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April 2011

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Carboxylic acids, C6-8-neo-, esters with polypropylene glycol monomyristyl ether (INCI name: PPG-3 Myristyl Ether Neoheptanoate)

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 Sustainability, Environment, Water, Population and Communities.

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:

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Director
NICNAS

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Carboxylic acids, C6-8-neo-, esters with polypropylene glycol monomyristyl ether (INCI name: PPG-3 Myristyl Ether Neoheptanoate)

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Johnson & Johnson Pacific Pty Ltd (ABN: 73 001 121 446)
45 Jones Street
Ultimo, NSW 2007

NOTIFICATION CATEGORY
Limited-small volume: Synthetic polymer with Mn < 1000 Da (1 tonne or less per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
No details are claimed exempt from publication.

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, Hydrolysis as a Function of pH, Partition Co-efficient, Adsorption/Desorption, Flammability Limits, Autoignition Temperature and Explosive Properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Liquiwax PolyNH

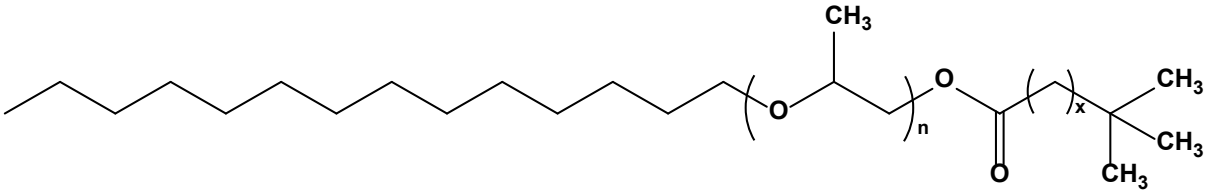
CAS NUMBER
325726-83-8

CHEMICAL NAME
Carboxylic acids, C6-8-neo-, esters with polypropylene glycol monomyristyl ether

OTHER NAME(S)
PPG-3 Myristyl Ether Neoheptanoate (INCI name)

MOLECULAR FORMULA
Unspecified

STRUCTURAL FORMULA



x = 1-3
n = 1-5, with an average of 3

MOLECULAR WEIGHT

Number Average Molecular Weight (Mn)	569 Da
Weight Average Molecular Weight (Mw)	591 Da

Polydispersity Index (Mw/Mn)	1.04
% of Low MW Species < 1000 Da	98.6%
% of Low MW Species < 500 Da	28.4%

ANALYTICAL DATA
Reference IR spectrum was provided.

3. COMPOSITION

DEGREE OF PURITY 99.8%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

Chemical Name Carboxylic acids, C_{6-8}-neo-
CAS No. 95823-36-2 *Weight %* <1%
Hazardous Properties Xi; R36/38*
*Classification provided by notifier

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight)
None

ADDITIVES/ADJUVANTS
None

POLYMER CONSTITUENTS

Chemical Name	*CAS No.*	*Weight % starting*	*Weight % residual*
Poly[oxy(methyl-1,2-ethanediyl)], α-tetradecyl-ω-hydroxy-	63793-60-2	75-80	<1
Carboxylic acids, C_{6-8}-neo-	95823-36-2	20-25	<1

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Clear, colourless to pale yellow liquid

Property	Value	Data Source/Justification
Freezing Point	-1 °C	MSDS
Boiling Point	>150 °C at 101.3 kPa	MSDS
Density	900 kg/m^3 at 25 °C	MSDS
Vapour Pressure	Not determined	Based on the high molecular weight of the polymer the vapour pressure is expected to be low.
Water Solubility	≤5 g/L at 20 °C	Measured. However, water solubility of 5.1×10^{-9} g/L was also calculated by WSKOW (v1.41) (US EPA, 2009).
Hydrolysis as a Function of pH	Not determined	Not expected to readily hydrolyse under ambient environmental conditions.
Partition Coefficient (n-octanol/water)	Log Pow = 9.5 at 25 °C	Calculated by KOWWIN (v1.67) (US EPA, 2009) for a representative structure of the notified polymer.
Adsorption/Desorption	log K_{oc} = 5.8	Calculated by KOCWIN (v2.00) (US EPA, 2009) for a representative structure of the notified polymer.
Dissociation Constant	Not determined	The notified polymer does not contain any dissociable functionality.
Flash Point	>150 °C at 101.3 kPa	MSDS
Autoignition Temperature	Not determined	Not expected to autoignite based on the flash point
Explosive Properties	Not determined	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. The notified polymer is incompatible with acids, alkalis, oxidising agents and corrosive substances.

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 do 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 imported as a component (≤10%) of finished cosmetic products. In the future, it may be imported at 100% concentration for local reformulation.

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

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

PORT OF ENTRY
Sydney, by wharf and air

IDENTITY OF MANUFACTURER/RECIPIENTS
Johnson & Johnson Pacific Pty Ltd

TRANSPORTATION AND PACKAGING
The products containing the notified polymer (≤10%) will be imported in ≤300 mL containers suitable for retail sale. These will be packaged in cardboard cartons in shippers. The cartons/containers will be distributed within Australia to retail outlets by road.

USE
The notified polymer will be used as a skin conditioning agent and emollient in a variety of rinse-off and leave-on cosmetic products at concentrations ≤10%.

OPERATION DESCRIPTION
The notified polymer will be imported as a component of finished cosmetic products at ≤10% concentration. In future, the notified polymer may be introduced at 100% concentration for local reformulation processes.

If reformulation occurs, the procedures for incorporating the notified polymer into products will likely vary depending on the nature of the cosmetic and personal care products formulated, and may involve both automated and manual transfer steps. In general, it is expected that the notified polymer will be manually weighed into a container and transferred into a mixing vessel where it will be blended with other ingredients. The resulting blends (containing the notified polymer at ≤10% concentration) will then be filled into retail containers using automated filling machines. The finished products will then be packed for distribution to retail outlets.

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
Professional compounder	1	8	12
Chemist	1	3	12
Packers	2	8	12
Store Persons	2	4	8
Salon workers	unspecified	unspecified	unspecified

EXPOSURE DETAILS
Transport and storage workers may come into contact with the notified polymer at 100% concentration or as a component of end-use products (at ≤10%) only in the event of accidental rupture of containers.

If reformulation takes place, exposure to the notified polymer (at ≤100% concentration) may occur during weighing and transfer stages, blending, quality control analysis and cleaning and maintenance of equipment. Exposure is expected to be minimised through the use of mechanical ventilation and/or enclosed systems and through the use of personal protective equipment such as overalls, safety glasses and impervious gloves.

Exposure to the notified polymer in end-use products may occur in professions where the services provided involve the application of cosmetic and personal care products to clients (e.g. hair dressers, workers in beauty salons). Such professionals may use some personal protective equipment (PPE) to minimise repeated exposure, and good hygiene practices are expected to be in place. If PPE is used, exposure of such workers is expected to be of a similar or lesser extent than that experienced by consumers using products containing the notified polymer.

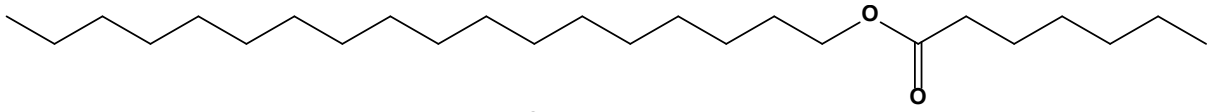
6.1.2. Public exposure
There will be widespread and repeated exposure of the public to the notified polymer through the use of the rinse-off and leave-on cosmetic and personal care products. The principal route of exposure will be dermal, while ocular and inhalation exposure is also possible, particularly if products are applied by spray.

6.2. Human health effects assessment

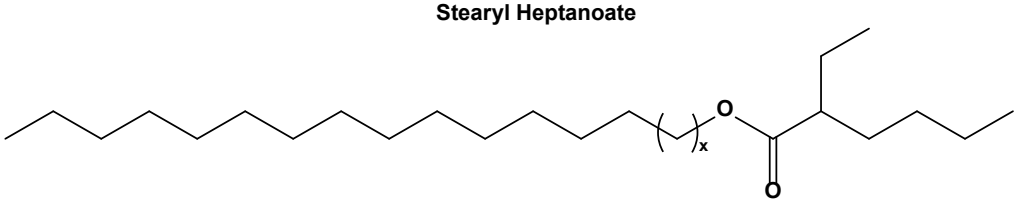
The results from toxicological investigations conducted on the notified polymer are summarised in the table below. Details of these studies can be found in Appendix B.

Endpoint	*Result and Assessment Conclusion*
in vitro skin irritation – irritection assay	non-irritating
in vitro eye irritation – irritection assay	minimally-irritating
Skin sensitisation – human volunteers – RIPT	no evidence of sensitisation

The following information was provided for structurally similar analogues of the notified polymer, stearyl heptanoate (CAS number: 66009-41-4) and cetearyl octanoate (see structures on the following page). Note that while the analogue chemicals contain alkyl chains connected *via* ester linkages, they do not contain polypropylene glycol (PPG) moieties (as is present in the notified polymer). However, published data are available to support the use of chemicals containing PPG functional groups in cosmetic products (e.g. CIR, 2001 and CIR, 2010).



Stearyl Heptanoate



Cetearyl Octanoate
x = 1-3

	Stearyl Heptanoate[1]	Cetearyl Octanoate[2]
Rat, acute oral	LD_{50} >16 mL/kg bw; low toxicity	LD_{50} >8 mL/kg bw; low toxicity
Rat, acute dermal	-	LD_{50} >9.4 mL/kg bw; low toxicity
Rabbit, Skin Irritation	Slightly irritating	Slightly irritating
Rabbit, eye irritation	Irritating	Slightly irritating
Skin Sensitisation	No evidence of sensitisation; RIPT human	No evidence of sensitisation; Guinea pig
Rabbit, repeat dose dermal toxicity	-	28 days: NOAEL >4.0 mL/kg bw/day 90 days: NOAEL >2.0 mL/kg bw/day
Mutagenicity – bacterial reverse mutation	Non mutagenic	-
Genotoxicity – in vivo mouse micronucleus assay	Non genotoxic	-

[1]Date source: CIR (1995);
[2]Data source: CIR (1982).

Toxicokinetics, metabolism and distribution.
While passive diffusion of the notified polymer across the gastrointestinal (GI) tract and dermal absorption may occur, it is expected to be limited by the likely low water solubility (measured: ≤5 g/L at 20 ºC; calculated: 5.1×10^{-9} g/L), high partition coefficient (calculated: Log Pow = 9.5 at 25 ºC) and relatively high molecular weight (Mn ≥500 Da) of the notified polymer.

Acute toxicity.
Structurally similar analogues of the notified polymer are reported to be of low acute oral and dermal toxicity. Acute inhalation toxicity data were not provided for the notified polymer. However, the notified polymer is expected to have a low vapour pressure, therefore inhalation of vapour is not anticipated.

Irritation and Sensitisation.
The notified polymer was predicted to be non-irritating to the skin and minimally irritating to the eye, based on the results from *in vitro* assays that are not currently validated for regulatory purposes. Studies conducted on analogues of the notified polymer indicate that the polymer may be slightly irritating to the eye and slightly irritating to the skin.

The notified polymer and one analogue chemical showed no sensitisation in human repeat insult patch tests. The other analogue of the notified polymer was not a skin sensitiser in guinea pigs.

Based on these studies, it is expected that the notified polymer may have some slight irritation properties but would not be a skin sensitiser.

Repeated Dose Toxicity.
No repeat dose toxicity data were provided for the notified polymer. 90-day and 28-day repeat dose dermal toxicity studies in rats established NOAELs of >2 mL/kg bw/day and >4 mL/kg bw/day, respectively for an analogue of the notified polymer.

Mutagenicity.

No genotoxicity data were provided for the notified polymer. An analogue of the notified polymer was not mutagenic in a bacterial reverse mutation study and was not clastogenic in an *in vivo* mouse micronucleus assay.

Health hazard classification
Based on the limited information provided (non-validated studies and data for analogues without PPG moieties), 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
Reformulation
The notified polymer will potentially be handled by workers at up to 100% concentration as imported, and at ≤10% concentration in end-use products. The greatest risk that may be expected with the handling of the notified polymer in concentrated form is potential irritating effects (particularly to the eye). Therefore, precautionary control measures should be taken, including the use of automated processes and PPE, to minimise worker exposure to the polymer in a concentrated form (as introduced for reformulation processes). Provided such controls are in place, the risk to the health of workers from use of the notified polymer is not considered to be unacceptable.

End-Use
Beauty care professionals will handle the notified polymer at ≤10% concentration in cosmetic products, similar to public use. Therefore, the risk for beauty care professionals who regularly use products containing the notified polymer is expected to be of a similar or lesser extent than that experienced by members of the public who use such products on a regular basis.

Based on the information available, the risk to workers associated with use of the notified polymer at ≤10% concentration in cosmetic products is not considered to be unacceptable.

6.3.2. Public health
At the proposed use concentration of up to 10% notified polymer in rinse-off and leave-on cosmetic products, acute toxicity effects (such as skin and eye irritation) are not expected. Given a 90-day repeat dose dermal toxicity study on a structurally similar analogue established an NOAEL of >2.0 mL/kg bw/day, quantitative risk assessment is not considered to be required to estimate the Margin of Exposure (MoE) for combined uses of cosmetics containing the notified polymer.

Therefore, when used in the proposed manner, the risk to the public associated with the use of the notified polymer at up to 10% concentration in rinse-off and leave-on 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 polymer will be imported as a component of finished cosmetic products or as a raw material for local reformulation. An insignificant quantity of the notified polymer is expected to be released to landfill as residue in containers and released to sewer from the cleaning of blending equipment.

Accidental spills during transport or reformulation are expected to be collected with inert material and disposed of to landfill.

RELEASE OF CHEMICAL FROM USE
The notified polymer is a component in rinse-off and leave-on cosmetic products. Therefore, it is expected that the majority of the imported quantity of notified polymer will be released to sewer.

RELEASE OF CHEMICAL FROM DISPOSAL
Residue of the notified polymer in the empty containers (3%) is likely either to share the fate of the container

and be disposed of to landfill, or to be washed to sewer when containers are rinsed before recycling.

7.1.2 Environmental fate

No environmental fate data were submitted. However, the notified polymer is predicted to be not readily biodegradable by modules of the estimation program EPI suite (v4.10) (US EPA, 2009). The majority of the notified polymer will be disposed of to sewer, where it is likely to partition to the sludge due to its estimated high log K_{oc} (5.8). Sludge containing the notified polymer may be disposed of to landfill or used for soil remediation. Notified polymer in sludge, soil or landfill is expected to be immobile and to degrade slowly through biotic and abiotic processes to form water and oxides of carbon. Although the notified polymer has a moderate molecular weight and a high calculated partition coefficient (log K_{ow} = 9.5), calculations with EPI suite (v4.0) (US EPA, 2009) indicate a low bioconcentration potential (log BCF = 2.3).

7.1.3 Predicted Environmental Concentration (PEC)

Assuming that most of the notified polymer will be washed into the sewer, the following Predicted Environmental Concentration (PEC) in sewage effluent on a nationwide basis was calculated.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	1,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of polymer released to sewer	1,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	2.74	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:	0.65	µg/L
PEC - Ocean:	0.06	µg/L

The notified polymer is predicted to partition to sludge, hence the removal of >83% of the notified polymer from influent by sewage treatment plant (STP) processes is expected (Simple Treat; European Commission, 2003). However, in this worst case model, the majority of the notified polymer is assumed to be released in effluent. STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m^2/year (10 ML/ha/year). The notified polymer in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m^3). Using these assumptions, irrigation with a concentration of 0.647 µg/L may potentially result in a soil concentration of approximately 4.316 µg/kg. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated irrigation, the concentration of the notified polymer in the applied soil in 5 and 10 years may be approximately 21.58 µg/kg and 43.16 µg/kg, respectively. However, due to the absorptive characteristics of the notified polymer, these calculated values represent maximum concentrations only.

7.2. Environmental effects assessment

No ecotoxicity data were submitted. The notified polymer is not expected to be bioavailable based on its very high predicted partition coefficient (log K_{ow} = 9.5). Therefore, no effects on aquatic biota are predicted for the notified polymer at its water saturation concentration (EPI suite (v4.0) (US EPA 2009). Classification should only be based on toxic responses observed in the soluble range and, therefore, the notified polymer cannot be formally classified under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009).

7.2.1 Predicted No-Effect Concentration

A PNEC has not been calculated as the notified polymer is not expected to be bioavailable, based on its estimated log K_{ow} of 9.5, and is predicted to have no effect on aquatic biota at its water saturation concentration (EPI suite (v4.0), (US EPA 2009).

7.3. Environmental risk assessment

A risk quotient (PEC/PNEC) for the notified polymer was not calculated as a PNEC was not derived. However, the notified polymer is likely to have very limited aquatic exposure based on the expected efficient removal of the polymer from waste water by sorption to sewage sludge. The notified polymer is also not expected to be bioavailable to aquatic organisms in surface waters based on its intrinsic hydrophobicity. Therefore, when used as proposed the notified polymer is not expected to pose a risk to the environment.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the limited information 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
Based on the reported use pattern, the notified polymer is not considered to pose an unacceptable risk to the environment.

Recommendations

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer during reformulation processes:
  - Automated processes, where possible

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer during reformulation processes:
  - Avoid contact with eyes and skin

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer during reformulation processes:
  - Overalls, gloves and goggles

  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 *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.

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(1) of the Act; if
- the importation volume exceeds one tonne per annum notified chemical;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the polymer has changed from a component of rinse-off and leave-on cosmetic and personal care products at ≤10% concentration, or is likely to change significantly;
- the polymer has begun to be manufactured 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 the notified polymer and 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 ≤5 g/L at 20 ºC.

Method	Approximately 0.5 g of the test polymer was mixed with 49.5 g of water in a beaker and stirred with magnetic bar for 15 minutes. The mixture was transferred to a burette and allowed to stand for 2 hours for phase separation. A 1 mL sample from the bottom water layer was weighed and dried (105 ºC, 2 h), in duplicate. The average non-volatile matter value was calculated and expressed in weight percent which is equivalent to concentration of the notified polymer in 100 g of water. The solubility of the notified polymer was reported as 0.5 wt% (5 g/L) maximum in water.
Remarks	As the summary report did not provide observations on the quality of the 1 mL water sample or the extent of phase separation these results should be treated with caution. The water solubility of 5.1×10^{-9} g/L was also calculated by WSKOW (v1.41) US EPA (2009) and the notified polymer is deemed to be within domain of this model. The low estimated water solubility is consistent with the predominantly hydrophobic structure of the notified polymer.
Test Facility	ARCH (2010)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Irritation – skin – *in vitro*

TEST SUBSTANCE: Notified polymer

METHOD: Dermal Irritection assay (non-validated test method)

Remarks - Method: This *in vitro* method is designed to mimic the protein alterations that are produced when irritants are applied to the skin. The general protocol involves application of the test substance to a synthetic biobarrier (composed of a semi-permeable membrane) that is coated with a dye-containing keratin-collagen matrix. The sample then permeates through the barrier and gradually interacts with a globulin/protein solution.

Irritant chemicals disrupt the ordered keratin/collagen structure and result in dye release. In addition, irritants induce changes in the protein conformations in the solution. The extent of dye release and denaturation may be determined spectrophotometrically at 450 nm. Comparison of the measurements obtained with standard values allows calculation of the Human Irritancy Equivalent (HIE) score. HIE≤0.9 = predicted non-irritant; 0.9<HIE≤1.2 = non-irritant/irritant; 1.2<HIE≤5 = irritant.

RESULTS

Dose Applied (µL)	*HIE Score*	*Predicted dermal irritancy*
25	0.21	Non-irritant
50	0.18	Non-irritant
75	0.17	Non-irritant
100	0.14	Non-irritant
125	0.11	Non-irritant

CONCLUSION: The notified polymer is predicted to be non-irritating to the skin.

TEST FACILITY: Bioscreen (2006)

B.2. Irritation – eye – *in vitro*

TEST SUBSTANCE: Notified polymer

METHOD: Ocular Irritection assay (non-validated test method)

Remarks - Method: This *in vitro* method is designed to mimic the protein alterations that are produced when irritants are applied to the cornea. Following application of the test substance to a synthetic biobarrier (composed of a semi-permeable membrane), it permeates through the barrier and gradually interacts with a globulin/protein solution.

Irritants induce changes in the protein conformations in the solution. The extent of denaturation and disaggregation may be determined spectrophotometrically at 405 nm. Comparison of the measurements obtained with standard values allows calculation of the Irritection Draize Equivalent (IDE) score. IDE≤12.5 = predicted minimal irritant; 12.5<IDE≤30 = mild irritant; 30<IDE≤51 = moderate irritant; 51<IDE≤80 = severe irritant.

RESULTS

Dose Applied (µL)	*IDE Score*	*Predicted dermal irritancy*
25	6.0	Minimal irritant
50	6.3	Minimal irritant
75	6.8	Minimal irritant

Dose Applied (µL)	*IDE Score*	*Predicted dermal irritancy*
100	7.9	Minimal irritant
125	9.1	Minimal irritant

CONCLUSION The notified polymer is predicted to be minimally-irritating to the eye.

TEST FACILITY Bioscreen (2006)

B.3. Skin sensitisation – human volunteers

TEST SUBSTANCE Notified polymer

METHOD Repeated insult patch test with challenge

Study Design Induction Procedure: Patches with 0.2 mL/0.2 g of the test material were applied 3 times per week (Monday, Wednesday and Friday) for a total of 9 applications. Patches were removed after 24 h. The sites were evaluated and scored prior to application of the next patch (in most instances, approximately 24 hours after removal).
Rest Period: 10-14 days
Challenge Procedure: A patch (as above) was applied to each subject on a previously unexposed site. Reactions were scored 24 and 48 hours post-application.

Study Group 14 M, 40 F; age range 20-65 years

Vehicle None

Remarks - Method Occluded

RESULTS

Remarks - Results No adverse reactions were noted. One subject was absent on application date and was discontinued.

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

TEST FACILITY AMA (2000)

BIBLIOGRAPHY

AMA (2000) 50 Human Subject Repeat Insult Patch Test Skin Irritation/Sensitization Evaluation (June, 2000), New City, U.S.A., AMA Laboratories, Inc. (Unpublished report submitted by the notifier).

ARCH (2010) Liquiwax PolyNH water solubility test (19 October, 2010). Tyler Place South Plainfield, USA, Arch Personal Care Products (Unpublished report submitted by the notifier).

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