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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Hostacerin AMPS

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Director
Chemicals Notification and Assessment

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANTS
Clairant (Australia) Pty Ltd of 675 Warrigal Road, Chadstone, VIC 3148 and L'Oréal Australia Pty Ltd/Marigny Manufacturing Australia Pty Ltd of 266 Bay Road, Sandringham VIC.

NOTIFICATION CATEGORY
The notified polymer meets the PLC criteria, with some doubt on whether it meets the criteria for water absorbability. The polymer was accepted for assessment as a PLC on the following grounds:

The notified polymer as introduced contains no respirable dust fraction and low levels of inspirable dust, leading to low risk of inhalation exposure and therefore low health risk by inhalation.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical name and polymer constituents and purity, CAS number, molecular weight, specific end-uses and end use concentrations, import quantities.

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

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANTS
None

NOTIFICATION IN OTHER COUNTRIES
No

2. IDENTITY OF CHEMICAL

MARKETING NAME
Hostacerin AMPS

3. COMPOSITION

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None

RESIDUAL MONOMERS
All residual monomers are below the relevant cut-offs for classification of the notified polymer as a hazardous substance.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED POLYMER (100%) OVER NEXT 5 YEARS
The notified polymer will not be manufactured in Australia

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

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

USE
- For use in cosmetic products.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

TRANSPORTATION AND PACKAGING
The notified polymer will be imported in 200 kg polyethylene containers, and the reformulated products will be packaged into consumer-sized 120-250 mL plastic bottles or 50 mL glass jars.

5.2. Operation Description

The notified polymer will not be manufactured in Australia, but will be imported as a powder of high purity. It will be reformulated into cosmetic products at L'Oréal/Marigny at Sandringham, VIC. The final concentration of the notified polymer in cosmetic products is <10%.

The products are blended and homogenised in a 1500 kg or 3000 kg sealed and temperature-controlled vessel. The end product is then pumped into a sealed holding tank that is manoeuvred via a pallet onto the packaging floor. The end-use product is filled via a circuit of pipes and pumps into an automated filling line. After filling, the empty holding tank is steam cleaned.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Store Personnel – Clariant		½ hour/day	2 days/year
Store Personnel – L'Oréal/Marigny	3	½ hour/day	24 days/year
Laboratory technicians	2	½ hour/day	24 days/year
Compounders	3	½ hour/day	24 days/year
Line setter	1	½ hour/day	24 days/year

Exposure Details
Store personnel will handle the notified polymer in sealed containers and no exposure is expected.

One compounder in a dispensary fitted with a dust-extraction system will weigh and dispense the polymer powder into small sealable plastic tubs ready for use. The polymer is then manually transferred to the blending vessel by the second compounder. Dermal, ocular and inhalation exposure to the powder may occur. Latex gloves, safety boots, industrial standard coveralls and dust mask are worn.

The third compounder is responsible for the cleaning of the holding tank. Heat resistant gloves, safety goggles, safety boots, and industrial standard coveralls are worn.

The line-setter monitors and maintains the filling line. Safety glasses, protective gloves and coveralls are worn.

5.4. Release

RELEASE OF CHEMICAL AT SITE
All reformulation process equipment will be washed with hot water and steam after each batch. The drums in which the notified polymer is imported are washed in the same manner. All resultant washwater will go to an on-site effluent plant. The effluent plant involves a batch treatment of 10000 L of effluent per cycle, with the resultant treated effluent being released to sewer. It is estimated that annually less than 10 kg of the notified polymer will go to the on-site treatment plant.

RELEASE OF CHEMICAL FROM USE

Since the notified polymer will be used in a range of skin care products, the majority of the notified polymer will end up in the sewer. A small amount (less than 200 kg) of the product will remain in the empty end user containers.

5.5. Disposal

From the skin product formulation processes all treated effluent from the on-site treatment plant containing less than 10 kg of notified polymer will enter the Melbourne Water sewage system.

Due to the nature of skin care products more than 95% of the notified polymer will be washed into domestic sewers across Australia. The empty user containers will be disposed of in domestic rubbish and being sent to landfills across Australia.

5.6. Public exposure

Members of the public may be exposed through dermal application of the cosmetics containing <10% of the notified polymer. Due to the diffuse release pattern, no significant public exposure to the notified polymer in the environment is expected. Public exposure to the technical grade polymer would only occur in the event of an accidental spill.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa	White powder
Melting Point	Thermal decomposition temperature >250º
Bulk Density	230 kg/m^3
Water Solubility	0.327 g/L at 20ºC (see fish toxicity study)
Remarks	Less than 2% of the polymer was extractable with water. This 2% only contains low MW fractions with the higher MW fraction remaining as a solid. When filtered this solid was found to contain highly crosslinked polymer. However, the fish toxicity results indicate a water solubility of around 327 mg/L.
Particle Size	Mean particle size 496 µm. Minimum 50 µm, approximately 10% <200 µm.
Flammability	Combustible solid
Explosive Properties	Dust explosion hazard
Degradation Products	May release ammonia under alkaline conditions

ADDITIONAL TESTS

Hydrolysis as a Function of pH	Not determined
Remarks	The notified polymer contains amide linkages that could be expected to undergo hydrolysis under extreme pH conditions. However, in the environmental pH range of 4 to 9, significant hydrolysis is unlikely to occur.
Partition Coefficient (n-octanol/water)	Not determined
Remarks	The partition coefficient has not been determined due to its expected low water solubility. Due to its likely hydrophobic nature, it is likely to partition into the octanol phase.
Adsorption/Desorption	Not determined

Remarks The notified polymer is expected to be relatively immobile in soil due to its expected low water solubility and high level of cross-linking.

Dissociation Constant Not determined

Remarks While the polymer is a salt of a strong acid, due to its high level of cross-linking it is unlikely that the polymer will significantly dissociate.

7. TOXICOLOGICAL INVESTIGATIONS

The following toxicological studies were submitted:
acute oral toxicity, skin and eye irritation, skin sensitisation (Buehler test) and bacterial reverse mutations assay.

Negative results for skin sensitisation, skin irritation and mutagenicity were observed. Acute toxicity was low (>2000 mg/kg bw).

Eye irritation testing in three New Zealand White rabbits showed effects at 1, 24 hours and 48 hours. Iris inflammation (Grade 1) was seen in one animal at 24 hours. Conjunctival redness (up to Grade 3) was seen in all animals at 1 and 24 hours; chemosis (to Grade 2) and discharge (Grade 1) were seen in all animals at 1 hour. Individual results are given in the following table.

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	0.66	1.0	1.33	3	48 h	0
Conjunctiva: chemosis	0	0	0	2	1 h	0
Conjunctiva: discharge	0	0	0	1	1 h	0
Corneal opacity	0	0	0	-	-	0
Iridial inflammation	0	0.33	0	1	24 h	0

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

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	Hostacerin AMPS (batch 224442)
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test.
Inoculum	Non-adapted activated sludge
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Titration with 0.05 N HCl
Remarks - Method	Sodium acetate was used as a reference substance (functional control). The concentration of the test substance was 30 mg/L.

RESULTS

Test substance		Sodium acetate	
Day	*% degradation*	*Day*	*% degradation*
6	3	6	57
13	10	13	81
20	3	20	87
28	7	28	90

Remarks - Results	The validity of study was confirmed since the reference substance reached greater than 60% degradation within 14 days.
CONCLUSION	The study results indicate that the test substance is not readily biodegradable since it did not reach (and maintain) 10% by day 28.
TEST FACILITY	Dr U Noack-Laboratorium (1999a)

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Hostacerin AMPS (batch 224442)
METHOD	OECD TG 203 Fish, Acute Toxicity Test - static. EC Directive 92/69/EEC C.1 Acute Toxicity for Fish – static.
Species	*Brachydanio rerio* (Zebra fish)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	2.3-2.5 mg $CaCO_3$/L
Analytical Monitoring	Column chromatography
Remarks – Method	The test solution at the nominal concentration of 1000 mg/L showed turbidity from the start, with additional material depositing on the water surface by the sixth hour.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
0	0	7	0	0	0	0	0
1000	327	7	0	0	0	0	0

LC50	>1000 mg/L at 96 hours.
NOEC (or LOEC)	1000 mg/L at 96 hours.

Remarks – Results	The turbidity of the test solution made the process of observing the behaviour of the fish difficult. The LC_{50} is based on the nominal concentration.
CONCLUSION	The results of the study indicate that the test substance is not toxic to fish up to the limit of its water solubility.
TEST FACILITY	Hoechst (1996)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Hostacerin AMPS (batch 224442)
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test.
Inoculum	Activated sludge
Exposure Period	3 hours
Concentration Range	320-3200 mg/L
Nominal	
Remarks – Method	Copper (II) sulphate pentahydrate p.a. Merck was used as a reference substance in the concentration range 58-180 mg/L.
RESULTS	
EC50	>3200 mg/L
NOEC	3200 mg/L
Remarks – Results	The validity of study was confirmed since the reference substance gave an EC_{50} of 93 mg/L. Thee highest concentration of the test substance inhibited the respiration of the microorganisms by 23%.
CONCLUSION	The results of the study indicate that the test substance is not toxic to activated sludge microorganisms.
TEST FACILITY	Dr U Noack-Laboratorium (1999b)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Release

Ultimately all of the notified polymer will be released to the environment. The means by which this will be done are given in Section 5.4, Release.

Fate

No indication has been provided as to whether the notified polymer will be removed in the on-site effluent treatment plant at the production formulation site. However, the biodegradation study has shown that the material is not readily biodegradable. Therefore, all the notified polymer that enters the treatment plant is assumed to be released to sewer. The usage of the products will mean that the notified polymer will be washed into the sewer with a small amount remaining in empty containers that will go to landfill. In landfill the containers will be ruptured, thus the notified polymer may leach out at very low concentrations and in a diffuse manner.

Predicted Environmental Concentration (PEC)

Maximum amount released to sewer	9600 kg
National population	19 million
Amount of water used per person	150 L
Number of days in year	365
Dilution factor for receiving water	10
PEC	0.9 µg/L

The polymer is not expected to cross biological membranes due to its high molecular weight. Therefore the notified polymer is not expected to bioaccumulate (Connell, 1990).

9.1.2. Environment – hazard assessment

One acute fish test was provided; in this study the NOEC was found to be 327 mg/L (measured concentration). This indicates that the notified polymer is practically non-toxic to fish.

9.1.3. Environment – risk characterisation

The PNEC is determined using the actual concentration and a safety factor of 1000 (since toxicity is only available for 1 level), giving a PNEC of 0.3 mg/L. The PEC/PNEC ratio is 0.003, indicating no immediate concerns to the aquatic environment.

Taking into account the use and release patterns, as specified in the notification, and the ecotoxicity of the notified polymer, the risk posed by it is expected to be low.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Dermal, ocular and/or inhalation exposure may occur during formulation, particularly during weighing and transfer to the mixing vessel. The solid polymer contains no respirable dust and low levels of inspirable dust, leading to low risk of inhalation exposure. However, exposure to significant amounts of the notified polymer is limited because of the engineering controls such as local and exhaust ventilation. In addition, adequate personal protective equipment is expected to be worn by workers.

During transport and storage, workers are unlikely to be exposed to the notified polymer except when packaging is accidentally breached.

9.2.2. Public health – exposure assessment

Cosmetic products containing the notified polymer are for sale to the general public. Members of the public will make dermal contact and possibly accidental ocular contact with products containing the notified polymer. However, exposure will be low because the notified polymer is present at low concentrations (<10%).

Predicted exposure:

Use Level	0.8 g per use * 2 applications/day (cosmetic)	1.6 g/day
Dermal Exposure	1.6 g/day * 0.10% (concentration of polymer)	160 mg/day
Adsorption	assume 10%	16 mg/day
Systemic exposure	(16 mg/day) / 60 kg bw	0.27mg/kg.bw/day

9.2.3. Human health - effects assessment

Toxicity studies indicate that the notified polymer is a slight eye irritant, but is not classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999). On exposure to water the notified polymer will be a solid or viscous liquid, and lung clearance mechanisms are expected to operate. The powder may cause mechanical irritation to the eyes. Repeated or prolonged skin contact may result in mild irritation.

9.2.4. Occupational health and safety – risk characterisation

The notified polymer will be introduced as a solid, and the solid polymer absorbs high levels of water. This leads to questions over the eligibility of the notified polymer as a PLC; however the solid polymer will contain no respirable dust and low levels of inspirable dust, leading to low risk of inhalation exposure. For a viscous liquid, lung clearance mechanisms are expected to operate, and water absorbing polymers that liquefy are not specifically excluded from the PLC criteria in the way that solid water absorbing polymers are.

The notified polymer is a slight irritant so there is a risk of eye irritation during weighing and transfer operations. The use of engineering controls such as exhaust ventilation will reduce this risk, however, eye protection is necessary.

After mixing, the notified polymer is not expected to pose significant OHS risks, particularly after reformulation to produce an aqueous gel as part of the cosmetics formulation.

9.2.5. Public health – risk characterisation

The notified polymer will not be available to the public. Members of the public may make dermal contact with products containing the notified polymer. However, the risk to public health will be negligible due to the low concentration of the notified polymer in the cosmetic products, the low predicted exposure to the polymer during use of the cosmetic product, and the low potential for the polymer to cross biological membranes.

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

10.1. Hazard classification

Based on the available data the notified polymer is not classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio (0.003), the polymer is not considered to pose a risk to the environment based on its reported use pattern.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

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

10.3.2. Public health

There is Negligible Concern to public health when used in the applications and concentrations described.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified polymer 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 a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

The label for the notified polymer 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.

12. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- Engineering controls (ventilation), work practices and personal protective equipment (eye protection) are required for the safe use of the notified polymer in particulate form during weighing and transfer operations. Further control measures should be selected on the basis of all ingredients in the formulation.
  - Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.
- 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

- The following control measures should be implemented by skin care manufacturers to minimise environmental exposure during formulation of products containing the notified polymer:
  - Containment of spills and disposal of spilt material to landfill
  - Containment, treatment and release to municipal sewer of all washwater and effluent.
  - Do not allow material to enter stormwater drains or any natural water body.

Disposal

- The notified polymer should be disposed of by municipal sewer to a treatment plant or to land fill. Incineration of residues is acceptable.

Emergency procedures

- Spills/release of the notified polymer should be handled by collecting the material, taking precautions to minimise dust, placing in a sealable container and disposing to landfill.

12.1. 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 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 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.

13. BIBLIOGRAPHY

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