occupational exposure to 28-4961 the following guidelines and precautions should be observed:

- Employers should ensure that the NOHSC exposure standard for inspirable dust, of 10 mg/m^3 , is not exceeded in the workplace during formulation;
- Hairdressers should work in accordance with the relevant State or Territory guidelines or codes of practice;
- Dust masks should be used by formulation workers if local exhaust ventilation is not in place;
- Safety goggles, chemical resistant industrial clothing and footwear and impermeable gloves should be used while handling the product containing the notified polymer;
- Spillage of the notified chemical should be avoided. Spillages should be cleaned up promptly with absorbents which should then be put into containers for disposal;
- Good personal hygiene should be practised to minimise the potential for ingestion;

- A copy of the MSDS should be easily accessible to employees.

If products containing the notified chemical are hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999), workplace practices and control procedures consistent with State and territory hazardous substances regulations must be in operation.

Guidance in selection of goggles may be obtained from Australian Standard (AS) 1336 (Standards Australia, 1994) and Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand, 1992); for industrial clothing, guidance may be found in AS 2919 (Standards Australia, 1987) and AS 3765.2 (Standards Australia, 1990); for impermeable gloves or mittens, in AS 2161 (Standards Australia/ Standards New Zealand, 1998); for occupational footwear, in AS/NZS 2210 (Standards Australia/ Standards New Zealand, 1994a); for respirators, in AS/NZS 1715 (Standards Australia/ Standards New Zealand, 1994b) and AS/NZS 1716 (Standards Australia/ Standards New Zealand, 1994c).

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* (NOHSC, 1994).

This MSDS was provided by the applicant as part of the notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under subsection 64(2) of the Act, the director must be informed if any of the circumstances stipulated in this subsection arise, and secondary notification of the notified chemical may be required. No other specific conditions are prescribed.

16. REFERENCES

Clubb A (1990) Acute Toxicity of 28-4961 (Resyn 28-4961) Sample 1 HWM in Bacteria (*Pseudomonas putida*), Project No. N0052/M1, Safepharm Laboratories Ltd, Derby UK.

Dahl S (1990) Health Hazards Associated with Hairdressing, COIF/91/8/E, University Centre of South Jutland, Esbjerg, Denmark.

Handley J. W. and Sewell, I. G. (1990) The Acute Toxicity of 28-4961 (Resyn 28-4961) Sample 1 HWM to Golden Orfe (*Leuciscus idus*), Project No. AT313-002/AQU, Safepharm Laboratories Ltd, Derby UK.

National Occupational Health and Safety Commission (1994) National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)]. Australian Government Publishing Service, Canberra.

National Occupational Health and Safety Commission (1999). Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1999)]. Canberra, Australian Government Publishing Service.

Standards Australia (1994) Australian Standard 1336-1994, Eye protection in the Industrial Environment. Standards Association of Australia.

Standards Australia/Standards New Zealand (1992) Australian/New Zealand Standard 1337-1992, Eye Protectors for Industrial Applications. Standards Association of Australia/ Standards Association of New Zealand.

Standards Australia/Standards New Zealand (1994a) Australian/New Zealand Standard 2210-1994, Occupational Protective Footwear. Standards Association of Australia/Standards Association of New Zealand.

Standards Australia/Standards New Zealand (1994b) Australian/New Zealand Standard 1715-1994, Use and Maintenance of Respiratory Protective Devices. Standards Association of Australia/Standards Association of New Zealand.

Standards Australia/Standards New Zealand (1994c) Australian/New Zealand Standard 1716-1994, Respiratory Protective Devices. Standards Association of Australia/Standards Association of New Zealand.

Standards Australia/Standards New Zealand (1998) Australian/New Zealand Standard 2161.2-1998, Occupational protective gloves, Part 2: General requirements. Standards Association of Australia/Standards Association of New Zealand.

Tufnell PP (1990) 28-4961 (Resyn 28-4961) Sample 1 HWM : Acute Oral Toxicity (Limit Test) in the Rat, Project No. 313/10, Safepharm Laboratories Ltd, Derby UK.

Winder C (1993) Chemical Hazards and Health Effects of Hairdressing. Journal of Occupational Health and Safety: Australia and New Zealand, 9 (4): 359-371.