File No PLC/521

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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

2-Butenediol acid (2Z)-, polymer with methoxyethene, calcium sodium salt

This Self 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 environmental risk assessment is conducted by the Department of the Environment and Heritage. The data supporting this assessment will be subject to audit by NICNAS.

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Director
Chemicals Notification and Assessment

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1. APPLICANT AND NOTIFICATION DETAILS

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

NOTIFICATION CATEGORY
Synthetic Polymer of Low Concern

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Polymer Constituents, use and volume

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
No

NOTIFICATION IN OTHER COUNTRIES
USA, Canada, EU, Korea, Philippines

2. IDENTITY OF CHEMICAL

CHEMICAL NAME
2-Butenediol acid (2Z)-, polymer with methoxyethene, calcium sodium salt

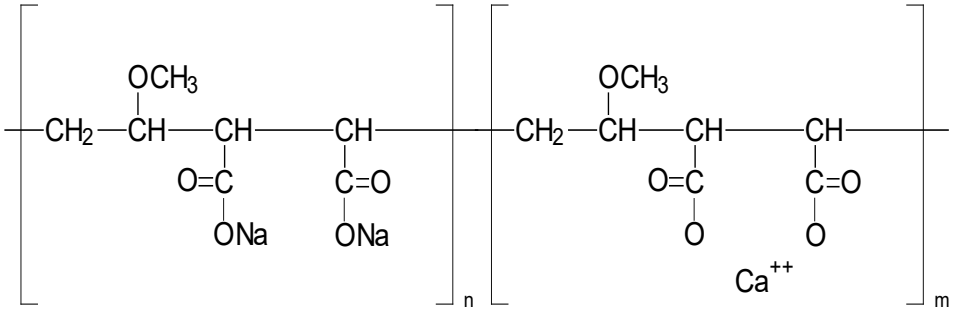
MARKETING NAME(S)
Gantrez MS-955

OTHER NAME(S)
Polymer in Gantrez MS-955

CAS NUMBER
62386-95-2

MOLECULAR FORMULA
$(C_4H_4O_4.C_3H_6O)_n.Ca_xNa_y$

STRUCTURAL FORMULA



MOLECULAR WEIGHT

Number Average Molecular Weight (Mn)	Approx. 600,000 - 700,000
Weight Average Molecular Weight (Mw)	790,000
Polydispersity Index (Mw/Mn)	1.1 – 1.3
% of Low MW Species < 1000	0%
% of Low MW Species < 500	0%

3. PLC CRITERIA JUSTIFICATION

Criterion	*Criterion met (yes/no/not applicable)*
Molecular Weight Requirements	Yes
Functional Group Equivalent Weight (FGEW) Requirements	Yes
Low Charge Density	Yes
Approved Elements Only	Yes
No Substantial Degradability	Yes
Not Water Absorbing	Yes
Low Concentrations of Residual Monomers	Yes
Not a Hazard Substance or Dangerous Good	Yes

The notified polymer meets the PLC criteria.

4. INTRODUCTION AND USE INFORMATION

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

Gantrez MS-955 is a white/off white powder. It will be imported into Australia as an ingredient of a finished product manufactured overseas. The finished product will be a denture adhesive, and will contain 30% of Gantrez MS-955.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	1-3	3-10	3-10	3-10	3-10

USE

Gantrez MS-955 is a film former and fixative for use in denture adhesives.

5. PROCESS AND RELEASE INFORMATION

5.1. Operation Description

Gantrez MS-955 will only be imported into Australia as a component of a finished, packaged product. It will not be manufactured, processed or reformulated in Australia.

6. EXPOSURE INFORMATION

6.1. Summary of Occupational Exposure

The notified polymer will not be manufactured or reformulated in Australia. It is to be imported as part of a finished, packed denture adhesive product.

Therefore workers in Australia will not be exposed to the notified polymer and no safety procedures in the handling of the chemical are required for Australia.

During transport and storage of the finished product, workers are unlikely to be exposed to the notified polymer contained in the denture adhesives, unless the packaging is accidentally breached.

There is negligible risk of occupational exposure to the notified polymer of workers in Australia.

6.2. Summary of Public Exposure

The notified polymer will not be available to the public. Members of the public will come into contact with the finished denture adhesive containing the notified polymer. However, exposure during use of the denture adhesive will be low because the notified polymer is present at low concentrations and once applied is contained in an inert matrix is not bioavailable.

6.3. Summary of Environmental Exposure

6.3.1. Environmental Release

Release to the environment in Australia will only occur through use of the finished denture adhesive product, or accidental spills or leaks of the packaging of the finished product.

Extensive use of the finished product is expected Australia-wide. Under normal use losses of Gantrez MS-955 will be from residues of the finished product in containers. These containers would go to landfill.

Assuming that 1-2% of the product remains in a 50g tube when discarded, the total waste from residues of the finished product in the containers would be 0.5g to 1g of which there would be 0.15mg to 0.3mg Gantrez MS-955. This equates to 1-2% of the total imported volume, which equates to less than 0.02 to 0.06 metric tonnes in the first year and thereafter 0.06 to 0.2 metric tonnes annually.

Additional disposal of 90% of the adhesive containing Gantrez MS-955 will be upon removal of the dentures and separation and disposal of the adhesive.

This means that approximately 92% of the total imported volume will be disposed to landfill. This equates to 0.92 to 2.8 metric tonnes in the first year and thereafter 2.8 to 9.2 metric tonnes annually.

6.3.2. Environmental Fate

Gantrez MS-955 is slowly water-soluble and is expected to be hydrolytically stable and not readily biodegradable. The notified polymer is water soluble and not expected to associate with sediments and organic phases of soils and sediments. It is not readily biodegradable but will slowly degrade to simple carbon compounds through biological and abiotic processes

7. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa	White to off/white powder
Melting Point/Glass Transition Temp	Not determined
Density	600-750 kg/m^3 at 20°C
Water Solubility	>10g/L at 20°C after 15 minutes
Particle Size	10-200 microns. MMAD is 43.9 microns – 7.8% by weight below 10 microns and 98.0% by weight below 150 microns in diameter.
Reactivity	Stable under normal environmental conditions
Degradation Products	None known

8. HUMAN HEALTH IMPLICATIONS

8.1. Toxicology

The following toxicological end-points were submitted:

Endpoint	*Result*	*Classified?*	*Effects Observed?*
Rat, acute oral	LD50 > 5000 mg/kg bw	no	no
Rabbit, skin irritation	Non-irritating	no	no
Rabbit, eye irritation	Mildly irritating	no	yes
Rat & dog, oral repeat dose toxicity (90 days)	No toxic effects noted	no	no

All results were indicative of low hazard.

8.2. Human Health Hazard Assessment

The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard.

9. ENVIRONMENTAL HAZARDS

9.1. Ecotoxicology

No toxicological data were submitted.

:

9.2. Environmental Hazard Assessment

Gantrez MS-955 meets the PLC criteria and can therefore be considered to be of low hazard.

Anionic polyaliphatic polymers such as the notified polymer are known to be moderately toxic to algae. The mode of toxic action is overchelation of nutrient elements needed by algae for growth. The highest toxicity is for polyacrylates when there is a carboxylic acid on every other (or alternating) carbon(s) in the polymer backbone. This is not the case with the notified polymer, which should have a lower toxicity. In addition, when enough calcium is added to a polymer to satisfy its anionic charges, algal toxicity is observed to be mitigated.

10. RISK ASSESSMENT

10.1. Environment

It is expected that practically all waste generated from end-users of the finished denture adhesive product containing Gantrez MS-955 will be disposed of in landfills as inert solid waste. Gantrez MS-955 is not expected to be readily biodegradable.

The notified polymer is water soluble and not expected to associate with sediments and organic phases of soils and sediments. It is not readily biodegradable, however, is expected to degrade eventually to simple carbon compounds through biotic and abiotic processes. A very limited amount of the notifed polymer will be released to the aquatic compartment and therefore a low risk to the aquatic organisms is predicted based on the expected low aquatic toxicity.

Bioaccumulation of the notified polymer is not expected due to the very high water solubility and molecular weight.

10.2. Occupational Health and Safety

Due to the minimal worker exposure to the notified polymer as part of a finished product, in addition to the low toxicity potential and non-hazardous nature of ther notified polymer there is expected to be no OHS risk presented by this polymer.

10.3. Public Health

The notified polymer will not be sold to the public, only being available as a component of a denture adhesive, which once applied and cured it will be contained in an inert matrix and hence not bioavailable. This family of polymers have been in use worldwide for over 20 years.

Therefore, negligible risk to public health is anticipitated from the introduction of the notified polymer.

11. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

11.1. Environmental Risk Assessment

The polymer is not considered to pose a risk to the environment based on its reported use pattern.

11.2. Human Health Risk Assessment

11.2.1. Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

11.2.2. Public health

There is No Significant Concern to public health when used in the proposed manner.

12. MATERIAL SAFETY DATA SHEET

12.1. Material Safety Data Sheet

The notifier has provided MSDS as part of the notification statement. The accuracy of the information on the MSDS remains the responsibility of the applicant.

13. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- In the interest of occupational health and safety, the following guidelines and precautions should be observed for use of the notified polymer as introduced as Polymer in Gantrez MS-955:
  - Avoid dust formation.

- 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 NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Environment

- No concentration limits, control measures or monitoring are required in Australia as the notified polymer is a component of a fully finished, imported product.

Disposal

- No specific disposal requirements are required for the disposal of the notified polymer in Australia as it is a component of a fully finished, imported product.

Storage

- No specific storage requirements are required for the storage of the notified polymer in Australia as it is a component of a fully finished, imported product.

Emergency procedures

- No specific handling requirements for spills/release of the notified polymer in Australia are required as it is a component of a fully finished, imported product.

Transport and Packaging

No specific transport and packaging requirements for the notified polymer in Australia is required as it is a component of a fully finished, imported product.

13.1. Secondary Notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under subsection 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 subsection 64(2) of the Act:
- if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.