File No: LTD/1657

June 2013

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Siloxanes and Silicones, Me hydrogen, reaction products with starch (INCI name: Tapioca Starch Polymethylsilsesquioxane)

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 Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This Public Report is also available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

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

Director
NICNAS

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/1657	Akzo Nobel Pty Ltd	Siloxanes and Silicones, Me hydrogen, reaction products with starch (INCI name: Tapioca Starch Polymethylsilsesquioxane)	ND*	≤ 10 tonnes per annum	Ingredient in cosmetics

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified polymer is not recommended for classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

Human health risk assessment
Provided that control measures are in place to minimise worker exposure (including the use of respiratory protection by workers during reformulation activities, if ventilation is inadequate), 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
On the basis of assessed 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 isolation and engineering controls to minimise occupational exposure to the notified polymer:
  - Enclosed, automated processes during reformulation processes, where possible.
  - Adequate ventilation during reformulation processes and aerosol applications of products containing the notified polymer.

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure to the notified polymer:
  - Avoid inhalation of aerosol or powder.

- 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 tasks:
  - Respiratory protection, if ventilation is inadequate.

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

- Aerosol spray products intended for professional use containing the notified polymer should carry the following safety directions (or similar) on the label:
  - Spray only in well ventilated areas
  - Avoid inhalation of aerosol

- A copy of the (M)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 for the 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.

Public Health

- When formulating cosmetic powder products, the proportion of particles in the respirable size range should be minimised, where possible (e.g. through the use of binding agents).

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 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
  - information on the inhalation toxicity or potential for lung overloading effects of the notified polymer becomes available;
  - the concentration of the notified polymer exceeds or is intended to exceed 15% in aerosol sprays;
  - the polymer has a number-average molecular weight of greater than 70,000 Da;

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the polymer has changed from a component of cosmetic products or is likely to change significantly;
  - the amount of polymer being introduced has increased from 10 tonnes per annum, or is likely to increase, significantly;
  - the polymer has begun to be manufactured 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 (M)SDS of the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Akzo Nobel Pty Ltd (ABN: 50 000 119 424)
8 Kellaway Place
Wetherill Park NSW 2164

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

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

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: all physico-chemical endpoints (excluding particle size and water solubility)

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Dry-Flo TS

CAS NUMBER
68989-12-8

CHEMICAL NAME
Siloxanes and Silicones, Me hydrogen, reaction products with starch

OTHER NAME(S)
Tapioca Starch Polymethylsilsesquioxane (INCI name)

MOLECULAR FORMULA
Unspecified

MOLECULAR WEIGHT
10,000 – 70,000 Da

ANALYTICAL DATA
Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 90 %

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Off white powder

Property	Value	Data Source/Justification
Melting Point	Not determined	Expected to be > 100 °C
Boiling Point	Not determined	Expected to degrade before boiling
Density	Not determined	Expected to be > 1000 kg/m^3
Vapour Pressure	Not determined	Expected to be low based on the high molecular weight
Water Solubility	< 0.01 g/L at 20 °C	Measured
Hydrolysis as a Function of pH	Not determined	Not expected to significantly hydrolyse under environmental conditions (pH 4-5)
Partition Coefficient (n-octanol/water)	Not determined	Not expected to partition to organic phases based on its polarity
Adsorption/Desorption	Not determined	Expected to sorb to soil sediment and sludge based on its low water solubility and high molecular weight
Dissociation Constant	Not determined	The notified polymer is a salt and is ionised in this form
Particle Size	Inhalable fraction (< 100 μm): 100% Respirable fraction (< 10 μm): 13%	Measured (full study report not provided)
Flash Point/Flammability	Not determined	Not expected to be flammable under normal conditions of use
Autoignition Temperature	Not determined	Not expected to autoignite under normal conditions of use.
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

DISCUSSION OF PROPERTIES
For full 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 submitted physico-chemical data depicted in the above table, the notified polymer is not recommended for hazard classification according to the *Globally Harmonised System for the 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 be imported into Australia as the neat form (powder), and/or as an ingredient in finished cosmetic products.

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

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

PORT OF ENTRY
Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
Akzo Nobel Pty Ltd
TRANSPORTATION AND PACKAGING
The notified polymer as the neat form is expected to be imported into Australia by sea in containers suitable for

holding the bulk material, prior to reformulation, or in the case of finished products containing the notified polymer, in containers suitable for retail sale. The containers will be transported from the port of entry in Sydney to central distribution centres by road for storage in warehouses, prior to distribution to reformulators and retailers.

USE

The notified polymer will be used in leave-on and rinse-off cosmetic products at ≤ 95% concentration. A variety of cosmetic product types may contain the notified polymer, including powders, creams/lotions and products to be applied by spray. When used in aerosol products, the notified polymer will only be present at ≤ 15% concentration.

OPERATION DESCRIPTION

Reformulation

After distribution to reformulators, the notified polymer will be reformulated into end-use products, with the procedures for doing so expected to vary depending on the nature of the cosmetic products being formulated, and may involve both automated and manual transfer steps. In general, it is expected that the notified polymer will be manually weighed and transferred into a mixing vessel where it will be blended with other ingredients using closed systems. The resulting blends (containing the notified polymer at ≤ 95% concentration) will then be filled into retail containers using automated processes. The finished products will then be packed for distribution to retail outlets.

End use

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 or sprayed.

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 and Capping)	8	12
Store persons	4	12
Salon workers	Unspecified	Unspecified

EXPOSURE DETAILS

Transport workers and store staff may come into contact with the notified polymer (at ≤ 100% concentration) only in the event of an accidental rupture of containers.

During reformulation, 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. The principal route of exposure would be dermal, while ocular and inhalation exposure are also possible. Exposure is expected to be minimised through the use of mechanical ventilation and/or enclosed systems and through the use of personal protective equipment (PPE) such as coveralls, safety glasses and impervious gloves.

Exposure to the notified polymer at ≤ 95% concentration may occur in professions where the services provided involve the application of cosmetic products to clients (*e.g.* in beauty salons). The principal route of exposure will be dermal, while ocular and inhalation exposure is also possible, particularly if products are applied by spray or used in powder form. Such professionals may use some PPE to minimise repeated exposure, and good hygiene practices are expected to be in place. If PPE is used, dermal exposure of such workers is expected to be of either a similar or lesser level 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 at ≤ 95% concentration (or ≤ 15% concentration in products to be applied by aerosol spray), through the use of the rinse-off and leave-on cosmetic products. The principal route of exposure will be dermal, while ocular and inhalation exposure is also possible, particularly if products are applied by spray or used in powder form.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified polymer are summarised in the following table. For full details of the studies, refer to Appendix B.

Endpoint	*Result and Assessment Conclusion*
Skin irritation (in vitro)	non-irritating
Eye irritation (in vitro)	non-irritating

The notified polymer is not expected to be able to readily cross biological membranes due to its very high molecular weight (> 10,000 Da). However, absorption may occur following digestion.

The notified polymer was reported to be non-irritating under the conditions of in vitro skin (Epiderm™ Human Dermal Epithelial Model) and eye (EpiOcular Reconstructed Human Corneal Epithelium Model) irritation studies.

The particle size of the notified polymer indicates that a portion (around 13%) is in the respirable (< 10 μm) size range. In addition, the notified polymer is a high molecular weight (10,000-70,000 Da) polymer with low water solubility. Inhalation of respirable particles of polymers with molecular weights > 70,000 Da has been linked with irreversible lung damage due to lung overloading and impaired clearance of particles from the lung, particularly following repeated exposure (US EPA, 2013). While there is also a concern for polymers with molecular weights between 10,000 and 70,000 Da, it is acknowledged that there is a data gap for this range Therefore, there is uncertainty for the potential for lung overloading effects with respect to the notified polymer. If the notified polymer is inhaled at low levels and/or infrequently, it is assumed that it will be cleared from the lungs. However, high level and/or frequent exposure may result in lung overloading effects, though the level of exposure in humans that would result in any effects, as well as the severity, is uncertain.

Health hazard classification

Based on the available information, the notified polymer is not recommended for classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

The primary risk to human health associated with use of products containing the notified polymer will be due to the potential for lung overloading effects following repeated inhalation exposure (aerosols or powder form).

Reformulation

Although reformulation workers will handle the imported notified polymer frequently at concentrations of ≤ 100% in powder form (with 13% of particles noted to be in the respirable size range), exposure is expected to be minimised given the proposed use of PPE and largely enclosed, automated processes used in reformulation facilities. The risk to the health of reformulation workers is therefore not considered to be unreasonable, provided control measures are in place to minimise worker exposure (including the use of respiratory protection if ventilation is inadequate).

End users

The notified polymer is intended to be used in a range of cosmetics products at ≤ 95% concentration (and ≤ 15% concentration in products to be applied by aerosol spray). The risk to workers who regularly use non-aerosol spray 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. For details of the public health risk assessment see Section 6.3.2.

Regarding use in aerosol spray products, based on the high molecular weight and low water solubility of the notified polymer, the potential for lung overloading effects from repeated inhalation exposure to the notified polymer cannot be ruled out, particularly where there is high and/or frequent exposure. Thus the potential for lung overloading effects may be of specific concern to hairdressers who regularly use spray products containing the notified polymer, although the degree of exposure is likely to vary greatly depending on the amount and frequency of application and the spray environment (e.g. room size and degree of ventilation).

It has been reported that in aerosolised propellant hair sprays, only a small percentage (up to 5%) of the airborne droplets/particles are within the respirable size range (CIR, 2012). However, as there is the potential for lung overloading effects, with uncertainty regarding the level of exposure that would lead to any potential effects, it is recommended that hairdressers avoid inhalation of aerosols and use products in well ventilated areas to minimise exposure. Therefore, provided exposure of workers to aerosol hair sprays is limited through the use of control measures (e.g. users directed to only apply hair sprays in well ventilated areas and to avoid inhalation of the spray contents), the risk to the health of workers is not considered to be unreasonable

6.3.2. Public Health

The general public will have widespread and repeated exposure to cosmetic products containing the notified polymer at ≤ 95% concentration (and ≤ 15% concentration in products to be applied by aerosol spray). Local and systemic toxicity effects following dermal exposure to the notified polymer are not expected. However, as noted above, the greatest concern associated with use of products containing the notified polymer, is the potential for lung overloading effects following inhalation exposure.

Regarding use of the notified polymer in powders, it is expected that, where possible, binding materials will be included in the formulation of cosmetic powders, which is expected to increase the size of the product particles (and hence may limit the amount of material in the respirable size range). Regarding use in aerosol spray products (e.g. hair spray), the frequency of exposure of members of the public to the notified polymer is expected to be less than that of hairdressers (considered to represent a worst case scenario). Overall, it is assumed that if the notified polymer is inhaled at low levels and/or infrequently, that it will be cleared from the lungs.

Therefore, under the proposed use scenario, the risk to the health of members of the public 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 may be released at site if an accidental breakage or spill of the finished product occurs. Any spills are expected to be contained and disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

The majority of the annual import volume of the notified polymer is expected to be released to the sewer through the consumer use as an ingredient in cosmetics.

RELEASE OF CHEMICAL FROM DISPOSAL

It is expected that 1% of the notified polymer may remain in the imported containers during manufacture. Up to 3% of the annual import volume of the notified polymer residues is likely to remain in the end use containers and is expected to be disposed of to landfill.

7.1.2. Environmental Fate

Following its use in Australia, the majority of the notified polymer is expected to enter the sewer system before potential release to surface waters on a nationwide basis. The submitted biodegradation study on the notified polymer indicates that it is expected to be rapidly degraded in sewage treatment plants (STPs). In STPs the notified polymer is expected to be 90% removed from influent by adsorption to sludge (Boethling and Nabholz, 1997). The notified polymer that partitions and/or adsorbs to sludge will be removed with the sludge for disposal to landfill or used in soil remediation. In the event that a portion of the notified polymer is released to surface waters, it is expected to degrade rapidly. The notified polymer is not considered to be bioaccumulative

as it is not likely to partition to organic phases and fats based on its polarity. In the aquatic and soil compartments, the notified polymer is expected to readily degrade through biotic and abiotic processes to form water and oxides of carbon and silicon.

7.1.3. Predicted Environmental Concentration (PEC)

Since most of the notified polymer will be washed into the sewer, under a worst case scenario, assuming no removal of the notified polymer in sewage treatment plants (STPs), the resultant Predicted Environmental Concentration (PEC) in sewage effluent on a nationwide basis is estimated as follows:

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	10,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	10,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	27.40	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	0%	
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	6.06	µg/L
PEC - Ocean:	0.61	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 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 ~6.06 µg/L may potentially result in a soil concentration of approximately 40.4 µg/kg. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated irrigation, the concentration of notified polymer in the applied soil in 5 and 10 years may be approximately 202 µg/kg and 404 µg/kg, respectively. However, it is expected that 90% of the notified polymer will be removed from STP influent by adsorption to sludge and is also expected to rapidly degrade. Hence, the resulting concentration of notified polymer in the soil may be less than the predicted concentrations.

7.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on the notified chemical are summarised in the table below. Details of these studies can be found in Appendix C.

Endpoint	*Result (mg/L)*	*Assessment Conclusion*
Daphnia Toxicity (EC50, 48 h)	> 100	Not expected to be harmful to aquatic invertebrates at its solubility limit
Algal Toxicity (E_rC50, 72 h)	> 100	Not expected to be harmful to algae at its solubility limit

Classification should be based only on toxic responses observed in the soluble range. Under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009) the notified polymer has not been classified due to the absence of toxicity of the notified polymer at its solubility limit. The highest concentration tested for the notified polymer was 100 mg/L, which is 10 times more the solubility limit.

7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) has not been calculated for the notified polymer as it is not harmful to aquatic organisms up to its limit of solubility.

7.3. Environmental Risk Assessment

Based on the reported biodegradability study, the notified polymer is expected to be readily biodegradable and is also not likely to bioaccumulate. Based on the ecotoxicological data, the notified polymer is not expected to harmful to aquatic organisms up to the limit of its solubility. Based on the assessed use pattern of the notified polymer in cosmetic products, it is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Water Solubility < 0.01 g/L at 20 °C

Method	OECD TG 105 Water Solubility. EC Council Regulation No 440/2008 A.6 Water Solubility.
Remarks	Flask Method - Three samples (0.101, 0.103 and 0.108 g) of test item and reverse osmosis water (10 mL) were added to three separate flasks. The samples were shaken at approximately 30 °C for 24, 48 and 72 hours, respectively. After standing at 20 °C for less than 24 hours, the contents of the flasks were filtered through 0.45 µm membrane filters and analysed. At the end of the equilibrium periods, all of the samples still contained undissolved test item in the solution. After filtration, all of the samples were clear, colourless and free from undissolved test item. The dissolved total organic carbon concentration (TOC) of the test solutions was determined to be < 1.0×10^{-2} g/L at 20 °C. It was determined from a limit of quantification for the method of analysis (TOC: 1.0×10^{-3} g/L).
Test Facility	Harlan (2012)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Irritation – skin (in vitro)

TEST SUBSTANCE	Notified polymer
METHOD	Similar to OECD TG 439 In vitro Skin Irritation: Reconstructed Human *Epidermis* Test Method Epiderm
Vehicle	None
Remarks - Method	No significant protocol deviations. The exposure period was 1 hour at 37 °C. It is not clear whether a preliminary test was conducted to determine if the test substance was able to directly reduce MTT. Negative (DPBS) and positive (SDS) controls were run in parallel with the test substance.

RESULTS

Test material	*Relative mean viability (%)*	*SD of relative mean viability*
Negative control	100	7.3
Test substance	103.2	5.1
Positive control	7.8	0.7

SD = standard deviation

Remarks - Results	Optical density data were not reported (results were expressed only as the mean % cell viability of the tissues).
CONCLUSION	The notified polymer was non-irritating to the skin under the conditions of the test.
TEST FACILITY	CeeTox (2011a)

B.2. Irritation – eye (in vitro)

TEST SUBSTANCE	Notified polymer (see remarks)
METHOD	Determination of Ocular Irritation Potential Using the EpiOcular™ or Reconstructed Human Corneal Epithelium Model
Vehicle	None
Remarks - Method	The test substance (50 mg) was applied to the tissues. Following a 30 minute exposure period at ~37 °C, the tissues were rinsed and incubated at ~37 °C in fresh medium for 2 hours. The tissues were then treated with MTT and incubated at ~37 °C for 3 hours. Following extraction, the optical densities were determined (570 nm). In the study, 3 substances were tested simultaneously, with the exposure and incubation times dependent on whether the substance was liquid or solid. In this instance the test substance was described as being a liquid (therefore resulting 30 minutes/2 hours exposure/incubation times, rather than 90 minutes/18 hours exposure/incubation times, as were used for solid substances that were tested in the study). As the notified polymer is a solid and the study authors note that the test substance was used neat, there is some uncertainty regarding the specific preparation/concentration of the test substance as it is noted to be used in liquid form during the study.

It is not clear whether a preliminary test was conducted to determine if the test substance was able to directly reduce MTT.

Negative (sterile water) and positive (10% benzalkonium chloride) controls were run in parallel with the test substance.

RESULTS

Test material	*Relative mean Viability (%)*	*SD of relative mean viability*
Negative control	100	7.5
Test substance	102.5	4.8
Positive control	6.9	0.5

Remarks - Results: Optical density data were not reported (results were expressed only as the mean % cell viability of the tissues).

CONCLUSION: The notified chemical was considered to be non-irritating to the eye under the conditions of the test.

TEST FACILITY: CeeTox (2011b)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATION

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE:	Notified polymer
METHOD:	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test.
Inoculum:	Activated sludge
Exposure Period:	28 days
Auxiliary Solvent:	Nil
Analytical Monitoring:	CO_2 Evolution
Remarks – Method:	No significant deviations from the test guidelines were reported.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
1	-10.3	1	-5.4
3	-4.8	3	16.4
7	31.4	7	50.3
10	47.7	10	55.4
14	69.6	14	66.3
28	82.6	28	82.2

Remarks - Results	All validity criteria for the test were satisfied. No significant deviations from the test protocol were reported. The results tabulated above are based on the cumulative carbon evolved as CO_2. The total CO_2 production in the blank controls after 28 days was 35 mg/L, hence the acceptability criterion of maximal 40 mg/L was reached. The rapid degradation (CO_2 evolution greater than 60% within 14 days) of the reference item (sodium benzoate) confirmed the presence of an acceptable microbial community and confirmed system integrity. Degradation of the reference item detected in the toxicity control showed that the test substance is not toxic to the inoculums according to the test guideline. The test substance passed the criterion for ready biodegradability of > 60% degradation (ThOD) reached within the 10 day window. Therefore, the test substance is classified as readily biodegradable according to the test guideline.
CONCLUSION	The notified polymer is readily biodegradable.
TEST FACILITY	Smithers Viscient (2011a)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 202 *Daphnia* sp. Acute Immobilisation Test- Static EC Council Regulation No 440/2008 C.2 Acute Toxicity for Daphnia - Static
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	Nil
Analytical Monitoring	Nil
Remarks - Method	The test conditions (i.e. pH, DO and temperature) as well as all other validity criteria for the test were satisfied in accordance with the test guideline. No significant deviations from the test protocol were reported. It

was not mentioned in this study about any reference test conducted using the reference item, potassium dichromate, to verify the water quality and the health of the test species.

RESULTS

Nominal Concentration mg/L	*Number of D. magna*	*Number Immobilised*	
		24 h	*48 h*
0	20	0	0
6.25	20	0	0
12.5	20	0	0
25	20	0	0
50	20	0	0
100	20	0	0

E_iC50	> 100 mg/L at 48 hours (Nominal Concentration)
NOE_iC	100 mg/L at 48 hours (Nominal Concentration)
Remarks - Results	It was mentioned in the test report that the concentration of the stock solution of the notified polymer was 1000 mg/L. The stock solution was prepared without using a carrier solvent while its concentration was 100 times higher than the solubility limit of the notified polymer. The test substance was clearly visible in the solution after being stirred for 24 h. Hence it is believed that the test organisms were exposed to concentrations lower than the above mentioned nominal concentrations. No analytical measurements were performed to quantify the actual exposure concentrations of the test substance.

CONCLUSION The notified polymer is not harmful to aquatic invertebrates at concentrations up to its limit of solubility.

TEST FACILITY Smithers Viscient (2011b)

C.2.2. Algal growth inhibition test

TEST SUBSTANCE Notified polymer

METHOD OECD TG 201 Alga, Growth Inhibition Test.
EC Council Regulation No 440/2008 C.3 Algal Inhibition Test.

Species	*Pseudokirchneriella subcapitata*
Exposure Period	72 hours
Concentration Range	Nominal: 6.25, 12.5, 25, 50 and 100 mg/L
Auxiliary Solvent	Nil
Remarks - Method	The test conditions (i.e. pH, DO and temperature) as well as all other validity criteria for the test were satisfied in accordance with the test guideline. No significant deviations from the test protocol were reported. E_bC_{50} and E_rC_{50} values were empirically estimated as insufficient responses were obtained from this test to reliably estimate these values. The NOE_bC and NOE_rC were by calculation of statistical significance of biomass integrals and growth rates. It was not mentioned in this study about any reference test conducted using the reference item, potassium dichromate, to verify the water quality and the health of the test species.

RESULTS

Biomass		*Growth*	
E_bC_{50} mg/L at 72 h	*NOE_bC mg/L*	*E_rC_{50} mg/L at 72 h*	*NOE_rC mg/L*
> 100	*100*	*> 100*	*100*

Remarks - Results Results are reported for nominal concentrations only. The study met the

	validity criteria of the guideline. However, it was noted in the study report that the notified polymer did not fully dissolve in the treatment solution.
CONCLUSION	The notified polymer is not harmful to green algae at concentrations up to its limit of solubility.
TEST FACILITY	Smithers Viscient (2011c)

BIBLIOGRAPHY

Boethling, R.S. and V.J. Nabholz (1997). Environmental Assessment of polymers under the U.S. Toxic Substances Control Act, pp. 187-234, in Ecological Assessment of Polymers Strategies for Product Stewardship and Regulatory Programs, Hamilton, J.D. and R. Sutcliffe (eds.).

CeeTox (2011a) Skin Irritation Using Epiderm™ Model (EPI-200) (Study number 9154-100314, May 2011). Michigan, USA, CeeTox, Inc. (Unpublished report submitted by the notifier).

CeeTox (2011b) In Vitro Study for the Prediction of Acute Ocular Irritation of Chemicals Using the EpiOcular™ (OCL-200) Model (Study number 9154-100384, May 2011). Michigan, USA, CeeTox, Inc. (Unpublished report submitted by the notifier).

CIR (2012) Cosmetic Ingredient Review. CIR Precendents: Aerosols.

Harlan (2012) [Notified polymer] Determination of Infrared Spectrum and Water Solubility (Study Number 41200985, May, 2012). Derbyshire, UK, Harlan Laboratories Ltd (Unpublished report submitted by the notifier).

NOHSC (2004) Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

Smithers Viscient (2011b) Dry-Flo TS. Acute Toxicity to Water Fleas *Daphnia magna* Under Static Conditions (Study No 1167.002.110, July, 2011). Switzerland, Smithers Viscient AG (Unpublished report submitted by the notifier).

Smithers Viscient (2011c). Dry-Flo TS. 72 Hour Acute Toxicity Test with Fresh Water Green Alga-Pseudokirchneriella subcapitata (Study No 1167.002.430, July, 2011). Switzerland, Smithers Viscient AG (Unpublished report submitted by the notifier).

SWA (2012) Code of Practice: Managing Risks of Hazardous Chemicals in the Workplace, Safe Work Australia, http://www.safeworkaustralia.gov.au/sites/swa/about/publications/pages/managing-risks-of-hazardous-chemicals-in-the-workplace.

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.

US EPA (2013) High Molecular Weight Polymers in the New Chemicals Program. http://www.epa.gov/oppt/newchems/pubs/hmwtpoly.htm (Last updated 17/5/2013). (Accessed 17 May 2013).