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April 2009

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

2-Propenoic acid, polymer with 1-ethenyl-2-pyrrolidinone and 3-(2-propen-1-yloxy)-2,2-bis[(2-propen-1-yloxy)methyl]-1-propanol/(Acrylic Acid/VP Crosspolymer)

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health and Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment, Water, Heritage and the Arts.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at 334-336 Illawarra Road, Marrickville NSW 2204.

This Full Public Report is also available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

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Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
ISP (Australasia) Pty Limited (ABN 27 000 011 923)
73-75 Derby Street
Silverwater NSW 2128

NOTIFICATION CATEGORY
Polymer of Low Concern

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Other Names, Molecular Weight, Polymer Constituents, Residual Monomers/Impurities and Import Volume.

NOTIFICATION IN OTHER COUNTRIES
Canada (2008)

2. IDENTITY OF CHEMICAL

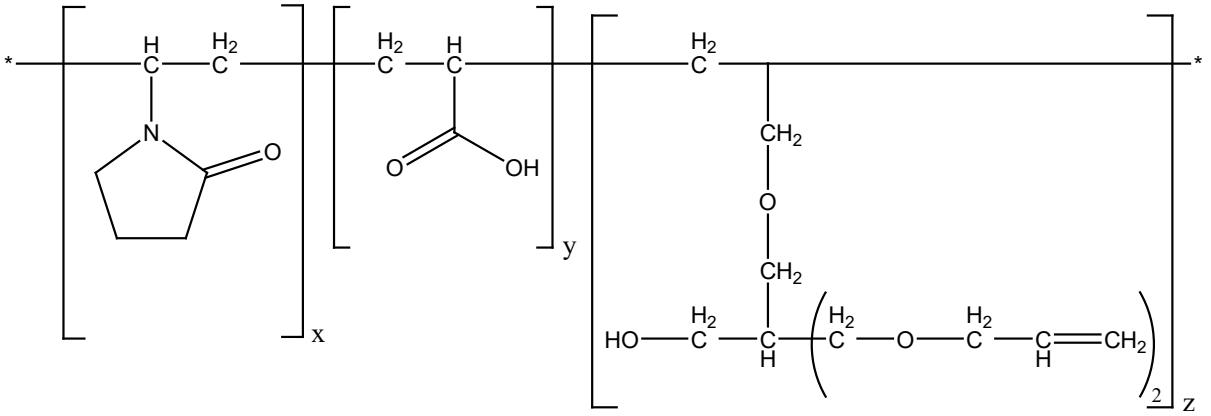
MARKETING NAME(S)
Acrylic Acid/VP Crosspolymer (INCI Name)
UltraThix P-100 (100% Acrylic Acid/VP Crosspolymer)

CHEMICAL NAME
2-Propenoic acid, polymer with 1-ethenyl-2-pyrrolidinone and 3-(2-propen-1-yloxy)-2,2-bis[(2-propen-1-yloxy)methyl]-1-propanol

CAS NUMBER
527685-31-0

OTHER NAME(S)
Acrylic acid-pentaerythritol triallyl ether-N-vinylpyrrolidone copolymer
HPVP/AA/PETE Terpolymer

STRUCTURAL FORMULA



Pendant allyl ether groups are expected to be further reacted to give a cross-linked polymer.

MOLECULAR WEIGHT (MW)
Number Average Molecular Weight (Mn) > 10,000 Da

The notified polymer contains only low concern functional groups as the pendant allyl ethers are expected to react to form a cross-linked polymer. If the polymer is not 100% cross-linked this will result in a small number of unreacted allyl ethers. However, given the high molecular weight and low levels of low molecular weight species, these are not considered to be a concern.

3. PLC CRITERIA JUSTIFICATION

Criterion	*Criterion met*
Molecular Weight Requirements	Yes
Functional Group Equivalent Weight (FGEW) Requirements	Yes
Low Charge Density	Yes
Approved Elements Only	Yes
Stable Under Normal Conditions of Use	Yes
Not Water Absorbing	Yes
Not a Hazard Substance or Dangerous Good	Yes

The notified polymer meets the PLC criteria.

4. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	White powder
Melting Point/Glass Transition Temp	> 400°C
Density	1334.5 kg/m^3 at 19.9°C
Water Solubility	Expected to be low based on structure (see discussion below)
Dissociation Constant	pKa = 6.81 (determined by titration)
Particle Size	Mass median aerodynamic diameter (MMAD) = 7.5389 µm % ≤ 10 µm = 68.55% % ≤ 100 µm = ~98%
Flammability	Not highly flammable
Auto-ignition temperature	> 400°C
Explosive properties	Not predicted to be explosive
Reactivity	Stable under normal environmental conditions
Degradation Products	None under normal environmental conditions

Discussion
The water solubility is expected to be in the low mg/L range as the notified polymer has high molecular weight and is cross linked, but the presence of a high proportion of carboxylic acid functionality facilitates dispersibility

in water, particularly at higher temperatures. Solubility could not be measured because of the lack of a sufficiently sensitive analytical method, but some information is available from aquatic toxicity testing. Water accommodated fractions (WAFs) prepared at nominal loadings up to 100 mg/L contained about 10% of the nominal loadings at ambient temperature, based on measurement of total organic carbon. The WAFs were cloudy white dispersions, clarifying over a few days when prepared at lower loadings. The dispersible material is presumably the lower molecular weight fraction with less cross-linking.

5. INTRODUCTION AND USE INFORMATION

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	1-3	1-3	1-3	1-3	1-3

Use
The notified polymer acts as a film former, viscosity-increasing agent and emulsion stabiliser in cosmetic and personal care products.

It is intended for use in clear styling gels, spray gels, cream gels, mousses, hair dyes, anti-frizz/shine/smoothing creams, surfactant-free oil dispersions, colour cosmetics, sun protection products, skin care products, lamellar gel formulations, oil/water emulsions, cream gels, suspended gels, clear skin gels and hydroalcoholic sprays.

The finished formulations containing the notified polymer at 0.25% to 2.5% are intended for consumers (approximately 98% of the introduction volume) and professional use by hairdressers, beauticians and cosmeticians. It is estimated that 60% of the imported notified polymer would be used in hair care formulations and 40% in skin care formulations.

Mode of Introduction and Disposal
The notified polymer will be imported into Sydney (neat) as a solid white powder in ~34 kg open head unlined fibre drums. It will be transported by truck to customers for reformulation without repackaging.

6. HUMAN HEALTH IMPLICATIONS

Hazard Characterisation

The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard. This is supported by toxicological endpoints observed in testing conducted on the notified polymer.

Endpoint	*Result*	*Effects Observed?*	*Test Guideline*
1. Rat, acute oral	LD50 > 2000 mg/kg bw	yes	OECD TG 425
2. Rat, acute dermal	LD50 > 2000 mg/kg bw	yes	OECD TG 402
4. Rabbit, skin irritation	non-irritating	no	OECD TG 404
5. Rabbit, eye irritation	slightly-irritating	yes	OECD TG 405
6. Skin sensitisation - non-adjuvant test (Buehler method).	no evidence of sensitisation.	no	OECD TG 406
8. Genotoxicity - bacterial reverse mutation	non mutagenic	no	OECD TG 471
9. Genotoxicity – *in vitro* chromosome aberration test	non genotoxic	no	OECD TG 473
10. Human, repeat insult patch test	no evidence of irritation/sensitisation	no	Non-standard protocol
11. Photoallergy	no evidence of sensitisation	no	Non-standard protocol
12. Phototoxicity	no evidence of phototoxicity	no	Non-standard protocol

All results were indicative of low hazard.

Acute oral toxicity

Five female rats were treated with 2000 mg/kg bodyweight in an acute oral toxicity study – up and down procedure according to OECD TG 425. No mortalities were observed. Diaorrhea, soiling and wetness of the anogenital area, chormorhinorrhea, emaciated appearance, loss of bodyweight and few faeces were observed in one animal. These were considered not to be treatment related as they were not observed in other animals treated with the same dose. Based on these observations, the LD50 was determined to be > 2000 mg/kg bw.

Acute dermal toxicity
2000 mg/kg bw of the notified polymer was applied to the intact skin of 5 male and 5 female New Zealand white rabbits in an acute dermal toxicity study according to OECD TG 402. Diaorrhea and few faeces in 1 female was observed on days 3 and 4 of the study. There were no other abnormal findings during the study. Based on these observations, the LD50 was determined to be > 2000 mg/kg bw following a single dermal exposure.

Eye irritation
The notified polymer was tested in an eye irritation test in rabbits according to OECD TG 405. Conjunctival redness, chemosis and discharge were noted in 3/3 animals 1 hour after instillation. These observations were absent in 2 animals 24 hours after instillation, with chemosis persisting in 1 animal until 24 hours, clearing by the 48-hour observation. Although the notified polymer is slightly irritating under the conditions of the test, it is not classified as an irritant under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

Skin sensitisation
A Buehler skin sensitisation test was conducted using the notified polymer at 100% for the induction and challenge phases in a method similar to OECD TG 406 with some protocol deviations. Under the conditions of the test, there was no evidence of skin sensitising potential of the notified polymer.

Human repeat insult patch test
The notified polymer at 10% in water was tested on 208 healthy human volunteers. It was applied to a marked site on the upper back of each test subject using a semi-occlusive patch 3 times a week for 3 weeks for the induction phase and at an adjacent test site approximately 2 weeks after the last induction application for the challenge test. The patches were removed approximately 24 hours after application and observations were recorded immediately prior to each proceeding application. No signs of irritation or sensitisation in any of the test subjects were observed at any time during the study. Therefore, the notified polymer was considered to be non-irritating and not a sensitiser under the conditions of the test.

Photoallergy
The notified polymer was tested at a concentration of 10% in water on the lower back of 25 healthy human volunteers. The minimal erythemal dose (MED: time or intensity of exposure to UV light irradiation required to cause mild erythema) was determined for each test subject. A semi-occlusive patch containing the notified polymer was applied to 2 sites on the lower back for approximately 24 hours for 1-2 times per week for 3-4 weeks for a total of 6 applications. One of the sites was irradiated with UV light at twice the predetermined MED for each subject, the other site was not irradiated. Each site was evaluated for signs of irritation 5 days per week after the initial application. Two weeks after the last application of the induction phase, 2 applications were applied to untreated sites on the lower back and a 3rd site marked but left untreated. One treated site was irradiated with approximately 10 joules (J) of UVA radiation. A 2nd site was treated but not irradiated and a 3rd site was not treated but not irradiated. These 3 sites were evaluated 24-, 48- and 72-hours following irradiation. No signs of irritation or sensitisation were observed at any of the observation points during the study. Therefore, the notified polymer was not considered irritating or sensitising following exposure to light under the conditions of the study.

Phototoxicity
The notified polymer was tested at a concentration of 10% in water on the lower back of 11 healthy human volunteers. The minimal erythemal dose (MED: time or intensity of exposure to UV light irradiation required to cause mild erythema) was determined for each test subject. An occlusive patch containing the notified polymer was applied to 2 sites on the lower back for approximately 24 hours. One of the treated sites was not irradiated, the other was irradiated with 0.5 MED of UVB radiation followed by 20 J of UVA radiation. A 3rd untreated site was irradiated in the same way. All test and control sites were evaluated 24- and 48-hours following irradiation. No signs of irritation were observed following treatment with the notified polymer with or without irradiation. Therefore the notified polymer was considered not to be phototoxic under the conditions of the study.

Occupational Health and Safety Risk Assessment

Reformulation into cosmetic and personal care products

The notified polymer was found to be of low toxicity via the dermal, ocular and oral routes in toxicity studies provided by the notifier. Therefore, it is expected to be generally a low health hazard to workers. However, the notified polymer may present a health risk to workers following inhalation exposure because it is a high molecular weight, water-insoluble polymer with a significant fraction (68%) of particulates in the respirable range (< 10 µm). The US EPA have expressed concern regarding high molecular weight (> 10,000 Da. or greater), insoluble polymer particles of respirable size, as they can potentially result in lung overloading leading to irreversible lung damage. The Australian recommended exposure standard for dust is 10 mg/m^3 [NOHSC 3008:(1995)], but a recommended exposure limit of 3 mg/m^3 has been suggested by the American Conference of Governmental Industrial Hygienists (ACGIH) for "respirable (insoluble) particulates (not otherwise regulated)".

The notifier expects that a dust extraction hood or vacuum tube will be in use during reformulation at the sites of weighing and addition to the mixing vessel to minimise inhalation exposure. Based on these measures, the EASE model predicts an atmospheric particulate concentration of 2-5 mg/m^3. Using low dust techniques and respiratory protection would further reduce inhalation exposure.

Once the notified polymer has been formulated into finished cosmetic or personal care products (≤ 2.5%) it is expected to be packaged using closed, automated filling and packing equipment and no further inhalation exposure is anticipated. Overall, provided appropriate control measures (eg. local exhaust ventilation, dust masks) are implemented to mitigate inhalation exposure to respirable particles, the risk to workers is not considered unacceptable.

Professional use of finished products

Beauticians and hairdressers may experience dermal and ocular exposure during application of various cosmetic and personal care products containing the notified polymer (≤ 2.5%). The level and route of exposure will vary depending on the product, method of application and work practices employed. Exposure is not expected to be significant given the low concentration of the notified polymer in finished products. The use of safety gloves would further reduce dermal exposure.

Overall, the OHS risk presented by the notified polymer is not expected to be unacceptable, based on the expected low exposure to workers and the low potential for toxicity as indicated by the toxicological tests supplied by the notifier.

Public Health Risk Assessment

The notified polymer will be present in cosmetic and personal care products at ≤ 2.5%. Dermal exposure to the notified polymer is expected to be extensive but will vary depending on individual use patterns. Although the public will be exposed to the notified polymer during use of cosmetic and personal care products, the risk to public health is not considered to be unacceptable given the low potential for toxicity as indicated by toxicological tests provided by the notifier.

In addition, the public may also accidentally ingest products containing the notified polymer (≤ 2.5%). There are no repeat dose oral toxicity data on the notified polymer. However, based on its expected low bioavailability, given its high molecular weight (> 10,000 Da.) and low water solubility, it is not expected to pose an unacceptable risk via the oral route.

7. ENVIRONMENTAL IMPLICATIONS

Hazard Characterisation

The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard. This is supported by environmental endpoints observed in testing conducted on the notified polymer.

Endpoint	*Result*	*Effects Observed?*	*Test Guideline*
Ready biodegradability	1.8% biodegradation	-	OECD TG 301B
Fish Toxicity (96 hours)	NOEL= 100 mg/L	no	OECD TG 203
Daphnia Toxicity (48 hours)	EL50 > 100 mg/L	yes	OECD TG 202
Algal Toxicity (72 hours)	E_rL50 > 100 mg/L	no	OECD TG 201

All results were indicative of low hazard. The toxicity tests were conducted using water accommodated fractions, which contained about 10% of their nominal loadings based on non-specific analysis (total organic carbon). The NOEL in daphnids was 13 mg/L (nominal test loading) with lethargy noted at higher loadings. Algal cell density, growth rate and biomass production were only reduced at the highest test loading. The NOEL was 40 mg/L (nominal test loading) for all three parameters, with no noticeable effects on cell morphology and no signs of aggregation or flocculation at any test loading.

Environmental Risk Assessment
The notified polymer is expected to be entirely released to sewer when it is washed from the skin and hair. Limited removal is expected during sewage treatment as the notified polymer is not readily biodegradable, but some sorption to sludge can be expected as the notified polymer is surface active. The predicted environmental concentration in rivers receiving effluent from sewage treatment works that allow complete passage of the maximum annual import quantity (3000 kg) can be estimated as 1.9 µg/L based on standard assumptions regarding water use by the Australian population. While the predicted no effect concentration cannot be calculated because of uncertainty regarding the actual exposure concentrations in the aquatic toxicity tests, the absence of observable effects at test loadings in the mg/L range allows the conclusion that the notified polymer is not expected to pose a risk to the environment when it is used as proposed.

8. CONCLUSIONS AND RECOMMENDATIONS

Human health risk assessment
Under the conditions of the occupational settings described, the notified polymer is not considered to pose an unacceptable risk to the health of workers.

When used in the proposed manner, the notified polymer is not considered to pose an unacceptable risk to public health.

Environmental risk assessment
Based on the reported use pattern, the notified polymer is not considered to pose a risk to the environment.

Recommendations

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical as introduced in powder form:
  - Local exhaust ventilation where manual handling of the notified chemical in powder form is carried out.

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical in resin form:
  - Avoid the formation of airborne dusts

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced in powder form:
  - Dust masks (adequate for respirable particulates) wherever airborne dusts are likely to be generated.

Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- In the interest of occupational health and safety, the following guidelines and precautions should be observed for use of the notified polymer as introduced in powder form
  - The level of atmospheric nuisance dust should be maintained as low as possible. The ASCC exposure standard for atmospheric dust is 10 mg/m^3 but a recommended exposure limit of 3 mg/m^3 has been suggested by the American Conference of Governmental Industrial Hygienists (ACGIH) for “respirable (insoluble) particulates (not otherwise regulated)”.

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

- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)], workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified polymer should be disposed of to landfill.

Storage

- The following precautions should be taken by ISP Australia Pty Ltd regarding storage of the notified polymer:
  - Ensure storage areas are well-ventilated

Emergency procedures

- Spills and/or accidental release of the notified polymer should be handled by containment, collection and subsequent safe disposal.

Regulatory Obligations

Secondary Notification
This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the polymer under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified polymer, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified polymer is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(1) of the Act; if
  - the notified polymer is introduced in a chemical form that does not meet the PLC criteria.

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the notified polymer has changed from a component of cosmetic or personal care products or is likely to change significantly;
  - the amount of notified polymer being introduced has increased, or is likely to increase, significantly;
  - the notified polymer has begun to be manufactured in Australia;
  - additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

Material Safety Data Sheet
The MSDS of the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.