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June 2021

**AUSTRALIAN INDUSTRIAL CHEMICALS INTRODUCTION SCHEME (AICIS)**

# PUBLIC REPORT

## Siloxanes and Silicones, di-Me, hydroxy-terminated, polymers with 3-(trimethoxysilyl)-*N*-[3-(trimethoxysilyl)propyl]-1-propanamine

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals Act 2019* (the IC Act) and *Industrial Chemicals (General) Rules 2019* (the IC Rules) by following the *Industrial Chemicals (Consequential Amendments and Transitional Provisions) Act 2019* (the Transitional Act) and *Industrial Chemicals (Consequential Amendments and Transitional Provisions) Rules 2019* (the Transitional Rules). The legislations are Acts of the Commonwealth of Australia. The Australian Industrial Chemicals Introduction Scheme (AICIS) is administered by the Department of Health, and conducts the risk assessment for human health. The assessment of environmental risk is conducted by the Department of Agriculture, Water and the Environment.

This Public Report is available for viewing and downloading from the AICIS website. For enquiries please contact AICIS at:


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# SUMMARY

The following details will be published on our website:

| ASSESSMENT REFERENCE | APPLICANT(S) | CHEMICAL OR TRADE NAME | HAZARDOUS CHEMICAL | INTRODUCTION VOLUME | USE |
|---|---|---|---|---|---|
| LTD/2105 | Colgate-Palmolive Pty Ltd | Siloxanes and Silicones, di-Me, hydroxy-terminated, polymers with 3-(trimethoxysilyl)-*N*-[3-(trimethoxysilyl)propyl]-1-propanamine | ND* | < 15 tonnes per annum | Component of hair care products |

*ND = not determined

# CONCLUSIONS AND REGULATORY OBLIGATIONS

**Hazard Classification**
Based on the limited available information, the assessed polymer cannot be classified using 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 assessed polymer is not considered to pose an unreasonable risk to the health of workers.

When used in the proposed manner, the assessed 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 assessed 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 assessed polymer during reformulation:
  - Enclosed/automated processes, where possible
  - Local exhaust ventilation and/or appropriate extraction systems, where possible

- 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 assessed polymer during reformulation:
  - Avoid contact with skin and eyes
  - Avoid inhalation of aerosols or mists

- 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 assessed polymer during reformulation:
  - Impervious gloves
  - Safety glasses or goggles
  - Respiratory protection if inhalation exposure may occur
  - Protective clothing

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 assessed 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 assessed polymer should be handled by physical containment, collection and subsequent safe disposal.

Disposal

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

**Regulatory Obligations**

*Specific Requirements to Provide Information*
This risk assessment is based on the information available at the time of the application. The Executive Director may initiate an evaluation of the chemical based on changes in certain circumstances. Under section 101 of the IC Act the introducer of the assessed chemical has post-assessment regulatory obligations to provide information to AICIS when any of these circumstances change. These obligations apply even when the assessed polymer is listed on the Australian Inventory of Industrial Chemicals (the Inventory).

Therefore, the Executive Director of AICIS must be advised in writing within 20 working days by the applicant or other introducers if:

- the final use concentration of the assessed polymer exceeds 4% in hair care products;
- the polymer has a number-average molecular weight of less than 1000 g/mol;
- the function or use of the polymer has changed from a component of hair care products, 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 Executive Director will then decide whether an evaluation of the introduction is required.

*Safety Data Sheet*
The SDS of a product containing the assessed polymer provided by the applicant was reviewed by AICIS. The accuracy of the information on the SDS remains the responsibility of the applicant.

# ASSESSMENT DETAILS

## 1. APPLICANT AND APPLICATION DETAILS

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

APPLICATION CATEGORY
Limited: Synthetic polymer with Mn greater than or equal to 1,000 g/mol

PROTECTED INFORMATION (SECTION 38 OF THE TRANSITIONAL ACT)
Data items and details taken to be protected information include: other name(s), molecular and structural formulae, molecular weight, analytical data, degree of purity, polymer constituents, residual monomers, impurities, import volume, identity of manufacturer and identity of test facilities.

VARIATION OF DATA REQUIREMENTS (SECTION 6 OF THE TRANSITIONAL RULES)
Schedule data requirements are varied for all physico-chemical endpoints.

PREVIOUS APPLICATION IN AUSTRALIA BY APPLICANT(S)
None

APPLICATION IN OTHER COUNTRIES
None

## 2. IDENTITY OF CHEMICAL

CAS NUMBER
189959-16-8

CHEMICAL NAME
Siloxanes and Silicones, di-Me, hydroxy-terminated, polymers with 3-(trimethoxysilyl)-*N*-[3-(trimethoxysilyl)propyl]-1-propanamine

OTHER NAME(S)
Amino bispropyl dimethicone (INCI name)

MOLECULAR WEIGHT
Number average molecular weight (Mn) is greater than 10,000 g/mol.

ANALYTICAL DATA
Reference IR spectra were provided.

## 3. COMPOSITION

DEGREE OF PURITY
Less than 50% in manufacturing mixture

## 4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: White liquid*

| *Property* | *Value* | *Data Source/Justification* |
|---|---|---|
| Melting Point/Freezing Point* | Less than 0 °C | SDS |
| Boiling Point* | Greater than 100 °C | SDS |
| Density* | 990 kg/m$^3$ at 25 °C | SDS |
| Vapour Pressure* | Less than 2.7 kPa at 20 °C | SDS |

| *Property* | *Value* | *Data Source/Justification* |
|---|---|---|
| Water Solubility | Dispersible and insoluble in water | SDS |
| Hydrolysis as a Function of pH | Not determined | Contains hydrolysable functionalities, but significant hydrolysis is not expected in the environmental pH range (4-9) |
| Adsorption/Desorption | Not determined | Expected to partition to soil and sludge based on estimated high molecular weight and potentially cationic functionality |
| Dissociation Constant | Not determined | Contains dissociable functionalities, but significant dissociation is not expected in the environmental pH range (4-9) |
| Flash Point | Not determined | Expected to be high based on the polymer structure |
| Autoignition Temperature | Not determined | Not expected to auto-ignite based on the polymer structure |
| Explosive Properties | Not determined | Contains no functional groups that imply explosive properties |
| Oxidising Properties | Not determined | Contains no functional groups that imply oxidising properties |

* Property of a mixture containing 30-60% assessed polymer

DISCUSSION OF PROPERTIES

*Reactivity*
The assessed 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 assessed 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 ASSESSED CHEMICAL (100%) OVER NEXT 5 YEARS
The assessed polymer will not be manufactured in Australia. It will be imported either in a formulation at < 50% concentration for reformulation into hair care products or in finished hair care products at up to 4% concentration.

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

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

PORT OF ENTRY
Sydney and Melbourne

TRANSPORTATION AND PACKAGING
The products containing the assessed polymer will be transported primarily by road to blenders in bulk packaging or to retail stores in packages suitable for retail sale.

USE
The assessed polymer will be used in leave-on and rinse-off hair care products (including aerosols) at up to 4% concentration.

OPERATION DESCRIPTION
The assessed polymer will be imported in a formulation at less than 50% concentration for reformulation into hair care products.

*Reformulation*
When reformulated, the assessed polymer will be blended into end-use hair care products at customer sites. Procedures will vary depending on the nature of the consumer product being formulated. Both manual and automated steps will likely be involved. For example, a chemist will sample and test the assessed polymer for QA purposes manually; a compounder will weigh an appropriate amount of the formulation containing the assessed polymer into a container and then add the amount directly into a mixing tank, with periodic sampling for quality control purposes also carried out during the reformulation process. Automated processes may include mixing and filling of end-use containers with finished products.

*End-use*
Finished hair care products containing the assessed polymer at up to 4% concentration will be used by the public and may also be used by professionals such as hairdressers and workers in hair salons. Depending on the nature of the product, these could be applied by hand or by using an applicator (including spray 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, warehouse and retail | 4 | 12 |
| Compounding | 8 | 12 |
| Quality control | 3 | 12 |
| Packaging | 8 | 12 |
| Professional users – (e.g. hairdressers and hair salon workers) | Unspecified | Unspecified |

EXPOSURE DETAILS

*Transport and storage*
Transport and storage workers may come in contact with the assessed polymer either at < 50% concentration in imported products or at up to 4% concentration in consumer products, only in the event of an unlikely accidental rupture of containers.

*Reformulation*
During reformulation into consumer products, dermal, ocular and inhalation exposure of workers to the assessed polymer at < 50% concentration may occur. Exposure will be minimised through the use of local exhaust ventilation, automated and enclosed systems and personal protective equipment (PPE) (including coveralls, eye protection, impervious gloves and respiratory protection if inhalation exposure may occur), as anticipated by the applicant.

*End use*
Exposure to the assessed polymer in end-use products at up to 4% concentration may occur in professions where the services provided involve the application of hair care products for clients (e.g. hair dressers and workers in hair salons). The principal route of exposure will be dermal, while ocular and inhalation exposure is 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 products containing the assessed polymer.

#### 6.1.2. Public Exposure
Although there will be widespread and repeated contact of the public with the assessed polymer through the use of a variety of hair care products, systemic exposure is expected to be limited due to limited dermal absorption given the high molecular weight of the assessed polymer (estimated to be greater than 10,000 g/mol with estimated 0% low molecular species of less than 1000 g/mol). Inhalation of vapour is not expected as the assessed polymer has low vapour pressure. Inhalation exposure to aerosols is not expected to be of concern given the assessed polymer is present in aerosol formulations at low concentrations (up to 4%). Furthermore, CIR reported that

expected particle sizes of dimethicone polymers in aerosol formulations would be primarily be in the range of 60-80 µm with < 1% would be under 10 µm (an upper limit for respirable particles) (CIR, 2003).

### 6.2. Human Health Effects Assessment

No toxicity studies were submitted for the assessed polymer. The results from investigations conducted on a formulation containing 30-60% assessed polymer are summarised in the following table. For details of the studies, refer to Appendix A. As the assessed polymer is a dimethicone polymer (dimethicone is the primary monomer), data on the dimethicone from two CIR reports (CIR, 2003 and CIR, 2021) were also used to derive hazard conclusion for the assessed polymer.

| *Endpoint* | *Result and Assessment Conclusion* |
|---|---|
| Acute oral toxicity – rat* | LD50 greater than 2000 mg/kg bw; low toxicity |
| Acute dermal toxicity – rat* | LD50 greater than 4000 mg/kg bw; low toxicity |
| Skin irritation – rabbit* | irritating |
| Eye irritation – *in vitro* isolated chicken eye test* | no prediction can be made |
| Eye irritation – rabbit* | irritating |
| Skin sensitisation – guinea pig, maximisation test* | evidence of sensitisation |
| Mutagenicity – bacterial reverse mutation* | non mutagenic |
| Mutagenicity – bacterial reverse mutation* | non mutagenic |

* Test substance was a mixture containing 30-60% assessed polymer

*Toxicokinetics*

No information on the toxicokinetics of the assessed polymer was provided. For dermal absorption, molecular weights below 500 g/mol are favourable for absorption and molecular weights above 1,000 g/mol do not favour absorption (ECHA, 2017). Based on the high molecular weight of the assessed polymer (estimated to be > 10,000 g/mol with estimated 0% low molecular species of < 1,000 g/mol), dermal absorption is expected to be limited.

*Acute Toxicity*

A formulation containing 30-60% assessed polymer has low acute oral toxicity (LD50 > 2,000 mg/kg bw) and low acute dermal toxicity (LD50 > 4,000 mg/kg bw) based on studies conducted in rats. The primary monomer of the assessed polymer (dimethicone) was not acutely toxic following oral, dermal (at 6-79% concentration) or inhalation exposure (CIR, 2003). Overall, the assessed polymer is expected to be low acute toxicity.

*Irritation*

A formulation containing 30-60% assessed polymer was found to be irritating to skin based on a study conducted in rabbits. It is likely that other ingredients in the formulation were irritating to skin as the primary monomer of the assessed polymer (dimethicone) was found to be a minimal skin irritant (CIR, 2003).

No prediction could be made for eye irritation of a formulation containing 30-60% assessed polymer in an *in vitro* bovine corneal opacity and permeability (BCOP) test while the formulation was found to be irritating to eyes in a study conducted in rabbits. It is likely that other ingredients in the formulation were irritating to eyes as the primary monomer of the assessed polymer (dimethicone) was found to be a mild to minimal eye irritant (CIR, 2003).

*Sensitisation*

A guinea pig maximisation test carried out on a formulation containing 30-60% assessed polymer showed evidence of skin sensitisation with 9/20 test animals displaying discrete, patchy erythema 24 hours after topical exposure to the test substance at 1% challenge concentration. However, the sensitisation effects were unlikely attributed to the assessed polymer as the primary monomer of the assessed polymer (dimethicone) (when tested undiluted and up to 79% concentration) was not a sensitiser in five assays (using mice and guinea pigs) and in a human repeat insult patch test when used as a negative and vehicle control (CIR, 2003; CIR 2021).

*Repeated dose toxicity*

The primary monomer of the assessed polymer (dimethicone) showed no adverse effects in mice and rats dosed orally for 90 days at concentrations up to 10% and in rabbits when applied dermally for 28 days (no-observed-adverse-effect level (NOAEL) = 1000 mg/kg bw/day) (CIR, 2003; CIR, 2021).

Rats administered with 0.1%, 0.3% or 1% dimethicone for 120 days showed changes in body weight or spleen weight in the animals treated at 1% concentration (CIR, 2021).

Rats administered with 0.3% dimethicone in the diet for two years were found to have changes in the ovaries and uterus and mild fatty changes in the liver and tubular epithelium of the kidneys while rats and rabbits administered with 1% dimethicone in the diet for up to one year did not show signs of systemic toxicity (CIR, 2021).

Test-substance related toxicological effects in rats administered with 100, 300 or 1000 mg/kg bw/day dimethicone in the diet for 12 months were limited to increased incidence of ocular opacities in females treated at 300 mg/kg bw/day, males treated at 1000 mg/kg bw/day and all treated males of the chronic recovery group (without dose correlation), supported by microscopic findings of keratitis and corneal dystrophy. The no observable effect level (NOEL) for systemic toxicity was established as 1000 mg/kg bw/day (CIR, 2021).

*Mutagenicity/Genotoxicity*
A formulation containing 30-60% assessed polymer was negative in two bacterial reverse mutation assays. The primary monomer of the assessed polymer (dimethicone) was also negative in all genotoxicity assays (CIR, 2003; CIR, 2021). Overall, the assessed polymer is expected to be non-genotoxic.

*Reproductive and developmental toxicity*
The primary monomer of the assessed polymer (dimethicone) was tested for reproductive and developmental toxicity orally in rats and dermally in rats, rabbits and monkeys. In some of the studies, treated males had significantly decreased body weight and/or decreased testes or seminal vesicles weights while no treatment-related adverse findings were noted in treated pregnant females or foetuses (CIR, 2003).

*Carcinogenicity*
The primary monomer of the assessed polymer (dimethicone) was negative in carcinogenicity assays conducted orally (tested at up to 5% concentration) in mice and rats and in a dermal (tested at an unknown concentration) carcinogenicity assay using mice (CIR, 2003; CIR, 2021).

***Health Hazard Classification***
Based on the limited available information, the assessed polymer cannot be classified using 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 assessed polymer is expected to be of low systemic toxicity, although risks following repeated exposure cannot be ruled out. Local effects such as skin and eye irritation are not expected at low end-use concentrations (up to 4%). Overall, the assessed polymer is considered safe as used in cosmetic formulations based on CIR opinions (CIR, 2003; CIR, 2021).

#### 6.3.1. Occupational Health and Safety

*Reformulation*
During reformulation, dermal, ocular and inhalation exposure of workers to the assessed polymer at less than 50% concentration may occur. It is stated by the applicant that engineering controls such as enclosed and automated processes and local ventilation will be implemented where possible, and appropriate PPE (coveralls, imperious gloves, eye protection and respiratory protection) will be used to limit worker exposure.

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

*End-use*
Workers involved in professions where the services provided involve the application of hair care products containing the assessed polymer to clients (*e.g.* hairdressers, beauty salon workers) may be exposed to the assessed polymer at up to 4% 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 various products containing the assessed polymer.

#### 6.3.2. Public Health
Hair care products containing the assessed chemical at up to 4% concentration will be available to the public. The main route of exposure is expected to be dermal and inhalation (if aerosol products are used), with some potential for accidental ocular or oral exposure.

The assessed polymer is considered safe as used in cosmetic formulations based on CIR opinions (CIR, 2003; CIR, 2021). The low end-use concentrations (up to 4%) are expected to further reduce the potential for systemic exposure and any local effects such as skin and eye irritation.

Therefore, based on the available information, the risk to the public associated with use of the assessed polymer at up to 4% concentration in hair care products 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 assessed polymer is not manufactured in Australia. Release of the assessed polymer at sites is expected to be limited to accidental spills during the transport, storage and product reformulation. Reformulation is expected to utilise engineering controls to limit release into the environment, but the applicant estimates that 1% of the assessed 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 assessed 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 assessed polymer may remain in the end use and bulk containers as residues, which are likely to be recycled or disposed of to landfill. The applicant expects this to account for 4% of the total import volume. During recycling of containers, residues containing the assessed 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 assessed 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 via partitioning to sludge by the STP. Approximately 4% of the assessed polymer may remain in the end use and bulk containers, which are either recycled or disposed of to landfill. The assessed 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 volume of the assessed polymer is released to the sewer from cosmetic uses over 365 days/year, with no removal of the assessed polymer by sewage treatment plant (STP) processes. The extent to which the assessed polymer is removed from the effluent in STP processes based on the properties of the assessed polymer has not been considered for the worst-case scenario.

| Predicted Environmental Concentration (PEC) for the Aquatic Compartment | | |
|---|---|---|
| Total Annual Import 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: | 41.10 | kg/day |
| Water use | 200 | 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 |

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 assessed 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 8.426 µg/L may potentially result in a soil concentration of approximately 56.18 µg/kg. Assuming accumulation of the assessed polymer in soil for 5 and 10 years under repeated irrigation, the concentration of the assessed polymer in the applied soil in 5 and 10 years may be approximately 0.28 mg/kg and 0.56 mg/kg, respectively.

### 7.2. Environmental Effects Assessment

No ecotoxicological data were submitted for the assessed polymer. The assessed polymer contains potentially cationic functionality with the estimated Functional Group Equivalent Weight (FGEW) greater than 5,000 g/mol, which indicates that reactive functional groups in the polymer are substantially diluted. Therefore, the assessed polymer is not expected to be harmful to aquatic organisms in environmental waters. Furthermore, due to the high molecular weight (MW > 1,000 g/mol), the assessed 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

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

# APPENDIX A: TOXICOLOGICAL INVESTIGATIONS

## A.1. Acute Oral Toxicity – Rat

| | |
|---|---|
| TEST SUBSTANCE | A formulation containing 30-60% assessed polymer |
| METHOD | OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method (2001) |
| Species/Strain | Rat/Wistar |
| Vehicle | None |
| Remarks – Method | No significant protocol deviations |

RESULTS

| *Group* | *Number and Sex of Animals* | *Dose (mg/kg bw)* | *Mortality* |
|---|---|---|---|
| 1 | 3 F | 2000 | 0/3 |
| 2 | 3 F | 2000 | 0/3 |

| | |
|---|---|
| LD50 | Greater than 2000 mg/kg bw |
| Signs of Toxicity | No signs of systemic toxicity were noted. |
| Effects in Organs | No abnormalities were noted at necropsy. |
| Remarks – Results | All animals showed expected body weight gains. |
| CONCLUSION | The test substance is of low acute toxicity via the oral route. |
| TEST FACILITY | Protected business information (1) |

## A.2. Acute Dermal Toxicity – Rat

| | |
|---|---|
| TEST SUBSTANCE | A formulation containing 30-60% assessed polymer |
| METHOD | OECD TG 402 Acute Dermal Toxicity – Limit Test (1987) |
| Species/Strain | Rat/Wistar |
| Vehicle | None |
| 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 F, 5 M | 4000 | 0/10 |

| | |
|---|---|
| LD50 | Greater than 4000 mg/kg bw |
| Signs of Toxicity – Local | No signs of local skin effects were reported. |
| Signs of Toxicity – Systemic | No signs of systemic toxicity were observed. |
| Effects in Organs | No abnormalities were noted at necropsy. |
| Remarks – Results | All animals showed expected body weight gains. |
| CONCLUSION | The test substance is of low acute toxicity via the dermal route. |
| TEST FACILITY | Protected business information (2) |

## A.3. Skin Irritation – Rabbit

| | |
|---|---|
| TEST SUBSTANCE | A formulation containing 30-60% assessed polymer |
| METHOD | OECD TG 404 Acute Dermal Irritation/Corrosion (2002) |
| Species/Strain | Rabbit/New Zealand White |
| Number of Animals | 1 F, 2 M |
| Vehicle | None |
| Observation Period | 14 days |

| | |
|---|---|
| Type of Dressing | Semi-occlusive |
| Remarks – Method | No significant protocol deviations |

RESULTS

| *Lesion* | *Mean Score* Animal No.* | | | *Maximum Value* | *Maximum Duration of Any Effect* | *Maximum Value at End of Observation Period* |
|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | | | |
| *Erythema/Eschar* | 2 | 2 | 2 | 2 | Less than 7 days | 0 |
| *Oedema* | 0.67 | 1 | 1 | 1 | Less than 14 days | 0 |

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

| | |
|---|---|
| Remarks – Results | Well defined erythema (grade 2) and very slight oedema (grade 1) was observed in all animals at the 1-hour observation. Well defined erythema (grade 2) persisted to the 72-hour observation and resolved by the 7-day observation in all animals. Very slight oedema (grade 1) persisted until the 72-hour or 7-day observation for 2/3 and 1/3 animals, respectively. All effects resolved by the 14-day observation in all animals. |
| CONCLUSION | The test substance is irritating to the skin. |
| TEST FACILITY | Protected business information (3) |

### A.4. Eye Irritation – *In Vitro* Bovine Corneal Opacity and Permeability Test

| | |
|---|---|
| TEST SUBSTANCE | A formulation containing 30-60% assessed polymer |
| METHOD | OECD TG 437 Bovine Corneal Opacity and Permeability Test Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring Classification for Eye Irritation or Serious Eye Damage (2013) |
| Vehicle | None |
| Remarks – Method | No significant protocol deviations<br><br>Sodium chloride (0.9%) was used as a negative control and ethanol was used as a positive control. |

RESULTS

| *Test Material* | *Mean Opacities of Triplicate Tissues* | *Mean Permeabilities of Triplicate Tissues* | *IVIS* |
|---|---|---|---|
| *Vehicle control* | 1* | 0.029* | 1.4 |
| *Test substance** | 8.7* | 0.206* | 11.8 |
| *Positive control** | 27.3* | 0.720* | 38.1 |

IVIS = in vitro irritancy score
* Corrected for background values

| | |
|---|---|
| Remarks – Results | The IVIS for the test substance was 11.8 (within > 3 and ≤ 55 where no prediction can be made according to the test guideline).<br><br>The controls gave satisfactory results confirming the validity of the test system. |
| CONCLUSION | No prediction on eye irritation could be made for the test substance. |
| TEST FACILITY | Protected business information (7) |

### A.5. Eye Irritation – Rabbit

| | |
|---|---|
| TEST SUBSTANCE | A formulation containing 30-60% assessed polymer |

| | |
|---|---|
| METHOD | OECD TG 405 Acute Eye Irritation/Corrosion |
| Species/Strain | Rabbit/New Zealand White |
| Number of Animals | 1 F, 2 M |
| Observation Period | 14 days |
| Remarks – Method | No significant protocol deviations |

RESULTS

| *Lesion* | *Mean Score* Animal No.* | | | *Maximum Value* | *Maximum Duration of Any Effect* | *Maximum Value at End of Observation Period* |
|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | | | |
| *Conjunctiva – Redness* | 1.33 | 2 | 2 | 2 | Less than 14 days | 0 |
| *Conjunctiva – Chemosis* | 0.67 | 2 | 2 | 2 | Less than 7 days | 0 |
| *Conjunctiva – Discharge* | 0 | 0 | 1.33 | 2 | Less than 7 days | 0 |
| *Corneal Opacity* | 0 | 0 | 0 | 0 | - | 0 |
| *Iridial Inflammation* | 0 | 0 | 0 | 0 | - | 0 |

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

| | |
|---|---|
| Remarks – Results | Moderate conjunctival redness and swelling (grade 2) in all animals was observed at the 1-hour observation. Conjunctival redness and swelling (grade 2) persisted until the 72-hour observation and reduced to slight conjunctival redness (grade 1) at the 7-day observation for 2/3 animals. Conjunctival redness (grade 2) persisted until the 24-hour observation for the remaining animals, which then reduced to slight conjunctival redness (grade 1) at the 48-hour observation. Slight conjunctival redness (grade 1) persisted until the 7-day observation. Conjunctival swelling (grade 2) persisted until the 24-hour observation for one animal and until the 72-hour observation for the remaining animals.<br><br>Slight conjunctival discharge (grade 1) was observed at the 1-hour observation in 2/3 animals. Moderate conjunctival discharge (grade 2) was observed in one animal at the 24-hour observation. This then reduced to slight conjunctival discharge (grade 1) at the 48-hour observation and persisted until the 72-hour observation. All effects resolved by the 14-day observation in all animals. |
| CONCLUSION | The test substance is irritating to the eye. |
| TEST FACILITY | Protected business information (4) |

**A.6. Skin Sensitisation – Guinea Pig Maximisation Test**

| | | |
|---|---|---|
| TEST SUBSTANCE | A formulation containing 30-60% assessed polymer | |
| METHOD | OECD TG 406 Skin Sensitisation – Maximisation Test (1992) | |
| Species/Strain | Guinea pig/*Cavia porcellus* | |
| PRELIMINARY STUDY | Maximum non-irritating concentration:<br>Intradermal: slight erythema at 10% | |
| MAIN STUDY | | |
| Number of Animals | Test Group: 10 per sex | Control Group: 5 per sex |
| Vehicle | Deionised water | |
| Positive Control | 2-mercaptobenzothiazole | |
| INDUCTION PHASE | Induction concentration:<br>Intradermal: 25%<br>Topical: 100% | |

| | |
|---|---|
| Signs of Irritation | Slight or moderate erythema was observed at the intradermal induction site after the 24-hour observation and reduced to slight erythema at the 48-hour observation. Slight to moderate erythema was observed in 6/10 males and 6/10 females after topical application. No animals in the control group exhibited signs of erythema. |
| CHALLENGE PHASE | |
| 1st Challenge | Topical: 1% |
| Remarks – Method | No significant protocol deviations. The concentration selection for the main test was based on the results of a pilot test conducted in 3 animals via intradermal injection at up to 100% concentration. |

RESULTS

| *Animal* | *Challenge Concentration* | *Number of Animals Showing Skin Reactions after: 1st Challenge* | |
|---|---|---|---|
| | | *24 h* | *48 h* |
| *Test Group* | 1% | 9/20 | 0/20 |
| *Control Group* | 1% | 0/10 | 0/10 |

| | |
|---|---|
| Remarks – Results | Slight erythema was noted in 9/20 test group animals at 24 hours following the challenge. No skin reactions were noted in any of the animals of the control group throughout the study and in any of the test animals at the 48-hour observation following the challenge. |
| CONCLUSION | There was evidence of reactions indicative of skin sensitisation to the test substance under the conditions of the test. |
| TEST FACILITY | Protected business information (5) |

**A.7. Genotoxicity – Bacteria**

| | |
|---|---|
| TEST SUBSTANCE | A formulation containing 30-60% assessed polymer |
| METHOD | OECD TG 471 Bacterial Reverse Mutation Test (1997)<br>Pre incubation procedure |
| Species/Strain | *Salmonella typhimurium*: TA1535, TA98, TA100, TA102, TA97a |
| Metabolic Activation System | S9 mix from Aroclor 1254 induced rat liver |
| Concentration Range in Main Test | a) With metabolic activation: 0.5 - 5 µL/plate<br>b) Without metabolic activation: 0.5 - 5 µL/plate |
| Vehicle | None |
| Remarks – Method | No significant protocol deviations<br><br>Negative control: sterile bideionised water<br>Positive controls:<br>With metabolic activation: 2-aminofluorene<br>Without metabolic activation: sodium azide (TA100, TA1535); 4-nitroquinoline-N-oxide (TA97a, TA98, TA102); |

RESULTS

| *Metabolic Activation* | *Test Substance Concentration (µL/plate) Resulting in:* | | |
|---|---|---|---|
| | *Cytotoxicity in Main Test* | *Precipitation* | *Genotoxic Effect* |
| *Absent* | greater than 5 | greater than 5 | negative |
| *Present* | greater than 5 | greater than 5 | negative |

| | |
|---|---|
| Remarks – Results | No significant increases in the frequency of revertant colonies were observed for any of the bacterial strains, with any dose of the test substance, either with or without metabolic activation. |

| | |
|---|---|
| | The positive and negative controls gave a satisfactory response confirming the validity of the test system. |
| CONCLUSION | The test substance was not mutagenic to bacteria under the conditions of the test. |
| TEST FACILITY | Protected business information (6) |

**A.8. Genotoxicity – Bacteria**

| | |
|---|---|
| TEST SUBSTANCE | A formulation containing 30-60% assessed polymer |
| METHOD | OECD TG 471 Bacterial Reverse Mutation Test (1997)<br>Plate incorporation (Test 1)/Pre incubation procedure (Test 2) |
| Species/Strain | *Salmonella typhimurium*: TA1535, TA1537, TA98, TA100<br>*Escherichia coli*: WP2*uvrA* |
| Metabolic Activation System | S9 mix from phenobarbital/β-naphthoflavone induced rat liver |
| Concentration Range in Main Test | a) With metabolic activation: 1.5 – 5000 µg/plate<br>b) Without metabolic activation: 1.5 – 5000 µg/plate |
| Vehicle | Sterile distilled water |
| Remarks – Method | No significant protocol deviations<br><br>Negative control: sterile distilled water<br>Positive controls:<br>With metabolic activation: 2-aminoanthracene (TA100, TA1535, TA1537, WP2*uvrA*); benzo[a]pyrene (TA98)<br>Without metabolic activation: 4-nitroquinoline-N-oxide (TA98); N-ethyl-N′-nitro-N-nitrosoguanidine (WP2*uvrA*, TA1535, TA100); 9-aminoacridine (TA1537) |

RESULTS

| *Metabolic Activation* | *Test Substance Concentration (µg/plate) Resulting in:* | | |
|---|---|---|---|
| | *Cytotoxicity in Main Test* | *Precipitation* | *Genotoxic Effect* |
| *Absent* | | | |
| Test 1 | greater than 1500 | greater than 5000 | negative |
| Test 2 | greater than 5000 | greater than 5000 | negative |
| *Present* | | | |
| Test 1 | greater than 5000 | greater than 5000 | negative |
| Test 2 | greater than 1500 | greater than 5000 | negative |

| | |
|---|---|
| Remarks – Results | In Test 1 (without metabolic activation), a slight but statistically significant increase in the frequencies of WP2*uvrA* revertant colonies was noted at the 150 µg/plate concentration. The increase was within historical control levels of the laboratory and had no dose response relationship attached and therefore was not considered to be toxicologically significant by the study authors.<br><br>No other significant increases in the frequency of revertant colonies were observed for any of the bacterial strains, with any dose of the test substance, either with or without metabolic activation.<br><br>The positive and negative controls gave a satisfactory response, confirming the validity of the test system. |
| CONCLUSION | The test substance was not mutagenic to bacteria under the conditions of the test. |
| TEST FACILITY | Protected business information (8) |

# BIBLIOGRAPHY

CIR (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. *Int J Toxicol*. 22 (Suppl 2):11-35.

CIR (2021) Amended Safety Assessment of Dimethicone, Methicone, and Substituted-Methicone Polymers as Used in Cosmetics. Accessed February 2021 <https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/TR807r.pdf>

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.

United Nations (2017) Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 7th revised edition. United Nations Economic Commission for Europe (UN/ECE), <https://unece.org/ghs-rev7-2017>