File No: STD/1531-33, 42 & 43

May 2015

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

STD/1531: Organoclay 5 in Garamite 1958, STD/1532: Organoclay 6 in Garamite 7305 (INCI Name: Benzalkonium Montmorillonite), STD/1533: Organoclay 7 in Garamite 7303 (INCI Name: Quaternium-90 Montmorillonite), STD/1542: Organoclay 8 - Quaternary ammonium compounds, benzyl(hydrogenated tallow alkyl)dimethyl, salts with bentonite (INCI Name: Hydrogenated Tallowalkonium Bentonite), and STD/1543: Organoclay 9 - Tixogel VZ/ VZ-V

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(S) OR TRADE NAME(S)	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
STD/1531	Coty Australia Pty Ltd Reschem Technologies Pty Ltd	Organoclay 5 in Garamite 1958	ND*	<150 tonnes per annum	Ingredient in cosmetics, coatings, polymers, inks and toners
STD/1532		Organoclay 6 in Garamite 7305 (INCI Name: Benzalkonium Montmorillonite)		<150 tonnes per annum	
STD/1533		Organoclay 7 in Garamite 7303 (INCI Name: Quaternium-90 Montmorillonite)		<150 tonnes per annum	
STD/1542		Organoclay 8 - Quaternary ammonium compounds, benzyl(hydrogenated tallow alkyl)dimethyl, salts with bentonite (INCI Name: Hydrogenated Tallowalkonium Bentonite)		<150 tonnes per annum	
STD/1543		Organoclay 9 - Tixogel VZ/ VZ-V		<150 tonnes per annum	

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified chemicals are 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). However, the notified chemicals may contain an impurity that has been associated with carcinogenic effects via the inhalation route.

Human health risk assessment
Provided that the recommended controls are being adhered to, under the conditions of the occupational setting described, the notified chemicals are not considered to pose an unreasonable risk to the health of workers.

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

Environmental risk assessment
On the basis of the PEC/PNEC ratio and the reported use pattern, the notified chemicals are not considered to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified chemical:
  - Enclosed, automated processes, where possible
  - Local exhaust ventilation and/or appropriate dust extraction systems when handling the notified chemicals 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 chemicals:
  - Avoid contact with skin and eyes
  - Use low-dust handling techniques
  - Ensure that relevant exposure standards (e.g. for silica or atmospheric dust) are observed

- 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 chemicals:
  - Coveralls, impervious gloves, goggles
  - Respiratory protection during manual handling tasks involving the notified chemicals (powder form) and during formulation processes for toners

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

- Spray applications should be carried out in accordance with the Safe Work Australia Code of Practice for *Spray Painting and Powder Coating* (SWA, 2012) or relevant State or Territory Code of Practice.

- Service personnel should wear disposable gloves and ensure adequate ventilation is present when removing spent printer cartridges containing the notified chemicals and during routine maintenance and repairs.

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

- If products and mixtures containing the notified chemicals 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

- The following measures should be taken by the suppliers to minimise public exposure to the notified chemicals:
  - Introducers should check for the presence of crystalline silica in the notified chemicals and ensure that its concentration is minimised.

Disposal

- Where reuse or recycling are not appropriate, dispose of the chemicals 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 chemicals should be handled by physical containment, collection and subsequent disposal.

Regulatory Obligations

Secondary Notification
This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the

notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(1) of the Act; if
- the notified chemicals are intended to be introduced in nanoform;
- any of the notified chemicals are intended to be used in cosmetic products at > 10% concentration;
- information becomes available on the systemic inhalation toxicity of the notified chemicals.

or

(2) Under Section 64(2) of the Act; if
- the function or use of the chemicals has changed from ingredients in cosmetics, coatings, polymers, inks and toners, or is likely to change significantly;
- the amount of each chemical being introduced has increased, or is likely to increase, significantly;
- the notified chemicals have begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the notified chemicals 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 products containing the notified chemicals provided by the notifier were 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)
Coty Australia Pty Ltd (ABN: 96 058 696 549)
Level 31, 1 Market Street,
Sydney NSW 2000

ResChem Technologies Pty Ltd (ABN: 90 315 656 219)
Suite 1103, 4 Daydream Street,
Warriewood NSW 2102

NOTIFICATION CATEGORY
STD/1531: Standard (Reduced fee notification): Chemical other than polymer (more than 1 tonne per year) – Similar to a chemical that has been previously assessed by NICNAS.
STD/1532-33, 42-43: Standard (Reduced fee notification): Chemical other than polymer (more than 1 tonne per year) – Chemical is being notified at the same time as a similar chemical.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: chemical name, other names, CAS number, molecular and structural formulae, analytical data, degree of purity, impurities, 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: most physico-chemical properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Not known

2. IDENTITY OF CHEMICALs

CHEMICAL NAME
STD/1542 (Organoclay 8):
Quaternary ammonium compounds, benzyl(hydrogenated tallow alkyl)dimethyl, salts with bentonite

CAS NUMBER
STD/1542 (Organoclay 8):
71011-24-0

MARKETING NAME(S)
Garamite 1958 (containing the notified chemical organoclay 5)
Garamite 7305 (containing the notified chemical organoclay 6 with INCI name: Benzalkonium Montmorillonite)
Garamite 7303 (containing the notified chemical organoclay 7 with INCI name: Quaternium-90 Montmorillonite)
Clayton APA (notified chemical organoclay 8 with INCI name: Hydrogenated Tallowalkonium Bentonite)
Tixogel VZ/VZ-V (notified chemical organoclay 9)

OTHER NAME(S)
STD/1531: Organoclay 5 (INCI name not assigned)
STD/1532: Organoclay 6 (INCI Name: Benzalkonium Montmorillonite)
STD/1533: Organoclay 7 (INCI Name: Quaternium-90 Montmorillonite)
STD/1542: Organoclay 8 (INCI Name: Hydrogenated Tallowalkonium Bentonite)
STD/1543: Organoclay 9 (INCI name not assigned)

MOLECULAR WEIGHT
Unspecified (expected to be high, based on clay component)

ANALYTICAL DATA
Reference FTIR spectra was provided.

3. COMPOSITION

DEGREE OF PURITY
>95%

HAZARDOUS IMPURITIES
Silica (Quartz) <3%

PREVIOUSLY ASSESSED SIMILAR CHEMICAL (STD/1414)
Stearalkonium Bentonite ,
130501-87-0 (CAS Number),
Stearalkonium Bentonite (INCI Name)

ANALOGUE IDENTITY
Analogue (used in the acute inhalation toxicity): Quaternary ammonium compounds, bis(hydrogenated tallow alkyl)dimethyl, salts with bentonite (CAS 68953-58-2)

4. PHYSICAL AND CHEMICAL PROPERTIES

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

Property	Value	Data Source/Justification
Melting Point/Freezing Point	>390 °C	Similar chemical data
Boiling Point	>500 °C at 101.3 kPa	Similar chemical data
Density	1400-1800 kg/m^3	(M)SDS (organoclays mixture)
Vapour Pressure	Not determined	Anticipated to be low based on structure.
Water Solubility	<0.04 x 10^{-3} g/L at 20°C	Measured data of a chemical that is structurally similar to the notified chemicals.
Hydrolysis as a Function of pH	Not determined	Hydrolysis of the notified chemicals are unlikely given no hydrolysable functionality is present.
Partition Coefficient (n-octanol/water)	log Kow = 5.87 at 25°C	Estimated from stearalkonium chloride, the organic component of a chemical that is structurally similar to the notified chemicals, using KOWWIN v1.68, EPI Suite v4.1 (US EPA, 2011).
Adsorption/Desorption	log K_{oc} = 4.08 at 25°C	Estimated from stearalkonium chloride, the organic component of a chemical that is structurally similar to the notified chemicals, using KOCWIN v2.00, EPI Suite v4.1 (US EPA, 2011).
Dissociation Constant	Not determined	The notified chemicals are salts but are not expected to significantly dissociate due to low water solubility.
Particle Size	Inhalable fraction (< 100 μm): 90-100% Respirable fraction (< 10 μm): 20-58% Fraction (< 0.1 μm): 0%	Measured on a number of organoclay mixtures using a Microtrac S3500 Blue Wave Particle Size Analyzer.
Solid Flammability	Not performed	-
Autoignition Temperature	190-340°C	(M)SDS (organoclays mixture)
Explosive Properties	Not determined	Contains no structural alerts for explosive properties.

Oxidising Properties	Not determined	Contains no structural alerts for oxidising properties.

DISCUSSION OF PROPERTIES
Particle size determinations were carried out with a light scattering method. While no particles less than 0.1 µm (100 nanometres) in size were detected, the absence of such particles cannot be confirmed based on this test method alone as the method is biased towards larger particles; as such, smaller particles may not be detected. Furthermore, the particles may have been measured in the agglomerated form, but could be scattered in the end-products and therefore present in smaller size.

Reactivity
The notified chemicals are expected to be stable under normal conditions of use. The (M)SDS for a mixture of organoclays notes that the notified chemicals may form combustible dust mixtures in air at concentrations ≥ 0.1 g/L.

Physical hazard classification
Based on the submitted physico-chemical data depicted in the above table, the notified chemicals are 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 chemicals will not be manufactured in Australia. Each of the notified chemicals will either be imported in neat form, in mixtures for reformulation or as a component of formulated products at up to 10% concentration.

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

Year	*1*	*2*	*3*	*4*	*5*
*Tonnes**	<150	<150	<150	<150	<150

* Volumes of import refer to each of the notified chemicals.

PORT OF ENTRY
Sydney and Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
Coty Australia Pty Ltd
Reschem Technologies Pty Ltd

TRANSPORTATION AND PACKAGING
The notified chemicals will be imported into Australia neat or as part of mixtures of organoclays, typically in sealed 20 kg or 200 kg drums.

The chemicals will also be imported as components of inks, toners and cosmetics. Ink will be packaged in tins and toner powder in 200 to 4000 mL sealed plastic containers. Finished cosmetic products containing the notified chemicals are expected to be packed in containers up to 500 mL. Outer packaging will include dozens inside a shipper, with multiple shippers per pallet and multiple pallets per container. The containers will be transported from the wharf in Sydney or Melbourne to the appropriate central distribution centres. They will then be packed into individual orders for delivery to major retailer warehouses.

USE
The notified chemicals will be used as a gelling agent, each at up to 10% concentration. The notified chemicals will be used either separately or in combination of no more than two. Uses in cosmetics may include leave-on and rinse-off products including nail, skin and facial products, and aerosol sprays.
The notified chemicals will also be used in the following products:
Paints and coatings
Polymeric systems
Putties and fillers

Printing inks
Toners in photocopiers and printers

OPERATION DESCRIPTION
The notified chemicals will be imported as finished formulated products at up to 10% concentration each, in neat form, or in mixtures at up to 100% concentration. The neat forms or mixtures will be used in the reformulation of cosmetics, surface coatings, polymers and printing products. Dockside and warehouse workers will transport the notified chemicals and finished products containing the notified chemicals from the wharf to the central distribution centres and place the pallets of products into the warehouse. Warehouse workers will be involved in transferring pallets in the central warehouse and in picking operations for stock transfer/delivery to distributors at the retailer's central distribution depots.

If reformulation occurs in Australia, the process for cosmetics, coatings and inks will usually involve weighing an appropriate amount of the notified chemicals into a separate container. This will be followed by a blending operation, which will be mainly automated and occur in an enclosed system with flame proof mixers and pumps designed not to create aerosols or a dust hazard and earthed for static discharges. The final step involves automatically filling the blend into containers of various sizes.

Formulation processes for toners mainly involve a melt mixing or hot compounding process. The notified chemicals at up to 10% will be blended with other components while molten to form a hot paste of cake mix. This viscous mixture is then cooled either by slabbing it out, by extruding it onto a cooling belt or by pelletising it and cooling the pellets, to form raw toner. The raw toner is then ground to a powder by jet mills or air-swept hammer mills. The over-size and under-size toner particles are sifted out and the powder is then blended with additives. Formulation with polymers may also involve hot melt processes.

After reformulation, products containing the notified chemicals at <10% concentration will be distributed to industrial end-users or to retail outlets.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and Storage	4	12
Professional compounder	8	12
Chemist	3	12
Packers (Dispensing & Capping)	8	12
Store Persons	4	12
Industrial End Users	8	231

EXPOSURE DETAILS

Transport and storage
Dockside and warehouse workers are not expected to have any contact with the notified chemicals, which are contained in sealed packages, except in the case of spills.

Reformulation:
Reformulation processes are expected to be largely enclosed and automated. However, workers may experience dermal, ocular or inhalation exposure to the notified chemicals at up to 100% concentration during transfer from the imported bags to the mixing sealed vessels, during quality control testing and maintenance, and during cleaning tasks. It is expected that the potential for inhalation exposure will be highest when the notified chemicals in powder form are weighed and transferred from the import containers to the mixing tank. Dermal and ocular exposure to workers should be mitigated through the anticipated use of personal protective equipment (PPE) including protective clothing, impervious gloves and goggles. Inhalation exposure to dust particles

generated from handling the notified chemicals in powder form is expected to be minimised through the use of respiratory protection, local exhaust ventilation and enclosed processes.

Compounders controlling the toner production process will wear personal protection masks, goggles, coveralls and dust masks, as required. The use of engineering controls to reduce atmospheric dust to permissible workplace concentrations are expected to be in place.

Use of cosmetics
Exposure to the notified chemicals in cosmetic products (at up to 10% concentration) may occur in professions where the services provided involve the application of cosmetic and personal care products to clients (e.g. hair dressers, workers in beauty salons). The principal route of exposure will be dermal, while ocular and inhalation exposure is also possible. Inhalation exposure is most likely to occur if products are applied by spray. Such professionals may use some PPE to minimise repeated exposure, but this is not expected to occur in all workplaces. However, 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.

Application of coatings
During application by brush and roller, workers may incur dermal and ocular exposure whilst manually decanting products containing the notified chemicals at up to 10% concentration, during manual application and when cleaning equipment. The exposure will be minimised by the use of eye protection, coveralls and gloves.

During spray application, workers may have accidental dermal and ocular exposure while mixing and loading products containing the notified chemicals at up to 10% concentration to spray guns, during spray applications and when cleaning equipment. According to the notifier, spray applications will be conducted within spray booths at industrial manufacturing facilities.

Use of polymer products
Workers may have dermal and ocular exposure to the notified chemicals at up to 10% concentration during mixing of the notified chemicals and other ingredients into diverse polymer systems. Worker exposure will be minimized by the use of eye protection, coveralls and gloves. Air respirators may be worn where ventilation is deemed inadequate. After curing, the notified chemicals are incorporated rigidly within the polymer matrix.

Use of inks and toners
The notified chemicals at up to 10% concentration will be contained within purpose-built plastic toner or ink containers. Dermal, ocular and inhalation exposure of workers will be minimised during printing operations in industrial settings, maintenance, repairs and cleaning of printing equipment by the use of PPE equipment.

Office workers may be exposed to the notified chemicals at up to 10% while replacing toner containers. However, the toner container is sealed and designed not to release toner until the sealing tape has been removed. Dermal exposure during use of the printer may occur if the printed or photocopied pages are handled before the toner has dried. During the printing operation, the toner or ink is transferred onto paper and fixed by heat. Once dried, the notified chemicals in the toner are bonded to the printed paper, and dermal exposure from contact with dried toner / ink is not expected.

6.1.2. Public Exposure

Use of cosmetics
Public exposure to the notified chemicals at up to 10% concentration is expected to be widespread and frequent through daily use of various cosmetic products. Exposure to the notified chemicals will vary depending on individual use patterns. The main route of exposure will be dermal. Ocular and ingestion exposure (from the use of face and lip products) and inhalation exposure (from the use of spray or powder products) to the notified chemicals may also occur.

Exposure can be estimated using data on typical use patterns of cosmetic product categories in which the notified chemicals may be used (SCCS, 2012; Cadby et al., 2002; ACI, 2010; Loretz et al., 2006). For the purposes of the exposure assessment, Australian use patterns for the various product categories are assumed to be similar to those in Europe. A lifetime average female body weight (BW) of 64 kg (enHealth, 2012) was used for calculation purposes.

Based on the expected high molecular weight of the notified chemicals and the estimated partition coefficient - log Pow value, a dermal absorption of 10% was assumed in the exposure calculations (ECHA, 2014).

The worst case scenario estimation using these assumptions is for a person who is a simultaneous user of all cosmetic products that contain the notified chemicals. This would result in a combined internal dose of 2.758 mg/kg bw/day. Specific use details of the notified chemicals are considered as exempt information.

Non-cosmetic uses
Where coatings are applied by the public using brushes or rollers (expected to be the main method of application), accidental dermal or ocular exposure to the notified chemicals may occur. Where aerosol paints are used, incidental inhalation exposure may also occur. However, it is expected that consumers would take reasonable precautions to avoid exposure to coatings during application. The public may come in contact with surfaces treated with coatings containing the notified chemicals; however, once dry the notified chemicals will be immobilised in the surface coating matrix and will not be available for exposure.

The public may also come into contact with surfaces treated with cured films 0.5 to 3 mm thick containing the notified chemicals. The notified chemicals will be immobilised within the polymer matrix and will not be available for exposure.

Similarly to office workers, the public may be exposed to the notified chemicals at up to 10% concentration through the dermal route while replacing the ink or toner container, or handling the printed and photocopy pages before the ink/toner has dried. During printing or photocopying operations, the ink or toner is transferred onto paper and fixed by heat. Once dried, the notified chemical is bonded to the printed paper, and dermal exposure to the notified chemicals from contact with dried ink/toner is not expected.

6.2. Human Health Effects Assessment

No toxicity data were submitted by the notifier. The results from toxicological data on the previously assessed similar chemical and an analogue to the notified chemicals are summarised in the following table. For full details of the acute inhalation study, refer to Appendix B.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 > 5,000 mg/kg bw; low toxicity
Rat, acute dermal toxicity	LD50 > 2,000 mg/kg bw; low toxicity
Rat, acute inhalation toxicity (analogue)	LC50 > 200 mg/L; low toxicity
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	severely irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – adjuvant test	no evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days	NOEL = 1,000 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – *in vivo* micronucleus test	non genotoxic

Toxicokinetics
Similar to other organoclay compounds, absorption of the notified chemicals following oral or dermal exposure is not expected (OECD, 2007). Given that the notified chemicals contain particles in the respirable size range, there is potential for accumulation in the lungs following inhalation exposure.

Acute toxicity
No acute toxicity data were provided for the notified chemicals. However, the similar chemical was of low acute toxicity via the oral and dermal routes in rats. A non-guideline study summary provided for this assessment indicated that an analogue of the notified chemicals is of low acute inhalation toxicity.

Irritation and Sensitisation
The similar chemical was slightly irritating to the skin of rabbits under the conditions of the test, with slight erythema and oedema noted following treatment at abraded skin sites.

In an eye irritation study in rabbits on the similar chemical, severe ocular irritation effects were noted, which persisted in some animals until the end of the observation period. In a second (more recent) study, only mild to moderate conjunctival effects were noted, with the irritation scores not warranting classification of the chemical

as an eye irritant. It is noted that in the former study, a significantly larger amount of test substance was instilled into the eyes of the treated animals (0.1 g versus 0.1 mL/~0.03 g in the latter study) and that the protocol required any residual solid substance to remain in the eyes for 24 hours prior to rinsing. Therefore, based on the studies provided, it is expected that the similar chemical has the potential to be only slightly irritating to eyes. This is consistent with the eye irritation effects expected from similar organoclay compounds (OECD, 2007).

The similar chemical did not cause skin sensitisation in guinea pigs (adjuvant test using the Magnusson and Kligman method).

Repeated dose toxicity
The No Observed Effect Level (NOEL) was established for the similar chemical by the study authors as 1,000 mg/kg bw/day in rats (the highest dose tested) based on the absence of test substance-related toxicologically significant effects at any of the doses administered.

Mutagenicity
The similar chemical was not mutagenic in a bacterial reverse mutation study and was not genotoxic in an *in vivo* micronucleus test.

Carcinogenicity
Some of the notified chemicals contain up to 3% quartz as an impurity, originating from their clay precursors. Crystalline silica in the form of quartz or cristobalite dust causes cancer of the lung (IARC, 2012). A recent Canadian evaluation of quartz and cristabolite considered that adequate data exists for a threshold approach to risk characterisation (Environment Canada, 2013).

Crystalline silica may display differences in the toxicity potential, when present in different forms, depending on the physico-chemical features of a specific form, such as polymorph characteristics (IARC, 2012) and association with other minerals (Miles, 2008).

It has been suggested that association of crystalline silica with clay or other aluminium containing compounds (as occurs with the similar chemical) inhibits its adverse effects (Duffin et al., 2001 as cited in IARC, 2012). The effects of crystalline silica after long residency in the lung have not been systematically assessed (IARC, 2012).

Health hazard classification
Based on the information provided, the notified chemicals are 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
Based on available data, the notified chemicals have some irritation potential, and may be accumulated in the lung. As the notified chemicals are of high molecular weight and are water insoluble, the potential for lung overloading effects cannot be ruled out. The powders have a high proportion of particles in the respirable size range. The chemicals also may contain an impurity that has been associated with carcinogenic effects following inhalation exposure. Therefore the greatest concern for the health of workers relates to inhalation, particularly when the chemicals are handled at 100% in powder form (e.g. when being weighed and transferred for reformulation). The risk would be reduced by measures that reduce exposure to the notified chemicals (e.g. local exhaust ventilation and/or appropriate dust extraction systems).

Based on the described processes and controls, exposure and risk to workers is likely to be lower for end-use of products containing the notified chemicals, as the powder is already incorporated in the end-use products.

Therefore, provided that control measures are in place to minimise worker exposure to the notified chemicals, including the use of PPE (particularly respiratory protection), ventilated environments and automated reformulation processes, the risk to the health of workers from use of the notified chemicals is not considered to be unreasonable.

6.3.2. Public Health

The public may come into contact with the notified chemicals (at up to 10% concentration), primarily through the use of a range of cosmetic products. Other exposures are expected to be of brief duration and incidental (application of coatings and printing uses) or only involve contact with dried surfaces where the chemicals are not expected to be bioavailable.

The potential systemic exposure to the public from the use of the notified chemicals in cosmetic products was estimated to be 2.758 mg/kg bw/day. Using a NO(A)EL of 1,000 mg/kg bw/day, which was derived from a repeated dose toxicity study on the similar chemical, the margin of exposure (MOE) was estimated to be 363. A MOE value greater than or equal to 100 is considered acceptable to account for intra- and inter-species differences; therefore, the MOE is considered to be acceptable. The irritation potential of the notified chemicals is expected to be reduced by their concentration (up to 10%) in end-use cosmetic products.

Overall, the risk to public health from exposure to the notified chemicals at up to 10% concentration in cosmetic and non-cosmetic 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 notified chemicals will be used as gelling agents at up to 10% concentrations (either individually or in a combination of no more than two) in cosmetics, surface coatings, polymers and printing industries. The notified chemicals are imported in finished products and may potentially be imported as raw materials for reformulation. In the case of reformulation and mixing processes, release of notified chemicals to the environment is expected to be negligible as these processes are likely to occur in a closed system in industrial settings. Residues in empty import containers are estimated to be 3% of the annual import volume and are expected to be disposed of to landfill or through a licensed waste contractor. Accidental spills during transport or reformulation are expected to be collected with inert material and disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

The majority of the notified chemicals are expected to be released to sewers in domestic situations across Australia as a result of use in cosmetic products. The notified chemicals may also be disposed of to landfill when certain cosmetics are removed from the body with cotton wool or tissues and disposed of via domestic garbage. Spills of the notified chemicals used in coatings are also expected to be collected and disposed of to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

Residues of the notified chemicals in end use containers are likely to share the fate of the container and be disposed of to landfill as domestic garbage, or to be washed to sewer when containers are rinsed before recycling.

The notified chemicals used in surface coatings are expected to be disposed of to landfill along with the used article at the end of its useful life. The polymer containing notified chemicals is expected to remain associated with the substrate to which it has been applied. The notified chemicals used in printing industries are expected to share the fate of the printed articles which are expected to be disposed of to landfill at the end of their useful life, or to be recycled after use. Hence, up to 50% of the total import volume of each of the notified chemicals may be released to sewers as residues in recycling waste waters. Empty containers containing residues of the notified chemicals are expected to be disposed of to landfill.

7.1.2. Environmental Fate

The majority of the notified chemicals are expected to be disposed of to sewer following use in cosmetic products. The notified chemicals do not dissociate up to 500ºC according to commentary on Quaternium 18-Bentonite, a representative component of the notified chemicals (CIR, 2000). The notified chemicals are not readily biodegradable (23-33% biodegradation after 28 days, OECD TG 301 B; Institut Fresenius, 2000) according to the fate study of a chemical which is structurally very similar to the notified chemicals. Based on the predicted high absorption coefficient (log Koc = 4.08), the notified chemicals are likely to partition to

sludge in Sewage Treatment Plant (STP) processes and eventually be disposed of to landfill. In landfill or in soil, the notified chemicals are expected to have low mobility, due to their low water solubility and anticipated high sorption to soil and sediment. They are expected to degrade by abiotic and biotic processes to water, oxides of carbon and nitrogen, and clay minerals. The notified chemicals are not expected to be bioavailable due to their limited water solubility and the organic component has low potential to bioaccumulate based on its low bioconcentration factor (log BCF = 1.85) predicted by a regression-based method using estimated log Kow (BCFBAF v3.01; log Kow = 5.87, KOWWIN; USEPA, 2011).

For the notified chemicals used in surface coatings, the captured overspray and the majority of articles to which the notified chemicals will be applied are expected to be disposed of to landfill. The notified chemicals are expected to be cured within an inert matrix adhering to articles following its use in coating applications. In their cured form, the notified chemicals are not expected to be mobile, bioavailable or biodegradable. Ultimately, the notified chemicals are expected to eventually degrade via biotic and abiotic processes in landfill, to form water, carbon and nitrogen, and clay minerals.

For the notified chemicals used in printing industries, approximately half of the printed paper containing notified chemicals is expected to be disposed of to landfill. The remaining half of the paper to which the inks containing the notified chemicals are applied to is likely to be recycled. During recycling processes, waste paper is repulped using a variety of chemical agents which, amongst other things, enhance detachment of ink from the fibres. The notified chemicals are anticipated to partially partition to sludge and/or sediment based on their low water solubility. Sludge from treatment plants may be collected for disposal to landfill or used in soil remediation. The majority of the notified chemicals in sludge are expected to be disposed of to landfill where they are anticipated to degrade by biotic and abiotic processes to form water, carbon and nitrogen, and clay minerals.

7.1.3. Predicted Environmental Concentration (PEC)

It has been conservatively assumed that most of the notified chemicals will be washed into the sewer, under a worst case scenario, with no removal of the notified chemicals in the sewage treatment plant (STP). The resultant Predicted Environmental Concentration (PEC) in sewage effluent on a nationwide basis, for an individual notified chemical, is estimated as follows:

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	150,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	150,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	410.96	kg/day
Water use	200	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:	90.87	µg/L
PEC - Ocean:	9.09	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1,000 L/m^2/year (10 ML/ha/year). The notified chemical 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 90.869 µg/L may potentially result in a soil concentration of approximately 605.8 µg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 3.029 mg/kg and 6.058 mg/kg, respectively.

7.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on a chemical that is structurally similar to the notified chemicals are summarised in the table below.

Fish Toxicity	96 h LC50 > 100 mg/L	Not harmful to fish up to the limit of water solubility
Daphnia Toxicity	48 h EC50 > 100 mg/L	Not harmful to aquatic invertebrates up to the limit of water solubility

Algal Toxicity	72 h E_rC50 > 100 mg/L	Not harmful to algae up to the limit of water solubility

Classification should be based only on toxic responses observed in the soluble range of the notified chemicals. The notified chemicals are not expected to be harmful to aquatic life up to their limit of solubility in water and are not classified for acuate aquatic hazard under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009).

7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) has been calculated from the lower limit of the endpoints of the aquatic organisms. An assessment factor of 250 has been used as acute toxicity endpoints are available for three trophic levels for a chemical that is structurally similar to the notified chemicals.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
LC50 (Invertebrates).	100	mg/L
Assessment Factor	250	
PNEC:	400	µg/L

7.3. Environmental Risk Assessment

Based on the above PEC and PNEC, the following Risk Quotient has been calculated.

Risk Assessment	***PEC µg/L***	***PNEC µg/L***	***Q***
Q - River:	90.87	400	0.227
Q - Ocean:	9.09	400	0.023

The risk quotient for discharge of effluents containing the notified chemicals to the aquatic environment, assuming a worst case with no removal during STP processes, indicates that the notified chemicals are unlikely to individually reach ecotoxicologically significant concentrations in surface waters, based on their maximum annual use quantity. The notified chemicals have a low potential for bioaccumulation. On the basis of the PEC/PNEC ratio, maximum annual use volume and assessed use patterns, the notified chemicals are not expected to pose an unreasonable risk to the environment.

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – inhalation

TEST SUBSTANCE	Analogue
METHOD	Comparable to OECD TG 403 Acute Inhalation Toxicity – Limit Test. (summary only provided)
Species/Strain	(5M,5F) Albino rats
Vehicle	None
Method of Exposure	Not known.
Exposure Period	1 hour
Physical Form	Assumed to be solid aerosol (particulate).
Particle Size	Not specified
Remarks - Method	5M and 5F rats were exposed to the test substance at an atmospheric concentration of 200 mg/L for 1 hour. The animals were observed for pharmacotoxic effects and mortality after 1, 3, 6 and 24 h after treatment and daily for 14 days.

RESULTS

Group	*Number and Sex of Animals*	*Concentration <units>*		*Mortality*
		Nominal	*Actual*	
1	5M,5F	200	Not known	1F

LC50	>200 mg/L/ 1 hour
Signs of Toxicity	One animal died
Effects in Organs	Not known
Remarks - Results	All animals at the end of 14 day observation period were subject to gross necropsy. Only 1 female out of (5M, 5F) died (No other information was cited).
CONCLUSION	The test substance is of low acute toxicity via inhalation.
TEST FACILITY	Consumer Product Testing

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