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May 2015

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

PS-111 Mod Starch Powder (INCI name: Sodium Hydrolyzed Potato Starch Dodecenyl Succinate)

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.

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:

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Director
NICNAS

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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
STD/1511	Akzo Nobel Pty Ltd.	PS-111 Mod Starch Powder (INCI name: Sodium Hydrolyzed Potato Starch Dodecenyl Succinate)	ND*	≤ 50 tonne/s 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
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 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 engineering controls where possible to minimise occupational exposure to the notified polymer:
  - Enclosed and automated processes
  - Exhaust ventilation when handling the polymer in powder form

- 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 as introduced:
  - Avoid skin and eye contact
  - Avoid generation of dust

- 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 as introduced:
  - Impervious gloves
  - Coveralls

- Eye protection such as safety glasses or goggles
- Respiratory protection if ventilation is inadequate

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

- 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.

Disposal

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

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by 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
- the notified polymer is proposed to be used in rinse-off cosmetics or hair sprays at concentration exceeding 15%.
- the notified polymer is proposed to be used in leave-on skin cosmetics;
- information on repeated dose toxicity of the notified polymer becomes available;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the polymer has changed from ingredient in cosmetics 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.

(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

This notification has been conducted under the cooperative arrangement with Canada. The health and environmental hazard assessment components of the Canadian report were provided to NICNAS and, where appropriate, used in this assessment report. The other elements of the risk assessment and recommendations on safe use of the notified chemical were carried out by NICNAS.

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Akzo Nobel Pty Ltd (ABN: 50000119424)
8 Kellaway Place,
Wetherill Park NSW 2164

NOTIFICATION CATEGORY
Standard (Reduced Fee Notification): Chemical other than polymer (more than 1 tonne per year) - Assessed by Comparable Agency

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: chemical name, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, polymer constituents, residual monomers, impurities, use details, 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 except water Solubility, hydrolysis as a function of pH, partition Co-efficient and particle Size.

NOTIFICATION IN OTHER COUNTRIES
Canada (2012)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
PS-111 Mod Starch Powder
Structure PS-111 Foam Enhancer.

OTHER NAME(S)
Sodium Hydrolyzed Potato Starch Dodecenyl Succinate (INCI name).

MOLECULAR WEIGHT
> 500 Da.

ANALYTICAL DATA
Reference GPC spectra were provided.

IDENTITY OF ANALOGUES

Analogue 1: Sodium Starch Octenyl Succinate (CAS No. 70714-61-3)
Chemical Name: Starch, hydrogen 1-octenylbutanedioate, sodium salt
The analogue polymer is the sodium salt of the reaction product of octenyl succinic anhydride with starch.
The finished product has a degree of substitution of 0.02.

Analogue 2: Aluminium Starch Octenyl Succinate (CAS No.: 9087-61-0)
Chemical Name: Starch, hydrogen octenylbutanedioate, aluminium salt
The analogue polymer is the aluminium salt of the reaction product of octenyl succinic anhydride with starch.

Analogue 3: Sodium D-Glucose (8 units) Dodecenyl Succinate (Modelling)

A QSAR structure for a 8:1 structure has been generated. Eight is the highest number of D-Glucose units in a Sodium D-Glucose (x units) Dodecenyl Succinate polymer that the EPI QSAR system will validate (QSAR (2014a&b)).

Analogue 4:
Chemical name: Amylopectin, hydrogen dodecenylbutanedioate, calcium salt (CAS No: 194810-88-3)

3. COMPOSITION

DEGREE OF PURITY
>90%

IDENTIFIED IMPURITIES/RESIDUAL MONOMERS
All impurities are present at below the relevant cut offs for classification as a hazardous substance.

4. PHYSICAL AND CHEMICAL PROPERTIES

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

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Expected to be >100°C based on melting points of other starches (MSDS).
Boiling Point	Not determined	-
Density	Not determined	-
Vapour Pressure	Not determined	Not expected to be high, based on the solid form of the notified polymer.
Water Solubility	> 100 g/L (149.5 – 158.2 g/L)	Measured. Study report not provided.
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionalities. However, the notified polymer is not expected to be significantly hydrolysed under the normal environmental pH range of 4-9.
Partition Coefficient (n-octanol/water)	Log Kow < 0	Based on visual assessment of solubilities in octanol and water; both OECD 107 and 117 are not applicable due to surface active properties of the substance.
Adsorption/Desorption	log K_{oc} = 3.845 (MCI method) log K_{oc} = - 2.801 (Kow method)	Calculated. KOCWIN v2.0, EPI Suite v4.1 (US EPA, 2011)
Dissociation Constant	Not determined	The notified polymer is a salt. Therefore, it will be ionised under normal environmental conditions (pH 4 – 9).
Particle Size	Inhalable fraction (< 108.8µm): 75 % Respirable fraction(<10.71µm): 10% Median particle size (by volume) = 51.3 µm. (Average of two determinations)	Measured.
Solid Flammability	Not determined	-
Autoignition Temperature	Not determined	Not expected to auto ignite under normal conditions. Potato starch has an autoignition temperature of 430°C [PPZ (2005)]
Explosive Properties	Not determined	Not expected to have explosive properties based on the lack of structural alerts.
Oxidising Properties	Not determined	Not expected to have oxidising properties based on the lack of structural alerts.

DISCUSSION OF PROPERTIES

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

Reactivity
Stated to pose a risk of dust explosion (MSDS).

Physical hazard classification
Based on the 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 as a neat powder and also as a component of finished cosmetic products.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	<50	<50	<50	<50	<50

PORT OF ENTRY
Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
Akzo Nobel Pty Ltd

TRANSPORTATION AND PACKAGING
The notified polymer may be imported in neat form in 100 kg open-head plastic drums lids, on pallets in containers. The drums will be transported from the dock to the notifier's warehouse by road where they will be stored before delivery to customers (cosmetic manufacturers).
The finished cosmetic products containing the notified polymer will be imported in plastic bottles (typically HDPE plastic bottles or tubes with sizes of 0-500 ml), transported from the wharf to central distribution centres and stored in the warehouse. They will then be delivered to retail customers by road.

USE
The notified polymer will be used as an ingredient at up to 15% in rinse-off cosmetics and hair sprays.

OPERATION DESCRIPTION
The notified polymer will not be manufactured in Australia. When reformulated in Australia, it will be blended into end-use cosmetics with other ingredients at customer sites. Procedures will vary depending on the nature of the cosmetic product being formulated. In a typical process, both manual and automated steps will be involved. For example, manual processes could include weighing of an appropriate amount of the notified chemical into a container then adding the chemical directly into a flame proof mixing tank, with periodic sampling for quality control purposes carried out during the manufacturing process. Automated processes may include mixing stages and filling of end-use containers with products.

Finished products containing the notified chemical (≤ 15% concentration) may be used by consumers and professionals, such as hairdressers and workers in beauty salons. Depending on the nature of the product, the application could be by hand, spray or using an applicator.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

Number and category of workers

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*

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
Store Persons	4	12
End Users	2	100

EXPOSURE DETAILS

Transport and storage

Transport and storage workers may come in contact with the notified polymer either in neat form (at 100% concentration) or at various concentrations in cosmetic products (up to 15%), only in the event of accidental rupture of containers. Inhalation exposure to the polymer may also occur if the packaging is breached.

Reformulation

During reformulation into cosmetic products, dermal, ocular and inhalation exposure of workers to the notified polymer at up to 100% may occur during weighing out and during certain stages of the reformulation such as quality control, cleaning, sampling, maintenance, or by accidental spills during the packing process. Inhalation exposure to the polymer in powder form may occur during weighing and transfer of the polymer to the mixing vessel. Exposure is expected to be minimised through the use of exhaust ventilation and/or automated/enclosed systems as well as through the use of PPE, such as coveralls, safety glasses and impervious gloves.

In case of inadequate ventilation, workers are expected to use respirators. Solvent resistant protective gloves are expected to be used during the handling of the finished products.

End-use

Exposure to the notified chemical in end-use products (at up to 15% concentration) may occur in professions where the services provided involve the application of cosmetic products to clients (e.g. hairdressers, workers in beauty 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 notified chemical.

Workers in retail industry will only be exposed to the notified polymer in the event of accidental spillage or packaging breaches.

6.1.2. Public Exposure

Cosmetic products containing the notified polymer will be sold to public; hence public exposure will be widespread and frequent through daily use of cosmetics containing the notified polymer at concentrations up to 15%. Exposure to the notified polymer will vary depending on the type of product and individual use patterns. The principal route of exposure will be dermal, with incidental ocular exposure, and inhalation exposure is also possible if products are applied by spray. Public exposure is expected to be limited, due to the rinse-off nature of cosmetic products containing the notified polymer.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified polymer and Analogue 4 are summarised in the following table. For full details of these studies, refer to Appendix B.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 >5000mg/kg bw; low toxicity (Analogue 4)
Human, (21-day cumulative skin irritation study)	slightly irritating (Analogue 4)
Rabbit, skin irritation	slightly irritating (Analogue 4)
Rabbit, eye irritation	slightly irritating (Analogue 4)
Guinea pig, skin sensitisation – Buehler Method.	no evidence of sensitisation (Analogue 4)
Human, Skin sensitisation (RIPT)	No evidence of sensitisation (product containing notified polymer at low concentration)
Mutagenicity – bacterial reverse mutation	Non mutagenic (notified polymer)

Phototoxicity	No evidence of phototoxicity (notified polymer)

Toxicokinetics, metabolism and distribution.
No data on the toxicokinetics of the notified polymer was provided. Dermal absorption may be limited by the molecular weight (NAMW >500 Da) and the estimated low log Pow value. However it is noted that low molecular weight species are present and these would have higher potential for dermal absorption. In addition, the polymer is expected to have surfactant properties that can enhance the dermal absorption of the polymer itself or of other chemicals. The particle size distribution of the notified polymer indicates that a portion (~10%) is in the respirable size range (<10 μm).

Acute toxicity.
Acute toxicity data on the notified polymer was not provided. A study on Analogue 4 in rats according to OECD guidelines indicated low acute oral toxicity (LD50 >5000 mg/kg bw).

Irritation and sensitisation.
No skin or eye irritation data on the notified polymer was available. Analogue 4 was mildly irritating to rabbit skin in a dermal primary irritation study, and was considered a probable mild irritant based on a 21-day cumulative skin irritation study in human volunteers.

Analogue 4 was slightly irritating to the eye in a rabbit study according to the OECD guidelines. The eye irritation potential of the products containing Analogue 2 at a concentration of 15% and 25% were considered mild and minimal, respectively, according to the Draize classification system in two eye irritation studies (CIR 2002).

A product containing the notified polymer at 10.6% demonstrated no irritation or sensitization potential in a HRIPT study. However, the test was carried out at a very low concentration (1% of the product equivalent to 0.1% of the notified polymer), reducing the relevance of the result. Analogue 4 was non-sensitising to Guinea pigs in a Buehler test. Analogue 2 when tested up to 25% in a formulation was not a sensitizer in clinical RIPTs (CIR 2002).

Repeated dose toxicity.
No data on repeated dose toxicity was provided for the notified chemical. A 1980 2-generation feeding study on Analogue 1 was described in CIR (2002). The NOAEL (3,000 mg/kg bw/day) determined was based on increased liver and kidney weights.

Mutagenicity/Genotoxicity.
The notified polymer was negative in a bacterial reverse mutation study carried out to OECD guidelines.

Phototoxicity.
The notified polymer was evaluated for phototoxicity at concentrations ranging from 68.1 to 1000 μg/ml in the *in vitro* neutral red uptake phototoxicity assay (BALB/3T3 clone A31 mouse embryo fibroblast cultures). The notified polymer was not considered to have phototoxicity potential.

Impurities
The notified polymer contains an impurity at <10% that is expected to be irritating, and may therefore increase the irritation potential of the polymer.

Other
The notified polymer is currently under evaluation by CIR as part of a review of Plant Polysaccharide Gums. The CIR Expert Panel requested additional information from industry regarding the method of manufacture and chemical characterisation of modified polysaccharide gums (group containing the notified polymer). Analogue 2 was previously reviewed by CIR (2002), and was considered safe as used in cosmetic formulations provided that heavy metal concentration limits were observed.

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

Limited toxicological information is available on the notified polymer. Based on information on the polymer or on analogues with considerably higher molecular weight, the notified polymer has irritation potential. Analogue information is not considered adequate to address repeated dose toxicity. However, it is noted that Analogue 1 has food additive approval in Australia (FSANZ, 2015).

Dermal, ocular and inhalation exposure of workers to the notified polymer at up to <100% in powder form may occur during different stages of reformulation. A proportion (10%) of particles are noted to be in the respirable size range and could reach the lung if inhaled. The proposed use of PPE and enclosed, automated processes should minimise the potential for exposure. Provided that adequate control measures are in place to minimise worker exposure (including the use of respiratory protection if ventilation is inadequate), the risk to workers from use of the notified polymer is not considered to be unreasonable. The level of atmospheric nuisance dust should be maintained as low as possible. The NOHSC exposure standard for atmospheric dust is 10 mg/m^3 [NOHSC:3008(1995)].

Workers involved in professions where the services provided involve the application of cosmetic products containing the notified polymer to clients (e.g., hairdressers and beauty salon workers) may be exposed to the notified polymer (≤ 15% concentration). The risk to these workers is expected to be of similar or lesser extent than that experienced by consumers using products containing the notified polymer. Such professionals may use PPE (i.e, gloves and glasses) to minimise repeated exposure, and good general hygiene measures are expected to be in place to minimise the potential for exposure. Based on the information available, the risk to workers associated with use of the notified polymer is not considered to be unreasonable.

6.3.2. Public Health

Toxicological information on the notified polymer is limited. Based on information on the polymer or on analogues with considerably higher molecular weight, the notified polymer has irritation potential. The proposed uses of the notified polymer are predominantly rinse-off products (e.g. cleansers), therefore dermal exposure is expected to be low, and irritation potential would be reduced at the proposed concentrations of use (up to 15%).

Inhalation exposure may occur from use of the notified polymer at up to 15% in spray products, including aerosols. However, due to the nature of the final products, airborne particle size distributions and concentrations in the breathing zone, incidental inhalation is not expected to lead to local respiratory effects or systemic effects.
The repeated dose toxicity effects of the notified polymer have not been determined. Limited data on an analogue of higher molecular weight indicated low repeated dose toxicity.

Therefore, based on the information available, the risk to the public associated with the proposed use of the notified chemical primarily in rinse-off cosmetic products at ≤ 15% concentration 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 will not be manufactured in Australia; therefore there will be no release of the notified polymer to the environment from this activity. Environmental release during importation, transport and distribution may occur as a result of accidental spills. In the event of a spill, the notified polymer is expected to be contained and collected with an inert absorbent material and disposed of in accordance with local regulations.

During reformulation processes, limited release of the notified polymer is expected as blending will take place in industrial settings with engineering controls. Washings from cleaning of equipment are expected to be reused or released to the sewer. A small amount of the notified polymer is expected to be generated as waste from residues

in empty containers and spills during reformulation. Empty containers containing the notified polymer will either be recycled or disposed of through an approved waste management facility.

RELEASE OF CHEMICAL FROM USE

The majority of the notified polymer is expected to be released to the sewer across Australia as a result of its use in cosmetic products, which will be washed off the hair and skin of consumers and disposed of to the sewer. A small percentage of the notified polymer is expected to be disposed of to landfill as residues in empty end use containers.

RELEASE OF CHEMICAL FROM DISPOSAL

It is expected that some of the products containing the notified polymer will remain in end-use containers. The containers are expected to be disposed of through domestic garbage disposal and will enter landfill, or be subjected to recycling processes.

7.1.2. Environmental Fate

The notified polymer is readily biodegradable based on the provided biodegradation study, carried out OECD 301 B test guidelines. In this test the notified polymer was biodegraded by 84% after 28 days. The majority of the notified polymer will enter the sewer system as a result of the use of the notified polymer in cosmetic products on a nationwide basis. Based on visual assessment of solubilities in octanol and water; it is predicted to have very low adsorption coefficient (log $K_{oc} < 0$). Therefore, a significant partitioning to sludge is not expected. The notified polymer has low potential to bioaccumulate based on its low log Kow value and expected surfactant properties. In surface waters, the notified polymer is expected to disperse and degrade through biotic and abiotic processes to form water and oxides of carbon.

The notified polymer is expected to have low volatility from water (log H = 8.03×10^{-30} $Pa/m^3/mol$; HENRYWIN v3.201; US EPA, 2011) and hence it is not likely to significantly volatilise to air during use or sewage treatment based on calculation for a representative component of the notified polymer. In the event of release to atmosphere, the notified polymer is not expected to persist in the air compartment based on calculations (AOPWIN v1.92; US EPA, 2011) for a representative component of the notified polymer.

A proportion of notified polymer may be applied to land when treated sewage effluent is used for irrigation or when sewage sludge is used for soil remediation, or disposed of to landfill. Notified polymer residues in landfill and soil are expected to be mobile based on its high adsorption coefficient, and are expected to degrade to form water and oxides of carbon.

7.1.3. Predicted Environmental Concentration (PEC)

The calculation for the Predicted Environmental Concentration (PEC) is summarised in the table below. Based on the reported use in cosmetic products, it is assumed that 100% of the total import volume of the notified polymer will be released to the sewer. The release is assumed to be nationwide over 365 days per year. It is conservatively assumed that 0% of the notified polymer will be removed during sewage treatment processes.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	50,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	50,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	136.99	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:	30.29	µg/L
PEC - Ocean:	3.03	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m2/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/m3). Using these assumptions, irrigation with a concentration of 30.29 µg/L may potentially result in a soil concentration of approximately 201.9 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 1.0 mg/kg and 2.0 mg/kg, respectively.

7.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on the notified polymer are summarised in the table below.

Endpoint	*Result*	*Comments*	*Assessment Conclusion*
Daphnia Toxicity (48 h)	EC50 >100 mg/L	PS-111 Mod Starch Powder (contains >90% of notified substance); OECD 202. The results are based on a single nominal dose of 100 mg/L.	Not harmful to aquatic invertebrates
Algal Toxicity (72 h)	EC50 >100 mg/L	PS-111 Mod Starch Powder (contains >90% of notified substance); OECD 201. The results are based on nominal doses ranging from 6.25 to 100 mg/L; measured concentrations by TOC were 92-98% of nominal	Not harmful to algae

On the basis of the acute toxicity data, the notified polymer is not harmful to fish, aquatic invertebrates and algae. Therefore, the notified polymer is not formally classified for either the acute or chronic toxicity under the Globally Harmonised System of Classification of Chemicals (GHS; United Nations, 2009).

7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) for the notified polymer has been calculated and is presented in the table below. The PNEC is calculated based on the lower endpoints for the test species (daphnia and algae, EC50) for the notified polymer. Two acute ecotoxicity endpoints for aquatic species from only two trophic levels are available. Therefore, an assessment factor of 1000 has been used.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
LC50 (Invertebrates).	100	mg/L
Assessment Factor	1,000	
PNEC:	100	µg/L

7.3. Environmental Risk Assessment

Based on the above PEC and PNEC values, the following Risk Quotient (Q) has been calculated:

Risk Assessment	***PEC µg/L***	***PNEC µg/L***	***Q***
Q - River:	30.29	100	0.303
Q - Ocean:	3.03	100	0.030

The risk quotient for discharge containing the notified polymer to the aquatic environment indicates that the notified polymer is unlikely to reach ecotoxicologically significant concentrations based on its reported use pattern and annual importation quantity. The notified polymer has low potential for bioaccumulation, and it is unlikely to persist in surface waters, air or soils. Therefore, on the basis of the PEC/PNEC ratio, maximum

annual import volume and assessed use pattern in cosmetics, the notified polymer is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Particle Size

Method LS particle Size analyser (Dry powder system, Beckman Coulter LS 13 320)

Particle size (μm) (Average of 2 determinations)	*Volume (%)*
< 10.71	10
< 22.72	25
< 51.275	50
< 108.8	75
< 172.65	90

Remarks The test report did not present a full analysis of the data. Based on the data tabulated above, respirable particles (< 10μm) are close to 10% by volume and inhalable (< 100μm) particles are close to 75% by volume. Based on the graphical data, some particles are < 0.1 μm.

Test Facility Akzo Nobel (2014)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Skin sensitisation – human volunteers

TEST SUBSTANCE	Product containing the notified polymer (10.6%) diluted 1 part to 99 parts of tap water
METHOD	Repeated insult patch test with challenge –In-house method.
Study Design	Induction Procedure: Test substance was applied to the upper arm of each subject for 24 hours for about 3 weeks using occlusive patches reaction were scored 48 or 72 hours after the application of each sample. A series of nine induction patchings was completed during the induction period. Rest Period: 14 days Challenge Procedure: The induction test site was observed and each subject queried as to whether any reaction was experienced during the rest period. The challenge patch was applied to the treated site for 24 hours (0.2 ml) and skin reactions were evaluated 48, 72 or 96 hours later.
Study Group	240 subjects, 169 F, 71 M (at the commencement of study) 227 subjects, 165 F, 62 M (finished the study) Age group: 18-69 years
Vehicle	Tap water
Remarks - Method	Occluded.
RESULTS	No serious adverse events occurred during the test. Four subjects exhibited low level of reactions during the induction phase and two subjects exhibited low level reactions during the challenge phase. The test substance did not induce dermal sensitization in this HRIPT.
Remarks - Results	227 subjects completed the test. 13 subjects discontinued. No subject discontinued due to test material reaction.
CONCLUSION	The test substance was non-sensitising under the conditions of the test.
TEST FACILITY	HRL (2009)

B.2. Genotoxicity – bacteria

TEST SUBSTANCE	Notified polymer (94%)
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. Plate incorporation procedure (Test 1) Pre incubation procedure (Test 2)
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA$^-$
Metabolic Activation System	S9 fractions from phenobarbitone/ β-naphthoflavone induced rat liver
Concentration Range in Main Test	50, 150, 500, 1500 and 5000 µg/plate (with/without metabolic activation)
Vehicle	Sterile distilled water
Remarks - Method	A preliminary toxicity test (0, 0.15, 0.5, 1.5, 5, 15, 50, 150, 500, 1500 and 5000 µg/plate) was carried out to determine the toxicity of the test material. Test 1 (Range finding test) was performed using the direct plate incorporation method. This procedure was repeated, in triplicate, for each bacterial strain and for each concentration of test material both with and without S9-mix. The test material formulations and vehicle control were dosed using the pre-incubation method in the Test 2 (main test). This procedure was repeated, in triplicate, for each bacterial strain and for each concentration of test material both with and without S9-mix.

The positive and untreated controls were dosed using the standard plate incorporation method.
The study was carried out to UK GLP standards, except that the test material was not analysed by the testing laboratory.

RESULTS

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

Remarks - Results
In the preliminary toxicity test, the test material was non-toxic to the strains TA100 or WP2*uvrA*$^-$ at 5000 µg/plate, with and without metabolic activation.
No toxicity or precipitation was observed in the mutation tests. The test substance did not cause a marked increase in the number of revertants per plate of any of the tester strains either in the presence or absence of S9. Negative controls were within historical limits. Positive controls confirmed the sensitivity of the test system.

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

TEST FACILITY
Harlan (2010)

B.3. Phototoxicity

TEST SUBSTANCE
Notified polymer

METHOD
OECD TG 432 (3T3 Neutral Red Uptake Phototoxicity Assay)
Test system
BALB/3T3 clone A31 mouse embryo fibroblasts
Vehicle
Hanks' Balanced Salt Solution (HBSS)
Positive control
CPZ (Chlorpromazine).
Range finding test
A range finding test was performed to determine the acceptable concentrations for the definitive test. Serial dilutions were made from the stock solution (1000µg/ml) to prepare test concentrations with a 3.16 dilution factor.
Definitive test
Based on the range-finding test, the definitive test was conducted in the concentration range of 68.1-1000 µg/ml for both no SSL (Solar stimulated light) and +SSL samples. The test was performed similar to the range finding test.
Remarks - Method
The Photo Irritant Factor (PIF) was calculated as cell viability without irradiation divided by cell viability with irradiation. In the first definitive test, the CPZ positive control failed one of the quality checks and the test was repeated. The second definitive test was aborted due to mechanical problem. The third definitive test was reported.

RESULTS

Range finding test

Test Article	*Concentration range*	*EC_{50} (No SSL)*	*EC_{50} +SSL*	*PIF(Photo Irritant Factor)*
Structure PS-11	*0.32-1000 µg/ml*	*532.8 µg/ml*	*558.3 µg/ml*	*1.0*
CPZ Positive control	*No SSL: 0.032-100 µg/ml +SSL :0.010- 31.6 µg/ml*	*17.4 µg/ml*	*0.6 µg/ml*	*29.0*

Definitive test

Test Article	*Concentration range*	*EC_{50} (No SSL)*	*EC_{50} +SSL*	*PIF(Photo Irritant Factor)*
Structure PS-11	*68.1-1000 µg/ml*	*629.9 µg/ml*	*748.8 µg/ml*	*0.8*
CPZ Positive control	*No SSL: 6.81-100 µg/ml +SSL :0.22- 31.6 µg/ml*	*25.1 µg/ml*	*0.9 µg/ml*	*27.9*

Remarks - Results The test substance is has a PIF of 0.8 and is therefore not considered to have phototoxic potential according to the PIF model, in which a positive result is defined as PIF>5. The PIF of the positive control was 27.9, which was consistent with the historical data at the test facility using this positive control in this test

CONCLUSION The test substance is not considered to have phototoxic potential in the 3T3 Neutral Red Uptake Phototoxicity Test.

TEST FACILITY MB Research Labs (2013)

B.4. Acute toxicity – oral

TEST SUBSTANCE Analogue 4

METHOD OECD TG 401 Acute Oral Toxicity.

Species/Strain Rat/Wistar Albino
Vehicle Corn oil
Remarks - Method No significant protocol deviation

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5 per sex	5000	0

LD50 >5000 mg/kg bw (95% confidence level)
Signs of Toxicity There were no deaths or test-substance related clinical signs or remarkable body weight changes during the study period.
Effects in Organs There were no remarkable necropsy findings
Remarks - Results

CONCLUSION The test substance is of low toxicity via the oral route.

TEST FACILITY MB Research Labs (1996a)

B.5. Irritation – skin

TEST SUBSTANCE Analogue 4 at 50% (w/w) in aqueous slurry

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion (1992).

Species/Strain	Rabbit/New Zealand White
Number of Animals	6, F
Vehicle	Distilled water
Observation Period	72 hours
Type of Dressing	Occlusive/
Remarks - Method	1 ml of 50% slurry of test material was applied topically for 24 hours to both intact and abraded sites of six rabbits. Sites were examined 24, 48, and 72 hours post-patch application. The methodology varied from the OECD TG 404 in having a longer exposure time, and in using both intact and abraded skin.

RESULTS

INTACT SKIN

Lesion	*Mean Score**						*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3	4	5	6			
Erythema/Eschar	0	0	0	0	0.7	0	1	48 h	0
Oedema	0	0	0	0	0	0	0	-	0

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

ABRADED SKIN

Lesion	*Mean Score**						*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3	4	5	6			
Erythema/Eschar	0	0	0	0	0.3	0	1	24 hours	0
Oedema	0	0	0	0	0	0	0	-	0

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

Remarks - Results One animal displayed very slight erythema at both the intact and abraded site, which cleared by 72 hours. No other dermal reactions were observed. The primary dermal irritation index was 0.09.
There were no deaths or test-substance related clinical signs or remarkable body weight changes during the study period.

CONCLUSION The test substance is slightly irritating to the skin.

TEST FACILITY Unilever Research U.S (1996a)

B.6. 21-day Cumulative Skin irritation study – human volunteers

TEST SUBSTANCE 1. Test material 1: Analogue 4 (100%, white powder) moistened with distilled water
2. Test material 2: Analogue 4 (50% w/v slurry with generic baby oil)

METHOD In house method

Study Design The individual test articles (0.2 gm) were applied to assigned sites (upper back of each subject) for 24 hours/application. Patches were removed and skin reactions were evaluated.
Applications were made every day for 21 consecutive days for individual test articles to the same site. Scoring for cumulative irritation was performed every 24 hours immediately prior to reapplication or until exce4ssive irritation was noted.
In addition to the test articles, 0.1% SLS solution as a positive control, and

saline and generic baby oil as negative controls were also tested concurrently for irritation potential.

Study Group: 23 subjects, Age group: >18years completed the study, from a group of 30.

Remarks - Method: Due to the nature of the test material, the quantity of the test material was reduced from 0.2 gm to 0.05 gm to facilitate adhesion of the patch to the subject's skin. In addition, the 50% w/v slurry designed to be composed of the test material and distilled water was composed of test material and generic baby oil, and was applied at a quantity of 0.2 ml to the patch. Due to this modification, an additional patch was tested prepared with 0.2 ml baby oil.

RESULTS: No serious adverse events occurred during the test. The positive and negative controls responded as expected. Cumulative applications of the moistened test material 1 (Analogue 4) resulted in dermal effects ranging from no evidence of irritation to erythema and papules. The superficial layer effects ranged from none to glazing with peeling and cracking. The cumulative score was 177.0. Application of test material 2 (50% Analogue 4) resulted in milder dermal reactions and a cumulative score of 50.6. The positive control had a score of 440.0 and the negative controls had scores of 10.7 and 9.4, confirming the validity of the test.

Remarks - Results

CONCLUSION: Both concentrations of the test materials (Analogue 4) were classified by the study authors as probable mild irritants when used under normal use conditions.

TEST FACILITY: Hill Top research (1996)

B.7. Irritation – eye

TEST SUBSTANCE: Analogue 4

METHOD: OECD TG 405 Acute Eye Irritation/Corrosion (1987).

Species/Strain: Rabbit/New Zealand White

Number of Animals: Six (5M, 1F)

Observation Period: 3 days

Remarks - Method

RESULTS

Lesion	*Mean Score**						*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3	4	5	6			
Conjunctiva: redness	1	0	0.7	1	0.7	0.7	2	< 72 h	0
Conjunctiva: chemosis	0	0	0	0	0	0	2	< 24 h	0
Conjunctiva: discharge	0.3	0	0.3	0.3	0.3	0.3	2	< 48 h	0
Corneal opacity	0	0	0	0	0	0	0	-	0
Iridial inflammation	0	0	0	0	0	0	1	< 24 h	0

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

Remarks - Results: There was no corneal opacity noted at any observation period, however the cornea of one animal showed lack of normal lustre at 1 h.. Iritis, noted in 2/6 eyes at the 1 h observation, cleared by 24 h. Conjunctival irritation, noted in all animals, cleared by the 72 h observation. There were no abnormal systemic signs noted during the observation period.

CONCLUSION The test substance is slightly irritating to the eye.

TEST FACILITY MB Research Labs (1996b)

B.8. Skin sensitisation- Guinea pig

TEST SUBSTANCE Analogue 4 at 50% dispersion in distilled water

METHOD OECD TG 406 Skin Sensitisation - Buehler Method

Species/Strain Guinea pig/Hartley

PRELIMINARY STUDY Irritation potential was evaluated in a range-finding study, and was not seen at any concentration. Due to the hydrophobic nature of the test substance, the highest concentration it could be tested at was 50%.

MAIN STUDY

Number of Animals Test Group: 20/F Control Group: 10/F

INDUCTION PHASE Induction Concentration:
topical: 50% test-material/distilled water

Signs of Irritation The test sites were clipped free of hair 24 hours prior to each dose application. No erythema was observed in test or control animals.

CHALLENGE PHASE

topical: 50% test material in distilled water

Remarks - Method No significant protocol deviations

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:: 1st challenge*	
		24 h	*48 h*
Test Group	50%	0	0
Control Group	50%	0	0

Remarks - Results There were no deaths or test substance-related clinical signs of toxicity or remarkable body weight changes during the study. There were no reactions indicative of sensitisation to the test substance following the challenge exposure. The positive control study using isoeugenol was performed within 6 months of the current study and the results were as expected.

CONCLUSION There was no evidence of reactions indicative of skin sensitisation to the test substance under the conditions of the test.

TEST FACILITY Unilever Research US (1996b)

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