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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME
(NICNAS)**

FULL PUBLIC REPORT

**2,5-Furandione, polymer with 2-methyl-1-propene, reaction products with
ethanolamine and ethylamine**

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**Director
Chemicals Notification and Assessment**

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FULL PUBLIC REPORT**2,5-Furandione, polymer with 2-methyl-1-propene, reaction products with ethanolamine and ethylamine****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

ISP (Australasia) Pty Ltd
73-75 Derby Street
Silverwater NSW 2181

NOTIFICATION CATEGORY

Synthetic Polymer of Low Concern

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

No details are claimed exempt from publication.

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)

None known

NOTIFICATION IN OTHER COUNTRIES

Being used in hair care products in USA, and EINECS exempt in EU.

2. IDENTITY OF CHEMICAL

CHEMICAL NAME

2,5-Furandione, polymer with 2-methyl-1-propene, reaction products with ethanolamine and ethylamine.

OTHER NAME(S)

Isobutylene/Ethylmaleimide/Hydroxyethylmaleimide Copolymer (INCI name)

MARKETING NAME(S)

Component of Aquaflex FX-64.

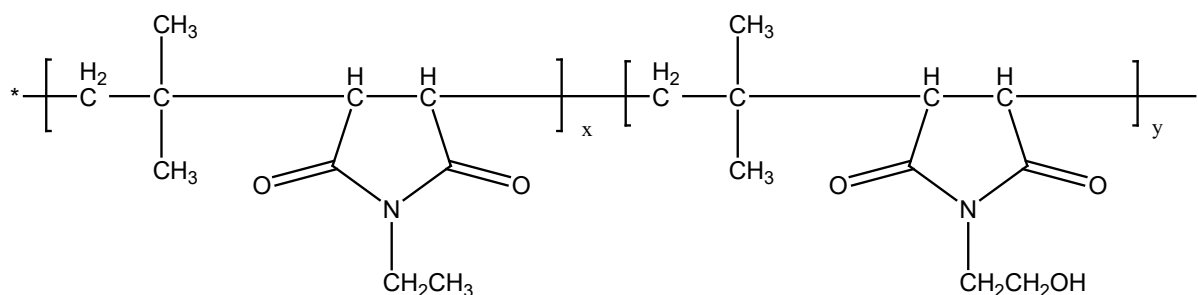
CAS NUMBER

283148-39-0

MOLECULAR FORMULA

Unspecified

STRUCTURAL FORMULA



The polymer is a 1:1 alternating copolymer of isobutylene and maleic anhydride that is imidised with a 65:35 mole percentage ratio of ethanolamine to ethylamine to form poly (isobutylene-co-maleimide). Other hydrolysis products formed as well include the di-acid, half-ester and maleamic acid (half-amide), as well as the amine salt.

MOLECULAR WEIGHT

Number Average Molecular Weight (NAMW)	50,000 to 60,000
Weight Average Molecular Weight (WAMW)	120,000
Polydispersity Index (WAMW/NAMW)	2.0-2.4
% of Low MW Species < 1000	1%
% of Low MW Species < 500	negligible

3. COMPOSITION

POLYMER CONSTITUENTS

<i>Chemical Name</i>	<i>CAS No.</i>	<i>Weight % starting</i>	<i>Weight % residual</i>
Maleic anhydride	108-31-6	47	< 0.1%
Isobutylene	115-11-7	27	< 0.1%
Ethanolamine	141-43-5	18	< 0.1%
Ethylamine	75-04-7	8	< 0.1%

PLC CRITERIA JUSTIFICATION

<i>Functional Group</i>	<i>Category</i>	<i>Equivalent Weight (FGEW)</i>
Imide, carboxylic acid.	Low	N/A as NAMW > 10,000

<i>Criterion</i>	<i>Criterion met</i>
Meets Molecular Weight Requirements	Yes
Meets Functional Group Equivalent Weight (FGEW) Requirements	Yes
Low Charge Density	Yes
Approved Elements Only	Yes
No Substantial Degradability	Yes
Not a Water Absorbing polymer	Yes
Low Concentrations of Residual Monomers	Yes
Not a Hazardous Substance or Dangerous Good	Yes

The notified polymer meets the PLC criteria.

4. INTRODUCTION AND USE INFORMATION

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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	1.2	1.2	1.2	1.2	1.2

USE

Component of hair gels/waxes for consumer use.

5. PROCESS AND RELEASE INFORMATION

5.1. Operation Description

The notified polymer will be imported in 180 kg metal drums as approximately 40% of Aquaflex FX-64, which also contains water and ethanol. The drums of Aquaflex FX-64 will be transported directly to customers for formulation of hair gel or wax.

At the cosmetic manufacturing site the Aquaflex FX-64 will be dispensed through a tap into a 1000 L stainless steel mixing vessel equipped with a mechanical stirrer. Other ingredients will be added to make hair styling formulations, and the mixture stirred until well blended. Manufacturing equipment is cleaned with hot water and rinsed after every batch. The finished product is tested for quality assurance before being filled into 200 g containers using automated equipment. The final packaged product containing up to 4.2% of the notified polymer will be sold to consumers through retail outlets.

6. EXPOSURE INFORMATION

6.1. Summary of Environmental Exposure

During the formulation of hair treatment the estimated annual losses of notified polymer are:

Spills	2.1 kg
Equipment cleaning	0.84 kg
<u>Import container residuals</u>	<u>12.0 kg</u>
Total Annual Loss	15.94kg

The majority of the notified polymer will be incorporated into the hair styling product and will be released to the environment during hair washing. Approximately 1% of the end product will remain in the empty end-users container, this equates to less than 12 kg of notified polymer annually.

Fate

Any spilt material and the import container linings with any residual material will go to landfill. The effluent, containing any notified polymer, generated during equipment cleaning will go to onsite holding/treatment tanks and will then be released to sewer.

The hair styling product will be washed down the drain thus releasing the majority of the notified polymer to sewer. The end-user container, containing any residual material will be disposed into general rubbish, which goes to landfill.

The notified polymer is expected to be moderately soluble in water and as such will be mobile in both the aquatic and terrestrial compartment. Residual chemical disposed of into landfill within empty containers or in spill clean-up material, may leach out but at very low concentrations and in a very diffuse manner.

Based on annual imports of 1200 kg per annum of the notified polymer, and assuming the majority of this is eventually released to sewer and not removed during sewage treatment processes, the following Predicted Environmental Concentration can be estimated

Amount of notified polymer entering sewer annually	1200 kg
Population of Australia	20 million
Amount of water used per person per day	200 L
Number of days in a year	365
PEC _{sewer}	$\frac{1200\ 000\ 000}{20\ 000\ 000 \times 200 \times 365}$ mg/L

= 0.0008 mg/L

= 0.8 µg/L

When released to receiving waters (ocean) the concentration is generally understood to be reduced by a further factor of at least 10. However, as the hair styling products containing the notified polymer will be used nationwide, no further dilution on released to receiving waters will be assumed as a worst-case estimate.

6.2. Summary of Occupational Exposure

During transport and storage, workers are unlikely to be exposed to the notified polymer except when packaging of Aquaflex FX-64 or the final consumer product containing the polymer is accidentally breached.

Dermal and ocular exposure can occur during gel/wax formulation, QC and filling processes. However, exposure to significant amounts of the notified polymer is limited because of the engineering controls and personal protective equipment worn by workers.

The finished gel/wax product containing the notified polymer will not be used in an occupational setting.

6.3. Summary of Public Exposure

Hair cosmetic gel/wax products containing up to 4.2% of the notified polymer will be sold to the general public. It is estimated that approximately 3 g of product, containing approximately 0.1 g of the notified polymer, will be used in each application and that the products may be used daily. The products will be applied to dampened hair by hand, and worked through the hair with the fingers, in order to impart the desired style. Members of the public will therefore make dermal contact and possibly accidental ocular contact with products containing the notified polymer. However, exposure will be low because the notified polymer has a high molecular weight and would not be expected to pass through the skin, and the estimated quantity of polymer in contact with the skin at each application (0.1 g) is low.

7. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa	Yellow viscous solution (solution containing 40% of notified polymer)
Melting Point/Glass Transition Temp	Not applicable as supplied in solution
Density	900 kg/m ³ (solution containing 40% of notified polymer, temperature not supplied)
Water Solubility	1 g in 2 g water (500 g/L)
Dissociation Constant	Five (5) grams of the notified polymer were dissolved in 10 grams of water. The resultant solution was hazy but no undissolved polymer material was present. The notified polymer does not contain functional groups that would dissociate under normal pH conditions.
Reactivity	Stable under normal environmental conditions.
Degradation Products	None known.

8. HUMAN HEALTH IMPLICATIONS

8.1. Toxicology

The following toxicological studies were submitted, carried out on Aquaflex FX-64, rather than the notified polymer:

<i>Endpoint</i>	<i>Result</i>	<i>Classified?</i>	<i>Significant effects Observed?</i>
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1. Rat, acute oral	LD50 > 5000 mg/kg bw	no	no
2. Rat, acute dermal	LD50 > 2000 mg/kg bw	no	no
3. Rat, acute inhalation, as liquid aerosol	LC50 > 1.95 mg/L/4 hour	Not determined	no
4. Rabbit, skin irritation	non-irritating	no	no
5. Rabbit, eye irritation	slight to moderate irritation	no	yes
6. Rat, inhalation repeat dose toxicity - 90 days.	NOAEL 1.19 mg/m ³	Not determined	no
7. Genotoxicity - bacterial reverse mutation	non mutagenic	no	no
8. Human, repeat insult patch test	non irritating or sensitising	no	no

Results of eye irritation testing of Aquaflex FX-64

<i>Lesion</i>	<i>Mean Score*</i>	<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
<i>Conjunctiva: redness</i>	1.55	2	72 h	0
<i>Conjunctiva: chemosis</i>	1.33	2	72 h	0
<i>Conjunctiva: discharge</i>	1.33	2	72 h	0
<i>Corneal opacity</i>	1.1	2	72 h	0
<i>Iridial inflammation</i>	0.16	1	48 h	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for ALL animals.

8.1.1 Discussion of Observed Effects

Eye irritation scores for corneal opacity, iritis and conjunctival irritation were not sufficient to lead to classification, and no effects persisted to 7 days.

The 4-hour acute inhalation test was carried out at a dose of 1.95 mg/L, with no mortality or substantial health effects. This dose level is sufficient to exclude classification as very toxic or toxic by inhalation. However testing at 5 mg/L would be required to determine whether the notified polymer is classified as harmful by inhalation.

A repeat dose inhalation study in rats (90 days) did not test the notified polymer to the level need to determine classification (250 mg/m³ for 6 h/day). The highest dose tested was 20 mg/m³ for 2 h/day. The NOAEL of 1.19 mg/m³ was based on microscopic changes consistent with irritation. These effects were seen in the lung and mediastinal lymph nodes at all dose levels tested, and based on the data available are physiologically significant at doses of 5 mg/m³ and 20 mg/m³.

8.2. Human Health Hazard Assessment

The notified polymer meets the PLC criteria. Toxicological testing carried out on a hydro-alcoholic solution of the notified polymer indicated eye irritation, and irritation effects from repeated inhalation. Acute and repeat dose inhalation studies did not use a high enough dose to determine full classification for these endpoints. The notifier classified Aquaflex FX-64 as an eye irritant with risk phrase R36.

9. ENVIRONMENTAL HAZARDS

9.1. Ecotoxicology

No toxicological data were submitted.

9.2. Environmental Hazard Assessment

Since no ecotoxicological data were provided a hazard quotient (HQ = PEC/PNEC) cannot be calculated. However, based on the proposed use pattern of the notified polymer, the amount being imported and the nationwide use of the hair products and subsequent diffuse release, it is not expected to pose an unacceptable risk to the health of aquatic life.

10. RISK ASSESSMENT

10.1. Environment

It is unlikely that the notified polymer will present a hazard to the environment when handled

and used as indicated. Hence, environmental risk from the proposed use is expected to be low.

10.2. Occupational health and safety

The OHS risk presented by the notified polymer is expected to be low for the proposed method of use. As there is a risk of eye irritation to workers during formulation, eye protection is required during this process.

10.3. Public health

The risk to the public is expected to be low for the proposed method of use in a hair gel/wax, based on low bioavailability of the notified polymer which has MW >1000, and low quantity (0.1 g) of the material used in each application. There is a potential for eye irritation to occur during application of the product, with the extent of irritation depending on the characteristics of the other ingredients of the product.

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 Low Concern to public health when used as an ingredient of a hair gel/wax.

12. MATERIAL SAFETY DATA SHEET

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

REGULATORY CONTROLS

Labelling

- Packages containing Aquaflex FX-64 should be labelled “Avoid contact with eyes”.
- Marketers of consumer products containing the notified polymer should make an estimate of the eye irritation potential of those products and, if applicable, include a warning of possible eye irritation on the labels.

CONTROL MEASURES

Occupational Health and Safety

- Engineering controls, work practices and personal protective equipment should be selected on the basis of all ingredients in the formulation. They should take account of the flammability of Aquaflex FX-64 and its potential to cause some eye irritation:
 - Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.
- A copy of the MSDS for Aquaflex FX-64 should be easily accessible to employees.
- A revised copy of the MSDS for Aquaflex FX-64 must be submitted to NICNAS by **31**

August 2004. The MSDS should be revised according to the National Occupational Health and Safety Commission (NOHSC) Code of Practice for the Preparation of Material Safety Data Sheets 2nd Edition 2003.

- 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

- The following control measures should be implemented by hair product manufacturers to minimise environmental exposure during end product formulation of the notified polymer:
 - Process areas to be bunded;
 - Storm drains should not be within processor storage areas, to avoid any of the notified polymer entering the storm drains.

Disposal

- The notified polymer should be disposed of by landfill or incineration.

Emergency procedures

- Spills/release of the notified polymer should be handled by containment with absorbent material, collection and storage in sealable labelled container.

Transport, Packaging and Storage

- The notified polymer as supplied in hydro-alcoholic solution (Aquaflex FX-64) is a Dangerous Good (Class 3, Flammable Liquid) under the ADG code. All relevant requirements for transport, packaging, labelling and storage should be complied with.

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.
 - the notified polymer is used at a concentration of > 5% in a consumer product.
 - the notified polymer is used in a product designed to be applied by spraying, or where significant inhalation exposure could occur.

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.