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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

Polymer in Aculyn 46

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FULL PUBLIC REPORT**Polymer in Aculyn 46****1. APPLICANT**

ISP (Australasia) Pty Ltd of 73-75 Derby Street, SILVERWATER, NSW 2128 (ABN 27 000 011 923) has submitted a Polymer of Low Concern notification statement in support of their application for an assessment certificate for Polymer in Aculyn 46.

2. IDENTITY OF THE CHEMICAL

The chemical name, CAS number, molecular and structural formulae, molecular weight, spectral data and details of the polymer composition have been exempted from publication in the Full Public Report.

Marketing name: Polymer in Aculyn 46

3. POLYMER COMPOSITION AND PURITY

Details of the polymer composition have been exempted from publication in the Full Public Report.

4. PLC JUSTIFICATION

The notified polymer meets the PLC criteria.

5. PHYSICAL AND CHEMICAL PROPERTIES

The notified polymer will be imported as a 15% w/w aqueous solution. The physical and chemical properties given below are for the polymer solution unless otherwise stated.

Property	Result	Comments
Appearance	clear to milky white liquid	None
Melting Point	Not stated	None
Specific Gravity	1.04	
Water solubility	> 1 mg/L	see below

	(estimated)	
Particle size	not applicable	
Flammability	not flammable	
Autoignition temperature	not applicable	
Explosive properties	not explosive	
Stability/reactivity	not reactive	See below
Dissociation constant	not applicable	notified polymer does not contain any group which can undergo dissociation

5.1 Comments on physical and chemical properties

The notified polymer contains only reactive functional groups of low concern.

Due to the high solubility of one monomer the high molecular weight polymer, has an appreciable solubility in water of > 10 %. It is noted that one of the terminal groups for this polymer is a long chain hydrocarbon, which may reduce the solubility of the polymer in water.

Hydrolysis as a function of pH was not determined. The polymer contains a small proportion of functional groups that may undergo hydrolysis under extreme acid/base conditions. However, in the environmental pH range of between 4 and 9, the polymer is reported as stable.

Under normal conditions polymer will not undergo degradation though it may begin to thermally decompose under the influence of heat at 177°C. Thermal decomposition may yield acrylic monomers and in the event of fire combustion products including oxides of carbon and hydrogen may be produced.

6. USE, VOLUME AND FORMULATION

Use:

The notified polymer in Aculyn 46 is a cosmetic ingredient, which will be imported as 15% aqueous solution and used as a thickener in human hair colorants. Hair colorants will be produced in Australia.

Manufacture/Import volume:

The notifier estimates that the import volume of Aculyn 46 will be up to 4 tonnes per annum for the first five years, which is equivalent to 0.6 tonnes per annum of notified polymer.

Formulation details:

The notified polymer will be imported in aqueous solution in 205 L plastic drums. The imported product will be reformulated with other ingredients at one site in Australia to produce a common base containing 1.5% notified polymer. This common base is used to make a hair colorant, containing up to 3% Aculyn 46 (0.45% of notified polymer). Retail packages consist of 60 mL plastic moulded bottles.

7. OCCUPATIONAL EXPOSURE

The typical number and category of workers with a potential to be exposed to the notified polymer during its different stages is shown in the Table below.

Exposure route	Exposure details	Controls indicated by notifier
<i>Transport and storage</i>		
<i>waterside, transport and warehouse (10 workers, 4-6 hours/day, 100 days/year)</i>		
dermal, 15% and 0.45% solution	exposure is likely only in the event of an accident	Stored in banded area
<i>Formulation</i>		
<i>weighing and compounding (10 workers, 1-4 hours/day, 60 days/year)</i>		
dermal, 15% and 0.45% solution (common base)	manual weighing and transfer to the 2000L mixing vessel, and transfer to common base storage containers	local exhaust ventilation (mixing vessel); safety glasses, impervious gloves, coveralls and safety boots
	transfer of common base from storage containers to 180L stainless steel mixers; transfer to holding tank by hard piping; connecting, disconnecting transfer hoses and cleaning equipment	automated process, local exhaust ventilation (mixing vessel); transfer from mixing vessel to storage container then holding tank is automated; safety glasses, impervious gloves, coveralls and safety boots
<i>filling and packaging (20 workers, 4 hours/day, 60 days/year)</i>		
dermal, 0.45% solution	accidental spills during filling, capping and labelling	local exhaust ventilation
<i>Quality assurance</i>		
<i>sampling and laboratory testing (5 workers, 4 hours/day, 10-60 days/year)</i>		
dermal, 15% and 0.45% solution	sampling and testing Aculyne 46 and formulated product	impervious (neoprene) gloves, laboratory coats or coveralls and safety glasses
<i>Hair salons</i>		
<i>hairdressing (> 1 000 workers, 1-2 hours/day, 200 days/year)</i>		
dermal, 0.45% solution	Mixing at 1:1 with peroxide solution. Application of hair colorant	Impervious gloves are reportedly recommended in retail product instructions.

8. PUBLIC EXPOSURE

The final product will contain 0.45% of the notified polymer and will be sold to hairdressers and the public. It is expected during that during transport and storage, exposure of the general public to Aculyn 46 will only occur in the event of an accidental spillage.

The colorant will be diluted 1:1 with peroxide solution prior to application, giving a final concentration 0.225% notified polymer applied to hair. Following each application, the hair colorant will be washed off with water also removing the notified polymer as it reportedly does not adsorb to the hair. Application time for hair colorants is 0.5-1 hour per day, applied on 6-12 days per year. End use exposure is likely to be dermal, with the possibility of ocular and oral exposure.

A hair colorant product containing 0.225% of the notified polymer would result in a systemic exposure of 0.009 mg/kg/day, based of the following assumptions adopted from the European Commission (1996).

volume used per application	50 mL
body weight	60 kg
weight fraction of notified chemical	0.225 %
density of the product	1 g/cm ³ at 25°C
surface area of exposed skin	1180 cm ²
frequency of use	once every 4 weeks
fraction of product remaining on skin and absorbed	10%

This is a conservative exposure estimation, as any dermal absorption would be unlikely given the extremely high molecular weight of the notified polymer.

9. ENVIRONMENTAL EXPOSURE

9.1. Release

The notified polymer will not be manufactured in Australia. Release to the environment will result from formulation, with the majority of release occurring from use of the hair colorant.

The notifier estimates that accidental spillage may result in up to 2% (equivalent to 12 kg/year) of the total import volume of Aculyn 46 released to the environment. Spillages will be contained through bunding, collected onto absorbent material and sent off-site by licensed waste disposal contractors to landfill.

The notifier estimates that approximately 6 kg/year of the notified polymer will remain in import drums as residue and will be sent in the drums to landfill, by licensed waste disposal contractors.

The notifier estimates that washing the 2000 kg and 180 kg batch containers will generate waste polymer of approximately 1.35 kg/year and 0.23 kg/year respectively. Up to 3 kg/year of notified polymer may be lost through accidental spillage during the washing processes. In total, up to 4.6 kg/year of waste polymer may be generated from cleaning formulation equipment, which will be sent to an on-site treatment plant then discharged to the sewer.

Formulation of the hair colorant results in minimal release to the environment compared to release from use of the hair colorant. After application to hair, all of the notified polymer will be washed off and enter the sewer. It is assumed the colorant will be sold nationally resulting in widespread release to the environment.

After use, the product bottles containing residual hair colorant will presumably end up in domestic landfill. If it is assumed 1% of the hair colorant remains in the bottle, approximately 6 kg/year of the notified polymer will be disposed of to landfill at various sites throughout Australia.

9.2. Fate

Waste polymer generated from accidental spillage (< 12 kg/year), drum residues (approximately 6 kg/year) and final product bottle residues (approximately 6 kg/year), will end up in landfill. In landfill, the polymer could be expected to slowly partition to the aquatic compartment due to the predicted high solubility in water

Waste polymer generated from cleaning formulation equipment (up to 4.6 kg/year) will most likely pass through the on-site waste treatment plant and enter the sewer system because of the predicted high solubility in water. Although biodegradation data were not provided, waste polymer generated from formulation and use would not be expected to significantly biodegrade in sewerage treatment plants. Minimal partition to sludge would be expected and most would pass into receiving waters.

In the aquatic compartment, the polymer could be expected to degrade slowly through biotic processes. The polymer is not expected to cross biological membranes due to its high molecular weight and should not bioaccumulate (Connell, 1990).

10. EVALUATION OF HEALTH EFFECTS DATA

No toxicological data were submitted. The Material Safety Data Sheet (MSDS) for Aculyn 46 indicates that considering the toxicity of similar chemicals the polymer solution may cause slight skin and eye irritation and inhalation of vapour or mist may cause irritation of the respiratory tract.

11. EVALUATION OF ENVIRONMENTAL EFFECTS DATA

No ecotoxicological data were submitted.

12. ENVIRONMENTAL RISK ASSESSMENT

Assuming national usage and all polymer being released to the aquatic compartment, the Predicted Environmental Concentration (PEC) of the notified polymer in receiving waters is estimated at approximately 0.06 µg/L (ocean) or 0.29 µg/L (inland).

PEC calculation

Import rate	600 kg/annum
Release rate	600 kg/annum
Population (national)	19 million
Volume of sewage per annum	$19 \times 10^6 \times 365 \times 150 = 1040 \times 10^9$ L/year
Mean concentration in sewage	0.58 µg/L

(n.b. Assume each person releases 150 litres of water to sewer per day)

On release to receiving waters (after treatment at the sewerage treatment plant), it is usually assumed that the effluent is diluted by a factor of 10 for ocean outfall and a factor of 2 for discharge to inland waters. This gives a final PEC in receiving waters of 0.058 µg/L (ocean) or 0.29 µg/L (inland).

No ecotoxicity data were provided, however polynonionic polymers of molecular weight greater than 1 000 are of low environmental concern (Nabholz et al, 1993). The polymer is of high molecular weight and is unlikely to bioaccumulate. Consequently, release of the polymer to the water compartment at the low levels estimated above is unlikely to present an environmental hazard.

13. HEALTH AND SAFETY RISK ASSESSMENT

13.1. Hazard assessment

No toxicological information has been provided for the notified polymer, however, due to high molecular weight, low residual monomer content and lack of reactive functional groups, the polymer is unlikely to be a hazardous substance. The polymer solution (Aculyn 46) is not a hazardous substance. The MSDS for Aculyn 46 states that it is a slight skin, eye and respiratory irritant, and lists a number of potential health effects, namely headache, nausea, irritation of nose, throat and lungs.

13.2. Occupational health and safety

There is little potential for occupational exposure to the notified polymer in the transport and storage of the polymer solution except in the event of an accidental spill.

During the formulation processes (weighing, compounding, transfer and filling) and cleaning of equipment, the main exposure route for the notified polymer will be dermal and potentially ocular. The high molecular weight of the polymer will preclude absorption through the skin. Standard engineering controls such as enclosure, automation, local exhaust ventilation, and the use of personal protective equipment including coveralls, protective eye wear and

impervious gloves (neoprene gloves are recommended on the Aculyn 46 MSDS) should provide sufficient protection against the notified polymer.

The final hair colorant containing the notified polymer could contain a variety of additional ingredients which may cause adverse health effects. Therefore, hairdressers should wear protective gloves as a general safety precaution.

The notified polymer presents a low risk to human health, and the control measures described above will ensure sufficient protection.

13.3. Public health

Products containing the notified polymer are intended for use in professional hair salons and by the public. The colorant will be diluted by 50% prior to application, giving a final exposure concentration to the public of 0.225% of notified polymer.

A conservative exposure estimate indicates end users could potentially be exposed to 0.009mg/kg/day, given frequency of use once every 4 weeks and assumption of 10% dermal absorption.

Following each application, the hair colorant and the notified polymer will be washed off with water. Although the notified polymer is a slight skin, eye and inhalation irritant, it is unlikely to be of concern due to the occasional exposure, the low concentration in the product, and its potentially negligible dermal absorption. The risk to the public due to use of the notified polymer is considered low.

14. MSDS AND LABEL ASSESSMENT

14.1. MSDS

The MSDS of the notified polymer solution provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994a). It is published here as part of the assessment report. The accuracy of the information on the MSDS remains the responsibility of the applicant.

14.2. Label

The label for the notified polymer solution provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994b). The accuracy of the information on the label remains the responsibility of the applicant.

15. RECOMMENDATIONS

No special precautions are required for the notified polymer, however, in the interests of good OHS, the following guidelines and precautions should be observed to minimise occupational exposure to Polymer in Aculyn 46:

- Protective eyewear, chemical resistant industrial clothing and footwear and neoprene gloves should be used during occupational use of the products 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;
- 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 protective eyewear 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 3765.2 (Standards Australia, 1990); for impermeable gloves or mittens, in AS 2161.2 (Standards Australia/ Standards New Zealand, 1998); for occupational footwear, in AS/NZS 2210 (Standards Australia/ Standards New Zealand, 1994a).

Hairdressers

Hairdressers are encouraged to consult guidance documents for identifying and managing health risks in hairdressing that have been published by some state occupational health and safety authorities (Division of Workplace Health and Safety, 1994); (WorkCover NSW, 1997); (WorkCover Corporation, 1996). The notifier should advise the hairdressing industry of the availability of state government publications in addition to any current industry codes.

16. REQUIREMENTS FOR SECONDARY NOTIFICATION

Secondary notification may be required if:

- any of the circumstances stipulated under subsection 64(2) of the Act arise. If any importer or manufacturer of (the notified chemical) becomes aware of any of these circumstances, they must notify the Director within 28 days; or
- the notified polymer is introduced in a chemical form that does not meet the PLC criteria.

17. REFERENCES

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