File No.: LTD/2113

December 2019

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Siloxanes and Silicones, 3-[3-(diethylmethylammonio)-2-hydroxypropoxy]propyl Me, di-Me, Me stearyl, chlorides (INCI Name: Stearyl Dimethicone PG-Diethonium Chloride)

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (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 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 and Energy.

This Public Report is 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

TABLE OF CONTENTS

SUMMARY

The following details will be published in the NICNAS *Chemical Gazette:*

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/2113	Colgate-Palmolive Pty Ltd	Siloxanes and Silicones, 3-[3-(diethylmethylammonio)-2-hydroxypropoxy]propyl Me, di-Me, Me stearyl, chlorides (INCI Name: Stearyl Dimethicone PG-Diethonium Chloride)	ND*	< 15 tonnes per annum	Cosmetic ingredient

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard Classification
Based on the available information, the notified polymer cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia.

Human health risk assessment
Under the conditions of the occupational settings described, the notified polymer is not considered to pose an unreasonable risk to the health of workers.

When used in the proposed manner, the notified polymer is not considered to pose an unreasonable risk to public health.

Environmental Risk Assessment
Based on the assumed low hazard and reported use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified polymer during reformulation processes:
  - Enclosed/automated processes
  - Adequate general ventilation

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer during reformulation processes:
  - Avoid contact with skin and eyes
  - Avoid inhalation of aerosols

- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer during reformulation processes:
  - Impervious gloves
  - Safety glasses
  - Protective clothing

- Respiratory protection, if inhalation exposure may occur

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

- A copy of the SDS should be easily accessible to employees.

- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by physical containment, collection and subsequent safe disposal.

Disposal

- Where reuse or recycling are not appropriate, dispose of the notified polymer in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

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 polymer 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 polymer has a number-average molecular weight of less than 1000 g/mol;
- the concentration of the notified polymer exceeds, or is intended to exceed, 5% in cosmetic products;
- the notified polymer is proposed to be used in aerosol cosmetic spray products that are capable of generating respirable aerosols with $d_{ae} < 10$ µm during end use.

or

(2) Under Section 64(2) of the Act; if
- the function or use of the polymer has changed from a cosmetic ingredient , or is likely to change significantly;
- the amount of polymer being introduced has increased, or is likely to increase, 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.

Safety Data Sheet
The SDS of products containing the notified polymer provided by the notifier were reviewed by NICNAS. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Colgate-Palmolive Pty Ltd (ABN: 79 002 792 163)
Level 14, 345 George Street
SYDNEY NSW 2000

NOTIFICATION CATEGORY
Limited: Synthetic polymer with Mn ≥ 1,000 g/mol

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details exempt from publication include: specific other names, molecular and structural formulae, molecular weight, analytical data, degree of purity, polymer constituents, residual monomers, impurities, additives/adjuvants, import volume and identity of manufacturer.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Schedule data requirements are varied for all physical and chemical properties except for water solubility.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Stearyl Dimethicone PG-Diethonium Chloride (INCI Name)

CAS NUMBER
1311393-70-0

CHEMICAL NAME
Siloxanes and Silicones, 3-[3-(diethylmethylammonio)-2-hydroxypropoxy]propyl Me, di-Me, Me stearyl, chlorides

OTHER NAME(S)
Stearyl Dimethicone PG-Diethylmonium Chloride

MOLECULAR FORMULA
Unspecified

MOLECULAR WEIGHT
Number average molecular weight (Mn) is > 1,000 g/mol.

ANALYTICAL DATA
Reference FT-IR, and GPC, spectra were provided.

ANALOGUES

Analogue	CAS Number	Known as	MW (g/mol)
Dimethicone	9006-65-9	Polydimethylsiloxane	≥ 236.5

3. COMPOSITION

DEGREE OF PURITY
> 65%

DEGRADATION PRODUCTS
The notifier stated that the notified polymer is stable and not known to degrade under normal usage conditions.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Clear to hazy yellow liquid

Property	*Value*	*Data Source/Justification*
Glass Transition Temperature	-64.68 °C	Measured
Boiling Point	Not determined	Expected to decompose prior to boiling based on high molecular weight
Density	Not determined	The polymer is a solution in ethanol
Vapour Pressure	Not determined	Expected to be low based on high molecular weight
Water Solubility	< 0.25 g/L at 20 °C	Measured
Hydrolysis as a Function of pH	Not determined	Contains potentially hydrolysable functionalities, but not expected to hydrolyse under environmental pH (4-9)
Partition Coefficient (n-octanol/water)	Not determined	Expected to partition to the organic phase due to the low water solubility
Adsorption/Desorption	Not determined	Expected to partition to soil due to low water solubility
Dissociation Constant	Not determined	Cationic polymer in salt form
Flash Point	29 °C*	SDS
Flammability	Not determined	Imported product contains flammable solvent
Autoignition Temperature	Not determined	Imported product contains flammable solvent
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties.
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidising properties.

* Polymer in ethanol

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

Reactivity
The notified polymer is expected to be stable under normal conditions of use.

Physical Hazard Classification
Based on the limited physico-chemical data depicted in the above table, the notified polymer is not recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will not be manufactured in Australia. It will be imported at < 80% concentration for reformulation, or imported in end-use cosmetic products at ≤ 5% concentration.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 15	< 15	< 15	< 15	< 15

PORT OF ENTRY
Sydney, Melbourne

TRANSPORTATION AND PACKAGING
The product containing the notified polymer will be imported in metal pails (20 kg net). The formulated end use products containing the notified polymer will be contained in bottles or tubes up to one litre in size. The imported and end use products containing the notified polymer will be transported within Australia by road.

USE
The notified polymer will be used as a component of leave on and rinse off cosmetic products at ≤ 5% concentration, including aerosol spray products such as deodorant and hair sprays.

OPERATION DESCRIPTION

Reformulation
The reformulation procedure will likely vary depending on the nature of the formulated products, and may involve both automated and manual transfer steps. However, in general, it is expected that the reformulation processes will involve blending operations that will be highly automated and use closed systems with adequate ventilation, followed by automated filling (using sealed delivery systems) of the reformulated products into containers of various sizes.

End-use
The finished cosmetic products containing the notified polymer at ≤ 5% concentration will be used by consumers and professionals such as beauticians and hairdressers. Depending on the nature of the product, application of products could be by hand, sprayed or through the use of an applicator.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and storage	4	12
Professional compounder	8	12
Chemist	3	12
Packers (dispensing & capping)	8	12
Professional users – (e.g. hairdressers and beauty salon workers)	Unspecified	Unspecified

EXPOSURE DETAILS

Transport and storage
Transport and storage workers may come into contact with the notified polymer at < 80% concentration, only in the event of an accidental rupture of containers.

Reformulation
During reformulation into cosmetic products, dermal, ocular and inhalation exposure of workers to the notified polymer at < 80% concentration may occur. Exposure is expected to be minimised through the use of exhaust ventilation and/or automated/enclosed systems as well as through the use of personal protective equipment (PPE) such as coveralls, eye protection, impervious gloves and respiratory protection (when appropriate) as stated by the notifier.

Professional end-users
Exposure to the notified polymer in end-use products at ≤ 5% concentration may occur in professions where the services provided involve the application of cosmetic products to clients (e.g. hairdressers and workers in beauty salons). The principal route of exposure will be dermal, while ocular and inhalation exposure are also possible. Such professionals may use some 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 the products containing the notified polymer (see section 6.1.2).

6.1.2. Public Exposure

There will be widespread and repeated exposure of the public to the notified polymer at ≤ 5% concentration through daily use of a wide range of cosmetic products. The principal route of exposure will be dermal, while ocular and inhalation exposure are also possible, particularly from aerosol products.

6.2. Human Health Effects Assessment

Only *in vitro* eye irritation data was submitted for the notified polymer. For details of the study, refer to Appendix B.

Endpoint	*Result and Assessment Conclusion*
Eye irritation (*in vitro* HET-CAM at 10%)	non-irritating

* HET-CAM: Hen's Egg Test – Chorioallantoic Membrane

Toxicokinetics

No information on the toxicokinetics of the notified polymer was provided. For dermal absorption, molecular weights below 100 g/mol are favourable for absorption and molecular weights above 500 g/mol do not favour absorption (ECHA, 2017). Based on the high molecular weight (> 1,000 g/mol) of the notified polymer and low percentage (< 3%) of low molecular weight species (< 500 g/mol), dermal absorption is expected to be limited. Analogous dimethicone substances have been shown to have minimal gastro-intestinal and dermal absorption in animals and humans (Nair B and Elmore AR, 2003).

Acute Toxicity

Dimethicone polymers were found to be of low acute oral and dermal toxicity (Nair B and Elmore AR, 2003). Acute inhalation toxicity studies conducted with dimethicone, methicone and vinyldimethicone indicated a low level of toxicity in a range of different animal models. However, when administered to rats for 4 hours via whole body inhalation, aerosolised hexyl methicone with a mass median aerodynamic diameter (MMAD) of < 0.3 µm had a LC50 of 1.8 mg/L (combined sexes) (Nair B and Elmore AR, 2003).

Irritation and Sensitisation

The notified polymer was predicted to be non-irritating to eyes at 10% concentration in a HET-CAM test. The study author indicated that historical studies showed the chorioallantoic membrane (CAM) of the hen's egg is more sensitive to liquid irritants than the rabbit eye. As such, the 10% concentration was tested to simulate a 20% dose to rabbit eyes.

Dimethicone polymers have been shown to have minimal potential for skin and eye irritation and were not sensitising in animal studies and in a human repeated insult patch test (HRIPT) (Nair B and Elmore AR, 2003).

The notified polymer contains a quaternary ammonium functional group that is known to be a structural alert for skin corrosion and sensitisation (Barrett *et al*., 1994; Hulzebos *et al*., 2005). The potential for skin sensitisation is expected to be limited due to the high molecular weight of the notified polymer. However, the potential for irritation cannot be totally ruled out.

Repeated Dose Toxicity

Dimethicone polymers were found to be of low oral and dermal toxicity after repeated exposure (Nair B and Elmore AR, 2003).

Mutagenicity/Genotoxicity and Carcinogenicity

Several (*in vitro* and *in vivo*) genotoxicity studies performed on dimethicone showed no indication of mutagenic or genotoxic effects (Nair B and Elmore AR, 2003). Dimethicone was also tested in mice for carcinogenicity following repeated oral or dermal exposure, with no increase in the number of neoplasms observed (Nair B and Elmore AR, 2003).

Toxicity for Reproduction

Dimethicone was reported to produce a significant reduction in the average seminal vesicle to body weight ratio, but not in the absolute organ weight and only for one of three dimethicone samples tested (Nair B and Elmore AR, 2003). No developmental or reproductive effects were seen in female animals or their offspring following oral or dermal administration of dimethicone in a number of reproductive studies (Nair B and Elmore AR, 2003).

Health Hazard Classification
Based on the available information, the notified polymer cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia.

6.3. Human Health Risk Characterisation
Based on the available information, the notified polymer may have the potential to cause skin and eye irritation. Systemic toxicity is not expected via the dermal route, however inhalation toxicity cannot be ruled out.

6.3.1. Occupational Health and Safety

Reformulation
Dermal, ocular and inhalation exposure of workers to the notified polymer at < 80% concentration may occur during reformulation. The use of personal protective equipment (PPE) such as coveralls, eye protection, impervious gloves and respiratory protection (as appropriate), and engineering controls including automated/enclosed blending processes and local exhaust ventilation, as stated by the notifier, is expected to minimise exposure to workers.

Therefore, under the occupational settings described, the risk to the health of workers from use of the notified polymer is not considered to be unreasonable.

End use
Workers involved in professions where the services provided involve the application of cosmetic products containing the notified polymer to clients (such as beauticians and hairdressers) may come into contact with the notified polymer at ≤ 5% concentration. Such professionals may use PPE to minimise repeated exposure, and good hygiene practices are expected to be in place. If PPE is used, the risk to such workers is expected to be of a similar or lesser extent than that experienced by consumers using the products containing the notified polymer (for details of the public health risk assessment, see Section 6.3.2).

6.3.2. Public Health
Cosmetic products containing the notified chemical at ≤ 5% concentration will be available to the public. The principal route of exposure will be dermal, while ocular and inhalation exposure are also possible, particularly from aerosol products.

The notified polymer may have the potential to cause skin and eye irritation. Given the low end use concentration, irritation effects are not expected.

Systemic toxicity is not expected via the dermal route, however inhalation toxicity cannot be ruled out based on adverse effects observed in one acute inhalation toxicity study with small aerosol particles (MMAD < 0.3 µm). Droplets/particles with an aerodynamic equivalent diameter (d_{ae}) > 10 µm may enter the nasopharyngeal region through the nose/mouth or pass through the larynx to enter the trachea, bronchi and bronchioles. In these regions of the respiratory tract, mucus-secreting and ciliated cells form a protective mucociliary blanket that carries deposited droplets/particles to the throat to be sneezed or spit out, or swallowed. There is also scientific consensus that healthy people are able to clear particles with d_{ae} > 7 µm from the nasopharyngeal and bronchial regions within 24 hours through mucociliary action (CIR, 2012). However, droplets/particles with d_{ae} < 10 µm may reach the pulmonary region of the lung. In the pulmonary region, the clearance of water insoluble particles is mediated primarily by alveolar macrophages, and is slow and limited (CIR, 2012). Therefore, to avoid the potential for lung overloading effects, the notified polymer should not be used in spray products that are capable of generating respirable aerosols with d_{ae} < 10 µm during use. It has been proposed that the notified polymer may be used in spray products. Based on a CIR report (CIR, 2012), both pump sprays and propellant sprays (also called "aerosol sprays") produce aerosols, but the aerosols from pump sprays have much smaller fractions of respirable droplets/particles than aerosols from propellant sprays.

Therefore, provided that respirable aerosols containing the notified polymer are avoided, the risk to the public from use of the notified polymer at < 5% concentration in cosmetics via dermal and spray applications is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer is not manufactured in Australia. Release of the notified polymer at sites is expected to be limited to accidental spills during the transport, storage and product reformulation of the notified polymer. Reformulation sites are expected to utilise engineering controls to limit release into the environment, but the notifier estimates that 1% of the notified polymer will remain as residues from import containers, which will be washed to sewer after on-site treatment. Accidental spills and equipment washings are to be collected using absorbent materials placed in sealed containers, and disposed of according to local government regulations.

RELEASE OF CHEMICAL FROM USE

The majority of the notified polymer will primarily be rinsed into the sewer system as a part of its use in cosmetic products.

RELEASE OF CHEMICAL FROM DISPOSAL

A small proportion of the notified polymer may remain in the end use and bulk containers as residues, which are likely to be recycled or disposed of to landfill. The notifier expects this to account for 4% of the total import volume. During recycling of containers, residues containing the notified polymer are expected to be rinsed out with water and washed to sewer after on-site treatment.

7.1.2. Environmental Fate

No environmental fate data were submitted. The majority of the notified polymer will be washed into the sewer system as a part of its use in cosmetic products, where it is expected to be effectively removed by the sewage treatment plant (STP). Approximately 4% of the notified polymer may remain in the end use and bulk containers, which are either recycled or disposed of to landfill. The notified polymer is expected to eventually degrade into water and oxides of carbon, silicon, and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

A predicted environmental concentration (PEC) worst-case scenario has been calculated. It was assumed that 100% of the annual import quantity of the notified polymer is released to the sewer from cosmetics uses over 365 days/year, with no removal of the notified polymer by STP processes. The extent to which the notified polymer is removed from the effluent in STP processes based on the properties of the notified polymer has not been considered for the worst-case scenario.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	15,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	15,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	41.1	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	24.386	million
Removal within STP	0%	
Daily effluent production:	4,877	ML
Dilution Factor - River	1	
Dilution Factor - Ocean	10	
PEC - River:	8.43	µg/L
PEC - Ocean:	0.84	µg/L

7.2. Environmental Effects Assessment

No ecotoxicity data were submitted. The notified polymer contains cationic functionality with a Functional Group Equivalent Weight (FGEW) < 5,000 g/mol, and is therefore potentially harmful to aquatic organisms in environmental waters. However, due to the low water solubility, this effect is not expected to be significant. Due to the high molecular weight (MW > 1,000 g/mol), the notified polymer is not expected to be bioaccumulative.

7.2.1. Predicted No-Effect Concentration

A Predicted No-Effect Concentration (PNEC) was not calculated as no ecotoxicological endpoints were provided.

7.3. Environmental Risk Assessment

The notified polymer contains cationic functionality, which has the potential to cause harm in the environment. However, due to the low water solubility, the notified polymer is not expected to be harmful to aquatic organisms. Furthermore based on the cationic functionality it is expected to be efficiently removed from the sewage effluent in the STPs. Therefore, the notified polymer is not expected to reach ecotoxicologically significant concentrations in the environment.

Accordingly, based on the assumed low hazard and reported use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Glass Transition -64.68 °C

Method	American Society for Testing and Materials (ASTM) D3418-15 at a heating rate of 20 °C/min from -90 °C to 125 °C, and cooling rate of 10 °C/min using a Differential Scanning Calorimeter (DSC).
Remarks	The DSC has been calibrated according to ASTM E967-08(2014).
Test Facility	Cambridge (2019)

Water Solubility < 0.25 g/L at 20 °C

Method	In house method. Nominal concentrations of the notified polymer tested in distilled water.
Remarks	Test was completed by visual inspection only. Solutions with undissolved polymer presented as hazy.
Test Facility	Manufacturer (2019a)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Eye Irritation – *In Vitro* HET-CAM

TEST SUBSTANCE: Notified polymer (10% concentration)

METHOD: Determination of Ocular Irritation Potential Using the HET-CAM Test
Modification of method according to Kemper and Luepke (1986)

Vehicle: Not stated

Remarks – Method: The HET-CAM test is an alternative to Draize Test - Modified Kemper & Luepke Test.

White Leghorn eggs were incubated for 10 days at 37 °C. On the tenth day, the CAM was exposed by removing the outer shell and shell membrane. The inner egg membrane sac was wetted with physiological saline and the inner egg membrane removed to reveal the CAM. The test substance (0.3 mL) was applied onto the CAM of four eggs.

Johnson's baby shampoo and Head & Shoulders shampoo were used as positive controls.

The reactions of the CAM, the blood vessels, including the capillaries, and the albumin were examined and the following scores for irritant effects were applied as described below:

Effect	*Scores at time (min)*		
	0.5	2	5
Hyperaemia	5	3	1
Minimal Haemorrhage (Feathering)	7	5	3
Haemorrhage (obvious Leakage)	9	7	5
Coagulation and/or Thrombosis	11	9	7

Each reaction type can be recorded only once for each CAM. Scoring is according to the severity and time needed for the effect to occur. The earlier a symptom is recorded the higher the numerical value assigned to it. The maximum possible score per CAM is 32.

The recorded scores for every possible reaction were summed for each egg, with the average score for the tested eggs corresponding to the irritation index of the test substance as described below:

Mean score	*Irritation potential*
0 – 4.9	Practically none
5.0 – 9.9	Slight
10.0 – 14.9	Moderate
15.0 – 32.0	Severe

The study author indicated that historical studies showed the CAM of the hen's egg is more sensitive to liquid irritants than the rabbit eye. Therefore, 10% and 50% dilutions of the liquid test articles were used to simulate a 20% and 100% dose in a rabbit eye, respectively.

RESULTS

Test substance	*Mean scores*
Notified polymer (10%)	1.0
Johnson's Baby shampoo (50%)*	11.0
Head & Shoulders (50%)*	21.0

* Positive controls

Remarks – Results	No irritant effects were seen in CAMs exposed to the notified polymer at 10% concentration at the 0.5 minute observation. Hyperaemia was observed in one CAM treated with the notified polymer at the 2 minute observation and in one other at the 5 minute observation, the remaining two CAMs showed no evidence of irritation. Positive controls performed as expected confirming the validity of the test system.
CONCLUSION	The notified polymer at 10% concentration (equivalent to 20% concentration in rabbit eyes by the study author) is predicted to be non-irritating to the eye under the conditions of the test.
TEST FACILITY	Manufacturer (2019b)

BIBLIOGRAPHY

Barratt, M.D., Basketter, D.A., Chamberlain, M., Payne, M.P., Admans, G.D., Langowski, J.J. (1994) Development of an expert system rulebase for identifying contact allergens. Toxicology In Vitro. 8:837-839.

Cambridge (2019) Thermal Characterization (Study No. 813353-19, July, 2019). Mississauga, Ontario, Canada, Cambridge Materials Testing Limited (Unpublished report submitted by the notifier).

CIR (2012) CIR Precedents - Aerosols (September, 2012), Cosmetic Ingredient Review.

ECHA (2017) Guidance on Information Requirements and Chemical Safety Assessment Chapter R.7c: Endpoint specific guidance, June 2017, version 3.0. European Chemicals Agency, https://echa.europa.eu/documents/10162/13632/information_requirements_r7c_en.pdf.

Hulzebos, E., Walker, J.D., Gerner, I. and Schlegel, K. (2005) Use of structural alerts to develop rules for identifying chemical substances with skin irritation or skin corrosion potential. QSAR Combinatorial Science. 24:332-342.

Kemper, F.H. and Luepke, N.P. (1986). The HET-CAM Test: An Alternative to the Draize Test. FD Chem. Toxic. **24**, 495-496.

Nair, B., and Elmore, A.R., (2003) Final Report on the Safety Assessment of Stearoxy Dimethicone, Dimethicone, Methicone, Amino Bispropyl Dimethicone, Aminopropyl Dimethicone, Amodimethicone, Amodimethicone Hydroxystearate, Behenoxy Dimethicone, C24–28 Alkyl Methicone, C30–45 Alkyl Methicone, C30–45 Alkyl Dimethicone, Cetearyl Methicone, Cetyl Dimethicone, Dimethoxysilyl Ethylenediaminopropyl Dimethicone, Hexyl Methicone, Hydroxypropyldimethicone, Stearamidopropyl Dimethicone, Stearyl Dimethicone, Stearyl Methicone, and Vinyldimethicone, International Journal of Toxicology, 22(**Suppl. 2**):11–35.

Manufacturer (2019a) Water Solubility Determination of [Notified Chemical] (Study No. 20190703Sol1, October 2019). Toronto, Ontario, Manufacturer Corporation (Unpublished report submitted by the notifier).

Manufacturer (2019b) The Hen's Test – Utilizing the Chorioallantoic Membrane (HET-CAM) Final Report (Study No. V19-4766, July, 2019). Fairfield, New Jersey, United States of America, Manufacturer Corporation (Unpublished report submitted by the notifier).

United Nations (2009) Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 3rd revised edition. United Nations Economic Commission for Europe (UN/ECE), <http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html >