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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Acrylic Acid/Isobutyl Acrylate/Isobornyl Acrylate Copolymer

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 Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

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:

Street Address:	Level 7, 260 Elizabeth Street SURRY HILLS NSW 2010, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

Director
NICNAS

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Acrylic Acid/Isobutyl Acrylate/Isobornyl Acrylate Copolymer

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
L'Oreal Australia Pty Ltd (ABN: 40 004 191 673)
564 St Kilda Road
Melbourne, VIC, 3004

NOTIFICATION CATEGORY
Limited: Synthetic polymer with Mn ≥ 1000 Da.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: chemical name, other names, CAS number, molecular and structural formulae, molecular weight, polymer constituents, residual monomers/impurities, use details and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: Melting Point, Boiling Point, Density, Vapour Pressure, Partition Coefficient, Adsorption/Desorption, Dissociation Constant, Particle Size, Flash Point, Flammability Limits, Auto Ignition Temperature and Explosive Properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Mexomere PAS (<60% notified polymer)

MOLECULAR WEIGHT
>1000 Da

ANALYTICAL DATA
IR and GPC reference spectra were provided.

3. COMPOSITION

DEGREE OF PURITY >90%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
All hazardous impurities and residual monomers are present at levels under the concentration cut-offs for classification.

ADDITIVES/ADJUVANTS
The notified polymer is in dispersion with a solvent that may present an aspiration hazard (R65 classification provided by the notifier) and may result in irritation by skin contact (R38).

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
None under normal conditions of use.

DEGRADATION PRODUCTS
None under normal conditions of use.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: white solid (>90% notified polymer obtained by removal of solvent *via* distillation), Mexomere PAS is an off-white gel (<60% notified polymer)

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Polymer is in dispersion
Boiling Point	Not determined	Polymer is in dispersion (solvent boiling point >150 ºC)
Density	Not determined	Polymer is in dispersion (solvent density >700 kg/m^3
Vapour Pressure	Not determined	Polymer is in dispersion (vapour pressure of 7.7 kPa at 55 °C for Mexomere PAS is related to solvent)
Water Solubility	0.002 g/L at 25°C	Measured for the notified polymer
Hydrolysis as a Function of pH	Not determined	The notified polymer contains hydrolysable functionality, however, due to its low water solubility hydrolysis is not expected under environmental conditions
Partition Coefficient (n-octanol/water)	Not determined	The notified polymer is expected to partition from water to n-octanol due to its predominantly hydrophobic chemical structure
Adsorption/Desorption	Not determined	The notified polymer is expected to partition to soil, sediment and sludge due to its predominantly hydrophobic chemical structure and high molecular weight
Dissociation Constant	Not determined	The notified polymer contains acid groups (pKa ~ 4-5) which are expected to be ionised in the environmental pH range (4-9)
Particle Size	Mean diameter 102 nm	Measured; polymer is in dispersion
Flash Point	Not determined	Polymer is in dispersion (flammable solvent)
Autoignition Temperature	>430 °C	For Mexomere PAS; Stated on MSDS
Explosive Properties	Not determined	Expected to be stable under normal conditions of use. The notified polymer contains no functional groups that would imply explosive properties.

DISCUSSION OF PROPERTIES
For full details of tests on physical and chemical properties, refer to Appendix A.

Reactivity
Stable under normal conditions of use.

Dangerous Goods classification
Based on the submitted physical-chemical data in the above table the notified polymer is not classified according to the Australian Dangerous Goods Code (NTC, 2007). However the data above does not address all Dangerous Goods endpoints. Therefore consideration of all endpoints should be undertaken before a final decision on the Dangerous Goods classification is made by the introducer of the polymer.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will be introduced into Australia as a component in finished cosmetic products.

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

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

PORT OF ENTRY
The notified polymer will be imported in finished products into Melbourne, VIC.

IDENTITY OF MANUFACTURER/RECIPIENTS
The notified polymer is manufactured by Chimex S.A. in France. Upon arrival in Australia, the finished products containing the notified polymer will be warehoused in Sandringham, VIC.

TRANSPORTATION AND PACKAGING
The finished products containing the notified polymer will be supplied in ≤400 ml bottles and tubes suitable for retail sale. These bottles/tubes will further be packed in cardboard cartons and cardboard shippers. The cartons will then be transported within Australia by road to retail chains for distribution.

USE
The notified polymer is proposed to be used as a component of leave-on cosmetic products (*e.g.* lipsticks at ≤20% notified chemical, other face products at ≤5% notified chemical).

OPERATION DESCRIPTION
The notified polymer will be imported as a component of finished cosmetic products. Reformulation will not take-place in Australia.

The finished products containing the notified polymer will be used by consumers and professionals (such as workers in beauty salons). Depending on the nature of the product, application could be by hand or through the use of an applicator.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

Category of Worker	*Number*	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and Storage	10	4	12
Store Persons	2	4	12
Salon workers	unspecified	unspecified	unspecified

EXPOSURE DETAILS
Transport workers and store staff may come into contact with the imported products (≤20% notified polymer) only in the event of accidental rupture of containers.

Exposure to the notified chemical at concentrations up to 20% may occur in professions where the services provided involve the application of personal care products to clients (*e.g.* in beauty salons). Such professionals may use some personal protective equipment to minimise repeated exposure, and good hygiene practices are expected to be in place. Exposure of such workers is expected to be of either a similar or higher level than that experienced by consumers using products containing the notified chemical.

6.1.2. Public exposure
There will be widespread and repeated exposure of the public to the notified polymer at up to 20% concentration through the use of cosmetic and personal care products (*e.g.* lipsticks and other face products). The principal route of exposure will be dermal. Oral exposure to the notified chemical may occur, especially when an ingredient in lipsticks. Ocular exposure is also possible.

Data on typical use patterns of the product categories in which the notified chemical may be used are shown below (SCCP, 2006). For the purposes of the exposure assessment, Australian use patterns for the various product categories are assumed to be similar to those in Europe. The default dermal absorption of 100% was assumed for the systemic exposure calculation (European Commission, 2003). The actual level of dermal absorption may be lower than 100%. An adult bodyweight of 60 kg has been used for calculation purposes.

Product type	mg/event	events/day	**C** (%)	**RF**	**Daily exposure** (mg/day)	**Daily systemic exposure** (mg/kg bw/day)
Leave on						
Face cream	1540	1	5	1	77	1.28
Lipstick	57	1	20	1	11.4	0.19
TOTAL						**1.47**

C = concentration; RF = retention factor; 100% dermal absorption assumed.
Daily exposure = mg/event x events/day x C(%) x RF; Daily systemic exposure = daily exposure x dermal absorption (%) /60 kg

The worst case scenario estimation using these assumptions is for a person who is a simultaneous user of all products listed in the above table. This would result in a combined internal dose of 1.47 mg/kg bw/day.

6.2. Human health effects assessment

The results from toxicological investigations conducted on the notified polymer are summarised in the table below. Details of these studies can be found in Appendix B.

Endpoint (concentration of notified polymer tested)	*Result and Assessment Conclusion*
Rat, acute oral toxicity (>90%)	LD50 >2,000 mg/kg bw; low toxicity
Rat, acute dermal toxicity (>90%)	LD50 >2,000 mg/kg bw; low toxicity
Rabbit, skin irritation (<33%)	irritating
Skin Irritation – in vitro Episkin (<60%)	non-irritating
Skin Irritation – Human Volunteers (<25%)	non-irritating
Rabbit, eye irritation (<60%)	irritating
Mouse, skin sensitisation – Local lymph node assay (<30%)	no evidence of sensitisation
Skin sensitisation – human volunteers – RIPT (<20%)	no evidence of sensitisation
Skin sensitisation – human volunteers – RIPT (<20%)	no evidence of sensitisation
Mutagenicity – bacterial reverse mutation (<60%)	non mutagenic
Mutagenicity – bacterial reverse mutation (>90%)	non mutagenic
Genotoxicity – in vitro Micronucleus Test in Human Lymphocytes.	non genotoxic

Toxicokinetics, metabolism and distribution.
Based on the high molecular weight (>1000 Da) and low water solubility (0.002 g/L) of the polymer, the potential to cross the gastrointestinal (GI) tract by passive diffusion or to be dermally absorbed after exposure is limited.

The mean particle size of the polymer is 102 nm, with nearly 50% of particles falling within the nanoscale (1-100 nm). The notifier has advised that the notified polymer is not intentionally manufactured to give particle sizes in the nanoscale and that the particles may present as aggregates in cosmetic formulations. In the presence of the solvent, there is a spontaneous organisation of the polymer macromolecules in temporary polymeric micelles. As the solvent evaporates, a film is formed. Therefore, dermal absorption of polymer particles is not anticipated.

Acute toxicity.
The notified polymer was found to be of low acute oral and dermal toxicity in rats.

Irritation and Sensitisation.
-Skin:
The notified polymer (tested at <60% concentration) was a potential non-irritant based on an in vitro Episkin

skin irritation study. However, the notified polymer (tested at <33% concentration) was a skin irritant in rabbits. An unpublished study provided by the notifier indicated that the notified polymer is in dispersion with a solvent that may result in irritation by skin contact (R38 classification). Therefore, the irritation effects observed in the above study involving the notified polymer are primarily attributed to the solvent. The notified polymer (component of a lipstick formulation; <25% concentration) was not an irritant when applied to the lips of human volunteers.

-*Eyes:*
The notified polymer (tested at <60% concentration) was found to be irritating to the eyes of rabbits. The irritation scores obtained in the study (for <60% notified chemical) were not high enough to classify the polymer as an eye irritant (NOHSC, 2004). As the polymer is in dispersion with solvent, it is not clear whether the irritant effects are attributable to the polymer or the solvent.

-*Sensitisation*
The notified polymer (tested at <30% concentration) was found to be a non-sensitiser in a local lymph node assay in mice and in human repeat dose insult tests (tested at <20% concentration).

Repeated Dose Toxicity.
No repeat dose toxicity studies were conducted on the notified polymer.

Mutagenicity.
The notified polymer was not mutagenic in bacterial reverse mutation studies and was not clastogenic or aneugenic to human lymphocytes when tested in an in vitro micronucleus study.

Health hazard classification
Based on the data provided the notified polymer is not classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety
Beauty care professionals will handle the notified polymer at up to 20% concentration in leave-on cosmetic products, similar to public use. Therefore, the risk for beauty care professionals who regularly use products containing the notified chemical is expected to be of a similar or perhaps higher level than that experienced by members of the public who use such products on a regular basis. This is because the duration of exposure will be longer for workers applying products in many clients.

When used in the proposed manner, the risk associated with the use of the notified polymer at up to 20% concentration in cosmetic products is not considered to be unacceptable.

6.3.2. Public health
The main acute risk associated with the notified polymer is its potential to cause eye irritation. However, at the proposed use concentration of up to 20% notified chemical in facial cosmetics, eye irritation effects are unlikely to occur. Therefore, acute toxicity risk from the use of the notified chemical in leave-on cosmetic products is not expected to be unacceptable.

The notified polymer is likely to be present in dispersed form (and/or as aggregates) in end-use products. Following application to the skin, a film will form. Therefore, dermal absorption is not anticipated. Oral exposure to the notified chemical may occur, especially when an ingredient in lipsticks. While the notified polymer was found to be of low acute oral toxicity, no repeat dose toxicity studies are provided to estimate the risks from long-term repeated exposure to the notified polymer. However, due to the film-forming nature of the polymer in cosmetic products, dermal absorption is not expected to cause systemic effects from repeated exposure.

Therefore, based on the available data, when used in the proposed manner, the risk to the public associated with the use of the notified polymer at up to 20% concentration in cosmetic products is not considered to be unacceptable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical will not be manufactured or reformulated in Australia. It is imported as a component of finished cosmetic products (e.g. lipstick). There is unlikely to be any significant release to the environment from storage and transport, except in the case of accidental spills. Accidental spills are expected to be contained and disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

The notified polymer is a component in finished cosmetic products. The formulated product will be applied to the skin and will either be swallowed, wiped off by tissues and disposed of to domestic garbage, or washed off the body and/or drink containers with ultimate release to the sewer.

RELEASE OF CHEMICAL FROM DISPOSAL

Residue of the notified polymer in empty product containers will share the fate of the container. It is expected that up to 3% of the annual import volume will remain in the containers and be disposed of to landfill.

7.1.2 Environmental fate

No environmental fate data were submitted. The notified polymer is expected to be disposed of to both the sewer and landfill. The notified polymer maybe washed into the sewer in the form of dissolved polymer or as particulate matter. It is estimated that up to 90% of the notified polymer in influent is likely to adsorb to sediment and sludge in sewage treatment plants (Boethling and Nabholz, 1996), with the sludge eventually disposed of to landfill. In landfill, the notified polymer is expected to have low mobility in soil, due to its low water solubility and sorption to soil and sediment. The notified polymer is not expected to bioaccumulate, based on its high molecular weight. It is not likely to be readily biodegradable but it is expected to slowly degrade abiotically to form water and oxides of carbon.

7.1.3 Predicted Environmental Concentration (PEC)

A predicted environmental concentration (PEC) for a worst case scenario has been determined with the assumptions that 100% of the annual import volume will be released to sewer nationwide and that none of the notified polymer will be removed by sewage treatment processes.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	10,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	10,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	27.40	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	21.161	million
Removal within STP	0%	
Daily effluent production:	4,232	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	6.47	µg/L
PEC - Ocean:	0.65	µg/L

The above calculation represents a conservative worst case as a significant fraction of the imported quantity of notified polymer is expected to end up as solid waste in landfill, in used containers and on tissues. The notified polymer is also likely to be removed from influent by up to 90% during sewage treatment processes. Therefore, significant release of the notified polymer to the aquatic compartment is not expected.

7.2. Environmental effects assessment

The results from ecotoxicological investigations conducted on a test material containing a colloidal dispersion of the notified polymer in solvent are summarised in the table below. Summary details of these ecotoxicological studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Daphnia Toxicity	EC50 (48 h) = 23.25 mg/L*	Not harmful to aquatic invertebrates*
Algal Toxicity	I_rC50 (72 h) >181.5 mg/L	Not harmful to algae

*Attributed to the toxicity of the solvent.

The toxicity of the test material found towards daphnia was attributed to the effect of the solvent, as long-term toxicity testing on the solvent found it to be very toxic to aquatic invertebrates with long lasting effects (ECB, 2008).

Anionic polymers that are soluble in water generally exhibit low toxicity towards fish and daphnia, yet may have toxicity concerns for algae. The highest toxicity is when pendant acid groups are on alternating carbons of the polymer backbone. However, as the notified polymer has low water solubility and does not have alternating pendant acid groups it is not expected to be toxic towards algae. This is supported by the results of the algal toxicity testing as detailed in the table above. Therefore, the notified polymer is expected to be of low concern to the aquatic environment.

7.2.1 Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) has not been calculated for the notified polymer as significant environmental release is not expected due to the notified polymer's adsorptive characteristics and also because polymers with low water solubility and low charge density are generally of low concern for the aquatic environment.

7.3. Environmental risk assessment

The risk quotient (Q = PEC/PNEC) has not been calculated as significant aquatic release of the notified polymer is not expected and also because the notified polymer is expected to have low toxicity to aquatic biota. The notified polymer is expected to be disposed of to the sewer where it is likely to adsorb to sludge, or be disposed of to landfill as residue in containers or on tissues. It is not expected to bioaccumulate and is likely to slowly degrade in landfill. Therefore, on the basis of its limited environmental release and low concern for the aquatic environment, the notified polymer is not expected to pose a risk to the environment.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the data provided the notified polymer is not classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

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

On the basis of the limited environmental release and low hazard to aquatic organisms, the notified polymer is not expected to pose a risk to the environment.

Recommendations

CONTROL MEASURES
Occupational Health and Safety

- No specific engineering controls, work practices or personal protective equipment are required for the safe use of the notified polymer itself. However, these should be selected on the basis of all ingredients in the formulation.

- 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.

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

Disposal

- The notified polymer should be disposed of to landfill.

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by physical 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 chemical 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 chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical 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(2) of the Act; if
  - the function or use of the polymer has changed from a component of cosmetic products at ≤20% concentration or is likely to change significantly;
  - the amount of polymer being introduced has increased from 10 tonnes per annum, or is likely to increase, significantly;
  - the polymer has begun to be manufactured or reformulated in Australia;
  - additional information has become available to the person as to an adverse effect of the polymer 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 products containing the notified polymer provided by the notifier were reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Water Solubility 0.002 g/L at 25°C

Method In house method similar to OECD TG120. A saturated solution of the dried test substance (Mexomere PAS) in water at 25°C was prepared at a nominal loading level of 10 g notified polymer per litre. After homogenisation by ultrasonic bath (15 min), the mixture was shaken (6 h) and allowed to stand overnight at ambient temperature (23°C). The mixture was centrifuged and an aliquot of the supernatant was dried to constant weight.

Remarks The water extractability of the notified polymer was reported as 0.02 g/100 g (0.02% w/w). This is equivalent to a saturation concentration of 0.002 g/L of notified polymer under the conditions of the test. The result of this test confirms that the notified polymer is only slightly soluble in water.

Test Facility L'Oreal (2009a)

Particle Size Mean diameter 102 nm

Method The particle size analysis was performed on a diluted sample of Mexomere PAS using Dynamic Light Scattering (DLS).

Remarks The mean diameter obtained was equal to 102 nm with a polydispersity index Q = 0.13

Test Facility L'Oreal (2010)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified polymer (>90%)
METHOD	OECD TG 420 Acute Oral Toxicity - Fixed Dose Method. EC Directive2004/73/EC B.1 bis Acute Toxicity (Oral) Fixed Dose Method.
Species/Strain	Rat/Wistar, female
Vehicle	Corn oil
Remarks - Method	No significant protocol deviations. All animals were dosed by gavage. The sighting study was conducted using 1 animal dosed at 300 mg/kg bw and 1 animal dosed at 2000 mg/kg. As there were no mortalities an additional four animals were dosed at 2000 mg/kg bw.
RESULTS	
Discriminating Dose	>2000 mg/kg bw
Signs of Toxicity	There were no deaths. No signs of systemic toxicity were noted.
Effects in Organs	No abnormalities were noted at necroscopy
Remarks - Results	Body weight gains were as expected.
CONCLUSION	The notified polymer is of low toxicity via the oral route.
TEST FACILITY	JRF (2009a)

B.2. Acute toxicity – dermal

TEST SUBSTANCE	Notified polymer (>90%)
METHOD	OECD TG 402 Acute Dermal Toxicity – Limit Test. EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal) – Limit Test.
Species/Strain	Rat/Wistar
Vehicle	Test substance moistened with distilled water
Type of dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 per sex	2000	0

LD50	>2000 mg/kg bw
Signs of Toxicity - Local	There were no clinical signs and no cutaneous lesions
Signs of Toxicity - Systemic	There were no deaths and no clinical signs of systemic toxicity
Effects in Organs	No abnormalities were noted at necroscopy
Remarks - Results	Body weight gains were as expected.
CONCLUSION	The notified polymer is of low toxicity via the dermal route.
TEST FACILITY	JRF (2009b)

B.3. Irritation – skin

TEST SUBSTANCE	Mexomere PAS (<60% notified polymer) – 2 Batches diluted to give a final concentration of <33% notified polymer.

METHOD
Similar to OECD TG 404 Acute Dermal Irritation/Corrosion.

Species/Strain: Rabbit/New Zealand White

Number of Animals: 3 males/batch

Vehicle: Polyisobutylene (Parleam), 55% Mexomere PAS in Parleam (*i.e.* final concentration <33% notified polymer)

Observation Period: ≤15 Days

Type of Dressing: Semi-occlusive.

Remarks - Method: Application of both batches of the undiluted test substance (100% Mexomere PAS, i.e. <60% notified polymer) for 3 minutes (single animal) and 1-hour (single animal) resulted in the observation of strong skin reactions after the 1-hour exposure period (including observation of well defined erythema and slight edema on days 2-9 inclusive).

The diluted substance was then tested (<33% notified polymer). The absence of severe skin reactions in the 3-minute and 1-hour exposure periods (both batches on single animals) resulted in a 4-hour exposure study in 3 animals. The test substance was removed from 1-animal per batch using an oil in water solution, and removed from the other 2 animals using the vehicle.

RESULTS

Batch: 1

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0.0	2.0	1.3	2	13 Days	0
Oedema	0.0	0.0	0.0	0	-	0

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

Batch: 2

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0.0	1.0	1.0	2	11 days	0
Oedema	0.0	0.0	0.0	0	-	0

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

Remarks - Results: For Batch 1: well defined erythema was observed for 1-animal from days 2-11 inclusive, and in a second animal from days 4-6 inclusive. Slight erythema was then evident before clearing. Dryness of the skin was also noted in 2 of the animals (days 6-13 and days 6-15).

For Batch 2: well defined erythema was observed in a single animal from Day 4-6 inclusive which then reduced to slight erythema on day 7 before clearing. A second animal showed slight erythema from days 1-11 inclusive. Dryness of the skin was also noted in 2 of the animals (days 7-12 and days 6-15).

It is reported that under the experimental conditions, no relevant differences on skin irritation and severity were noted between the tested batches.

CONCLUSION
The test substance is irritating to the skin. The classification scores do not warrant the test material to be classified as a skin irritant (NOHSC, 2004)

TEST FACILITY CIT (2007a)

B.4. Irritation – skin – in vitro human reconstructed Episkin

TEST SUBSTANCE Mexomere PAS (<60% notified polymer) – 2 Batches

METHOD Episkin[SM] Method (human reconstructed epidermis)
Vehicle i) None ii) Polyisobutylene (Parleam), 55% Mexomere PAS in Parleam (*i.e.* final concentration <33% notified polymer)
Remarks - Method Untranslated study. A summary only was provided.

The study was conducted at 2 concentrations [100% Mexomere PAS (<60% notified polymer), 30 mg; and 55% Mexomere PAS in Parleam (polyisobutylene; <33% notified polymer), 30 µL] and in duplicate. Following an incubation time of 18 hours, the skin was rinsed. Positive and negative controls were run in parallel with the tested substances and in duplicate, but no details of these were provided.

The tissue samples were then placed in MTT solution (0.33 mg/mL) for 3 hours at 37 ºC. Extraction from the tissue was conducted using isopropanol, and the optical density determined at 570 nm.

The substance was considered to be a potential irritant if the mean viability score was ≤50.

RESULTS

Batch and Concentration	*Mean Viability Score*
1 – 100% Mexomere PAS	92.4
2 – 100% Mexomere PAS	98.4
1 – 55% Mexomere PAS	86.9
2 – 55% Mexomere PAS	89.1

Remarks - Results Under the experimental conditions, no relevant differences were noted between the tested batches.

CONCLUSION The test substance is potentially non-irritating to the skin.

TEST FACILITY Episkin (2006)

B.5. Skin Irritation in Human Volunteers

TEST SUBSTANCE Lipstick containing 40% Mexomere PAS (<25% notified polymer)

METHOD
Remarks - Method The test was conducted in winter (cold and dry weather).

Applications were performed by the volunteers (38). The test substance was applied to the lips (as much as necessary, 2-6 times/day) of adult human females (50% dry lips, 50% normal lips). The test articles were weighed at the beginning and end of the study to determine amount used by volunteers.

Examinations were performed before use of the test article and after 2 and 4 weeks of application.

RESULTS
Remarks - Results The mean total amount of product applied by volunteers over the study period was 0.9 g. Analysis of results was performed on 38 volunteers (37 at end of the study).

Very good tolerance of the test article was noted for 33/38 volunteers who self-rated the product. The remaining 5/38 indicated having presented with some dryness (and discomfort). One volunteer withdrew from the study, having experienced tightness, dryness and prickling. No abnormal clinical signs were noted by the investigator after 2 and 4 weeks of use.

CONCLUSION The test substance was well tolerated under the conditions of the test by the majority of participants

TEST FACILITY IEC (2006)

B.6. Irritation – eye

TEST SUBSTANCE Mexomere PAS (<60% notified polymer) – 2 Batches

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
EC Directive 2004/73/EC B.5 Acute Toxicity (Eye Irritation).

Species/Strain	Rabbit/New Zealand White
Number of Animals	3 males/batch
Observation Period	9 days
Remarks - Method	No significant protocol deviations

RESULTS

Batch: 1

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	0.7	2.0	2.0	3	6 Days	0
Conjunctiva: chemosis	0.7	1.3	2.0	2	8 Days	0
Conjunctiva: discharge	0.7	NC	1.0	NC	6 Days	0
Corneal opacity	0.0	0.0	0.0	0	0	0
Iridial inflammation	0.0	0.0	0.0	0	0	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.
NC = not calculable, whitish purulent discharge observed at 24 and 48 h.

Batch: 2

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	1	1.3	1	2	5 Days	0
Conjunctiva: chemosis	1.7	1.7	1	2	5 Days	0
Conjunctiva: discharge	0.7	NC	0.3	NC	3 days	0
Corneal opacity	0.0	0.0	0.0	0	0	0
Iridial inflammation	0.0	0.0	0.0	0	0	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.
NC = not calculable, whitish purulent discharge observed at 24 h.

Remarks - Results For Batch 1: slight to moderate chemosis, slight to severe redness of the conjunctiva and clear to whitish purulent discharge were observed in all animals on days 1 and 2. Reactions persisted up to Day 3 (1 animal) or Day 8 (2 animals). Corneal opacity and iris lesions were not observed during the study. Alopecia around the eye was noted in 1/3 animals on Days 4 and 5.

For Batch 2: slight to moderate chemosis, slight to moderate redness of the conjunctiva and clear to whitish purulent discharge were observed in

all animals on days 1 and 2. Reactions persisted up to Day 3 (1 animal), Day 4 (1 animal) or Day 5 (1 animal). Corneal opacity and iris lesions were not observed during the study.

It is reported that under the experimental conditions, reactions were similar with both batches tested.

CONCLUSION The test substance with <60% notified polymer is irritating to the eye. The classification scores do not warrant the test material to be classified as an eye irritant (NOHSC, 2004).

TEST FACILITY CIT (2007b)

B.7. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE Mexomere PAS (<60% notified polymer)

METHOD OECD TG 429 Skin Sensitisation: Local Lymph Node Assay
EC Directive 2004/73/EC B.42 Skin Sensitisation (Local Lymph Node Assay)

Species/Strain Mouse/CBA/J Female

Vehicle Acetone/olive oil 4:1

Remarks - Method A preliminary test was conducted using 25 µL samples of 10, 25, 50 and 100% concentration (applied for 3 consecutive days). For the undiluted test substance, alopecia around the ears was noted in 1/2 animals treated and a high increase in ear thickness was recorded. Therefore, the highest concentration for the main test was 50%.

In the main test, 5 treated groups (4 animals/group) received the test substance at 2.5, 5, 10, 25 or 50% concentration. α-Hexylcinnamaldehyde was used as the positive control.

RESULTS

Concentration (% w/w)	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance		
0 (vehicle control)	141.11	
2.5	92.44	0.66
5	81.52	0.58
10	142.44	1.01
25	47.54	0.34
50	189.08	1.34
Positive Control		
25	582.01	4.12

Remarks - Results There were no deaths and no signs of systemic toxicity were noted in the study.

Body weight changes of the test animals were comparable to those seen in the control animals.

For animals treated with the 50% test substance, alopecia around the ears was noted in 3/4 animals on Day 2 and all animals on Days 3 and 6. In addition, erythema was noted in all animals on Day 6 and dryness of the skin was observed in all animals. An increase in ear thickness (15.36% between days 1 and 6) was also observed. For animals treated at 25%, erythema was noted on Day 6, the last day of observation

	A stimulation index of less than 3 was observed for all concentrations of the test material.
CONCLUSION	There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the test substance.
TEST FACILITY	CIT (2007c)

B.8. Skin sensitisation – human volunteers

TEST SUBSTANCE	Formulation containing 30% Mexomere PAS (<20% notified polymer)
METHOD	Repeated insult patch test with challenge
Study Design	Induction Procedure: Patches with 20 mg of the test material were applied 3 times per week (Monday, Wednesday and Friday) for a total of 9 applications. Patches were removed after 48 h (or 72 h for patches applied on Friday). Following patch removal, excess product was removed and the sites evaluated (within 25-30 minutes after removal). Rest Period: up to 19 days Challenge Procedure: Identical patches were applied to original sites and naïve sites. Patches remained in place for 48 h. Sites were graded at 30 minutes and 48 h post-patch removal.
Study Group	88 F, 22 M; age range 18-65 years
Vehicle	None
Remarks - Method	Semi-occluded The test substance was spread on a 1 cm x 1 cm patch then air dried for 60 minutes prior to patch application. Excess product was removed with petrolatum or make-up remover.
RESULTS	
Remarks - Results	102/110 completed the induction phase, 101/110 completed the challenge phase. No irritation or sensitisation was reported in these subjects. A single adverse event was reported (rash on the back of a subject, but not in the patch area). However, it is noted by the study authors to be unlikely related to the product.
CONCLUSION	The test substance was non-irritating and non-sensitising under the conditions of the test.
TEST FACILITY	TKL (2007)

B.9. Skin sensitisation – human volunteers

TEST SUBSTANCE	Formulation containing 30% Mexomere PAS (<20% notified polymer)
METHOD	Repeated insult patch test with challenge
Study Design	Induction Procedure: Patches with 160 mg of the test material were applied 3 times per week (Monday, Wednesday and Friday) for a total of 9 applications (study began on a Friday). Patches were removed after 48 h (or 72 h for patches applied on Friday). Sites were evaluated *ca.* 15 minutes after patch removal. Rest Period: 2 weeks (4 weeks maximum) Challenge Procedure: Patches were applied to original sites and naïve sites. Patches remained in place for 48 h. Sites were graded at 15 minutes and 48 and 96 h post-patch removal.
Study Group	81 F, 25 M; age range 18-57 years
Vehicle	None
Remarks - Method	Semi-occluded

The test substance was spread on a patch (400 mm^2) then air dried for 60 minutes prior to patch application.

RESULTS

Remarks - Results: 104/106 completed the study (withdrawal of 2 volunteers reportedly due to reasons independent of the test product). No adverse reactions are recorded.

CONCLUSION: The test substance was non-irritating and non-sensitising under the conditions of the test.

TEST FACILITY: EVIC (2007)

B.10. Genotoxicity – bacteria

TEST SUBSTANCE: Mexomere PAS (<60% notified polymer) – 2 Batches

METHOD: OECD TG 471 Bacterial Reverse Mutation Test.
EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria.

Species/Strain: *S. typhimurium*: TA1535, TA1537, TA98, TA100, TA102
Metabolic Activation System: Aroclor 1254-induced rat liver (S9 homogenate)
Concentration Range in Main Test: a) With metabolic activation: 312.5, 625, 1250, 2500 and 5000 µg/plate
b) Without metabolic activation: 312.5, 625, 1250, 2500 and 5000 µg/plate
Vehicle: Tetrahydrofuran (THF)
Remarks - Method: For each batch, a preliminary toxicity test was performed to define the dose levels for the main test, and then 2 mutagenicity studies were conducted. The preliminary test, mutagenicity studies without S9 and the first main study with S9 utilised the plate incorporation method. The second study with S9 utilised the preincubation method. Plates were done in triplicate.

Negative control: THF vehicle
Positive control: i) Without S9: sodium azide (TA1535, TA100), 9-aminoacridine (TA1537), 2-nitrofluorene (TA98), and mitomycin C (TA102); ii) With S9: 2-anthramine.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	>5000	>5000	≥312.5	Negative
Test 2	-	>5000	≥312.5	Negative
Present				
Test 1	>5000	>5000	≥312.5	Negative
Test 2	-	>5000	≥312.5	Negative

Remarks - Results: The above table is applicable for both batches of the test substance. Slight increases in the number of revertants were observed in some instances with TA98. However, as these were isolated instances and/or not dose-related, they were deemed not relevant by the study author, and are considered to be related to a lower than average value for the negative control in this study.

CONCLUSION: The test substance was not mutagenic to bacteria under the conditions of

the test.

TEST FACILITY CIT (2006)

B.11. Genotoxicity – bacteria

TEST SUBSTANCE Notified polymer (>90%)

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
Species/Strain *S. typhimurium*: TA1535, TA1537, TA98, TA100, TA102
Metabolic Activation System Aroclor 1254-induced rat liver (S9 homogenate)
Concentration Range in Main Test Test 1 (all strains except TA100)
a) With metabolic activation: 0.16, 0.8, 4, 20, 100 and 500 µg/plate
b) Without metabolic activation: 0.16, 0.8, 4, 20, 100 and 500 µg/plate
The data obtained from the preliminary study (concentrations: 1.6, 8, 40, 200, 1000, 5000 µg/plate) were used as the mutagenicity data for TA100 (Test 1).

Test 2: (all strains)
a) With metabolic activation: 6.25, 12.5, 25, 50, 100 and 200 µg/plate
b) Without metabolic activation: 6.25, 12.5, 25, 50, 100 and 200 µg/plate
Vehicle THF
Remarks - Method For each batch, a preliminary toxicity test was performed (for strain TA100) to define the dose levels for the main test, and then 2 mutagenicity studies were conducted. The preliminary test, mutagenicity studies without S9 and the first main study with S9 utilised the plate incorporation method. The second study with S9 utilised the preincubation method. Plates were done in triplicate.

Negative control: THF vehicle
Positive control: i) Without S9: sodium azide (TA1535, TA100), 9-aminoacridine (TA1537), 2-nitrofluorene (TA98), and mitomycin C (TA102); ii) With S9: 2-minoanthracene (TA100, TA1535, TA1537, TA102) and benzo[a]pyrene (TA98).

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	>5000	>500*	≥100**	Negative
Test 2	-	>200	≥50	Negative
Present				
Test 1	>5000	>500*	≥100**	Negative
Test 2	-	>200	≥50	Negative

*>5000 for TA100; **≥40 for TA100

Remarks - Results A slight increase in the number of revertants was observed in Test 1 for strain TA102 (in the presence of S9). However, this was not dose-related and deemed not relevant.

CONCLUSION The test substance was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY Covance (2009a)

B.12. Genotoxicity – in vitro

TEST SUBSTANCE	Notified polymer (>90%)
METHOD	Similar to Draft OECD TG 487 In vitro Micronucleus Test in Human Lymphocytes.
Cell Type	Human lymphocytes
Metabolic Activation System	Aroclor 1254-induced rat liver (S9 homogenate)
Vehicle	THF
Remarks - Method	The test substance was added 48 hours after culture initiation [mitogen stimulation by phytohaemagglutin (PHA)]. Cells were exposed to the test substance, with and without metabolic activation, for 3 h. A continuous 24-hour treatment in the absence of S9 was also included. Cultures were sampled 72 h after culture initiation (24 h after treatment). Negative control: THF vehicle and untreated control Positive control: i) Without S9: mitomycin C and vinblastine; ii) With S9: cyclophosphamide. A cytotoxicity range finding test was performed (concentrations: 0.4535 – 125.0 µg/mL) in order to select appropriate maximum concentrations for the main experiment. Test 1 with metabolic activation was repeated as the replication index value of the vehicle control was unacceptably low.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0, 12.5, 25, 50, 75*, 100*, 125*, 150, 175, 200, 225, 250	3 h + 21 h	24 h
Test 2	5, 10, 15, 20, 25, 30*, 35*, 40*, 45, 50, 60, 75, 100	24 h + 0 h	24 h
Present			
Test 1	0, 12.5, 25, 50, 75, 100*, 125*, 150*, 175, 200, 225, 250	3 h + 21 h	24 h

*Cultures selected for binucleate analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*		
	Cytotoxicity in Main Test	*Precipitation*	*Genotoxic Effect*
Absent			
Test 1	>250	≥125	Negative
Test 2	>100	≥40	Negative
Present			
Test 1	>250	≥150	Negative

Remarks - Results	The maximum concentration analysed was limited by the appearance of a precipitate at the end of the incubation period. For the cultures selected for analysis, cytotoxicity was noted as follows: i) Without S9 [conc. µg/mL (cytotoxicity)]: Test 1 - 75 (0%), 100 (3%), 125 (7%); Test 2 – 30 (2%), 35 (0%), 40 (0%) ii) With S9 [conc. µg/mL (cytotoxicity)]: Test 1 – 100 (4%), 125 (1%), 150 (0%). Based on the mean MNBN (micronucleated binucleate) cell frequency values, the notified polymer did not induce any statistically significant increases in the frequency of cells with micronuclei, in either the absence or presence of metabolic activation. The positive control chemicals induced statistically significant increase in

	the frequency of cells with micronuclei, thereby confirming the validity of the test system.
CONCLUSION	The notified chemical was not clastogenic or aneugenic to human lymphocytes treated in vitro under the conditions of the test.
TEST FACILITY	Covance (2009b)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.2.1. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Mexomere PAS (colloidal dispersion of notified polymer in solvent)
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	Not reported
Remarks - Method	Study summary only was provided: dilution of a stock suspension at 100.0 mg notified polymer/L agitated for ~24 h. In house screening, non Good Laboratory Practice (GLP) studies.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0	Not reported	4 × 5	Not reported	Not reported
0.781	"	"	"	"
1.56	"	"	"	"
3.12	"	"	"	"
6.25	"	"	"	"
12.5	"	"	"	"
50.0	"	"	"	"
100.0	"	"	"	"

LC50	23.25 mg/L at 48 h
NOEC (or LOEC)	Not reported
Remarks - Results	The harmful effect observed on the daphnids was attributed to the solvent in the test substance, as this solvent was found to be very toxic with long lasting effects in long term studies (ECB, 2008).
CONCLUSION	The notified polymer is not expected to be harmful to aquatic invertebrates.
TEST FACILITY	L'Oréal (2009b)

C.2.2. Algal growth inhibition test

TEST SUBSTANCE	Mexomere PAS (colloidal dispersion of notified polymer in solvent)
METHOD	OECD TG 201 Alga, Growth Inhibition Test.
Species	*Pseudokirschneriella subcapitata*
Exposure Period	72 hours
Concentration Range	Nominal: 0-181.5 mg notified polymer/L
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	Not reported
Remarks - Method	Study summary only was provided: dilution of a stock suspension at 181.5 mg notified polymer/L agitated for ~ 24 h. Three replicates per concentration tested (0, 3.88, 6.72, 20.2, 34.9, 60.5, 104.8 and 181.5 mg notified polymer/L). In house screening, non Good Laboratory Practice (GLP) studies.

RESULTS

Biomass		*Growth*	
I_yC50 mg/L at 72 h	*NOEC mg/L*	*I_rC50 mg/L at 72 h*	*NOEC mg/L*
Not reported	Not reported	>181.5	Not reported

CONCLUSION The notified polymer is not harmful to algae.

TEST FACILITY L'Oréal (2009b)

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