File No.: LTD/2158

November 2020

AUSTRALIAN INDUSTRIAL CHEMICALS INTRODUCTION SCHEME (AICIS)

PUBLIC REPORT

Crambe abyssinica seed oil phytosterol esters (INCI name)

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

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

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Executive Director
AICIS

TABLE OF CONTENTS

SUMMARY

The following details will be published on the AICIS website:

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/2158	Carst & Walker (Australia) Pty Ltd	Crambe abyssinica seed oil phytosterol esters (INCI name)	No	≤ 1 tonne per annum	Ingredient in cosmetics

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard Classification
Based on the available information, the assessed chemical is not recommended for classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia.

Human Health Risk Assessment
Under the conditions of the occupational settings described, the assessed chemical is not considered to pose an unreasonable risk to the health of workers.

When used in the proposed manner, the assessed chemical is 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 assessed chemical 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 safe work practices to minimise occupational exposure during handling of the assessed chemical as introduced:
  - Avoid contact with skin and eyes

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

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

Emergency procedures

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

Disposal

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

Regulatory Obligations

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

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

- the importation volume exceeds one tonne per annum assessed chemical;
- the final use concentration of the assessed chemical exceeds 15% concentration in cosmetic and personal care products;
- the function or use of the chemical has changed from an ingredient in cosmetics and personal care products or is likely to change significantly;
- additional information has become available to the person as to an adverse effect of the chemical on human health, or the environment.

The Executive Director will then decide whether an evaluation of the introduction is required.

Safety Data Sheet
The SDS of the assessed chemical and products containing the assessed chemical provided by the applicant were reviewed by AICIS. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND APPLICATION DETAILS

APPLICANT(S)
Carst & Walker (Australia) Pty Ltd (ABN: 28 085 896 822)
U 1, 5 Iron Road
MALAGA WA 6090

APPLICATION CATEGORY
Limited - small volume: Chemical other than polymer (1 tonne or less per year)

PROTECTED INFORMATION (SECTION 38 OF THE TRANSITIONAL ACT)
Data items and details taken to be protected information include: chemical name, other name(s), CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, impurities, use details, identity of analogue and identity of manufacturer.

VARIATION OF DATA REQUIREMENTS (SECTION 6 OF THE TRANSITIONAL RULES)
Schedule data requirements are varied for boiling point, hydrolysis as a function of pH, dissociation constant, flammability, autoignition temperature, explosive properties, and oxidising properties.

PREVIOUS APPLICATION IN AUSTRALIA BY APPLICANT(S)
None

APPLICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAMES(S)
Crambe abyssinica seed oil phytosterol esters (INCI name)

3. COMPOSITION

DEGREE OF PURITY
> 90%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Light yellow oily liquid with a faint characteristic odour

Property	*Value*	*Data Source/Justification*
Melting Point	-25.7 to -38.8 °C	Measured
Boiling Point	694 °C	QSAR (2020c)
Density	895 – 915 kg/m^3 at 20 °C	Product SDS
Vapour Pressure	2.44 × 10^{-17} kPa at 25 °C	QSAR (2020c)
Water Solubility	Insoluble in water	Product SDS
	< 4.0 × 10^{-7} mg/L at 25 °C	QSAR of analogue* (2020c)
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functional groups; however, chemical is insoluble in water.
Partition Coefficient (n-octanol/water)	log Pow > 12	QSAR of analogue* (2020c)
Adsorption/Desorption	log K_{oc} = 12.06 (MCI method)	QSAR of analogue* (2020c)
Dissociation Constant	Not determined	The assessed chemical does not have ionisable functional groups
Flash Point	> 200 °C	Product SDS
Flammability	Not determined	Not expected to be flammable under normal conditions of use
Auto-ignition Temperature	> 200 °C	Product SDS

Property	*Value*	*Data Source/Justification*
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidative properties

* The analogue is the major isomer in the mixture.

Reactivity
The assessed chemical is expected to be stable under normal conditions of use.

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

The assessed chemical has a flash point of > 200 ºC which is greater than 93 °C. Based on *Australian Standard AS1940* definitions for combustible liquid, the assessed chemical may be considered as a Class C2 combustible liquid if the chemical has a fire point below the boiling point.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF ASSESSED CHEMICAL (100%) OVER NEXT 5 YEARS
The assessed chemical will not be manufactured in Australia and will be imported into Australia either in pure form (> 90% concentration) or as a component of formulated end-use products at ≤ 15% concentration.

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

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

PORT OF ENTRY
Sydney, Melbourne, Perth

TRANSPORTATION AND PACKAGING
The assessed chemical will be imported as a raw material for blending into finished cosmetic products in Australia in 25 kg HDPE plastic jerry cans or 180 kg steel drums and will be generally shipped to Australia by sea on pallets in containers. Within Australia, the cans or drums will be transported by road to the warehouse for storage and later distributed to industrial customers by road for formulation into cosmetic products at ≤ 15% concentration in pack sizes of up to 500 mL that are suitable for retail sale.

The assessed chemical will also be imported as a component of finished consumer products at ≤ 15% concentration in pack sizes of up to 500 mL suitable for retail sale.

USE
The assessed chemical will be used as an additive in leave-on (e.g. body lotion, face lotion/cream, hand cream, deodorant, make up) and rinse off cosmetic products (e.g. shampoo, conditioner, shower gel, hand soap, facial cleanser) including aerosols (deodorant and hairspray) at ≤ 15% concentration.

OPERATION DESCRIPTION
The pure form of the assessed chemical will be transported to a blending facility for formulation and packaging. Formulated end-use consumer products will then be transported to retail outlets for sale to the public. The assessed chemical imported as a component of end-use products will be transported to a central warehouse for distribution to customer's warehouses and subsequently retailers.

Formulation and packaging
Formulation of the assessed chemical into finished consumer products may vary depending on the type of the cosmetic products being formulated. The assessed chemical is manually weighed and added into a closed loop flame proof mixing tank where it will be blended with additional additives to form finished cosmetic products. End use products containing the assessed chemical at ≤ 15% concentration will be filled into retail packaging of

various sizes. Samples of the assessed chemical and the finished cosmetic products will be taken at various stages of formulation for quality control testing.

End use
The finished cosmetic products containing the assessed chemical will be used by the public and may also be used in occupational settings by hairdressers and beauticians. Depending on the nature of the end products, application could be performed in a number of ways such as by hand, using 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
Compounder	8	12
Quality control chemist	3	12
Packers (Dispensing & Capping)	8	12
Store person	4	12
End user	8	365

EXPOSURE DETAILS
Transport and storage
The primary work activity undertaken by dockside transport and warehouse workers will include handling, loading and off-loading of pallets holding containers of the assessed chemical at > 90% concentration and finished end use products containing the assessed chemical at ≤ 15% concentration. Dockside and warehouse workers routinely wear uniforms and safety shoes and exposure of these workers will be limited to the unlikely event of a discharge, spill, ruptured or leaking container.

Formulation
During formulation, dermal, ocular and perhaps inhalation exposure of workers to the assessed chemical at > 90% concentration may occur during weighing and transfer stages, blending, quality control analysis, and cleaning and maintenance of the equipment. During this process, the compounder may be exposed to drips, spills and vapours, possibly through inhalation, ocular and dermal. This should only occur accidentally. The compounder is to wear personal protective equipment (PPE) such as safety glasses with shields, gloves, apron or coverall; however respiratory protection is not required as there would be plenty of ventilation. The quality control chemist is adequately protected for eyes and skin, hand and the whole body.

The applicant states that mixing and dispensing will be carried out in a closed system with flame proof mixers and pumps designed not to create aerosols or a dust hazard and earthed for static discharges. This procedure will also be carried out through the use of PPE such as protective clothing, goggles, impervious gloves and respiratory protection, if required when ventilation is inadequate.

Professional Use
The finished cosmetic products containing the assessed chemical at ≤ 15% concentration may also be used by professionals (eg. workers in beauty or hair salons, etc.), who may be exposed to the assessed chemical when applying products containing the assessed chemical to clients. While the principal route of exposure will be dermal, ocular exposure is also possible. PPE is not expected to be worn, however, good hygiene practices are expected to be in place.

6.1.2. Public Exposure
There will be widespread and repeated exposure of the public to the assessed chemical through the use of leave-on and rinse-off cosmetic products at ≤ 15% concentration. The main route of exposure will be dermal, while ocular and inhalation exposure are also possible, particularly if products are applied by spray. Data on typical use patterns of cosmetic product categories (SCCS, 2012; Cadby et al., 2002; ACI, 2010; Loretz et al., 2006), in which the assessed chemical may be used are shown in the following tables.

For the purposes of the exposure assessment via the dermal route, Australian use patterns for the various product categories are assumed to be similar to those in Europe. In the absence of dermal absorption data, a dermal absorption (DA) value of 10% was assumed for the assessed chemical due to large molecular weight (> 500), high partition coefficient (log Pow > 12), and insolubility in water. For inhalation exposure assessment, taking hairspray as a typical example, a 2-zone approach was used (Steiling et al., 2014; Rothe et al., 2011; Earnest, Jr., 2009). An adult inhalation rate of 20 m^3/day (enHealth, 2012) was applied and it was conservatively assumed that the fraction of the assessed chemicals inhaled is 50% of the amount sprayed, with remaining fraction ending up on the hair as intended for hair sprays. A lifetime average female body weight (BW) of 64 kg (enHealth, 2012) was used for calculation purposes.

Product type	**Amount** (mg/day)	**C** (%)	**RF**	**Daily systemic exposure** (mg/kg bw/day)
Body lotion	7820	15	1	1.83
Face cream	1540	15	1	0.361
Hand cream	2160	15	1	0.506
Deodorant (non-spray)	1500	15	1	0.352
Deodorant (spray)	690	15	1	0.016
Fragrances	750	15	1	0.176
Liquid Foundation	510	15	1	0.120
Mascara	25	15	1	0.006
Eyeliner	5	15	1	0.006
Eye shadow	20	15	1	0.005
Hair styling products	4000	15	0.1	0.094
Shower gel	18670	15	0.01	0.044
Hand wash soap	20000	15	0.01	0.047
Shampoo	10460	15	0.01	0.025
Hair conditioner	3920	15	0.01	0.009
Facial cleanser	800	15	0.01	0.002
Total				**3.579**

C - concentration; RF - retention factor.
Daily systemic exposure = (Amount × C × RF × dermal absorption)/body weight

Aerosol products (Inhalation exposure)

Product type	*Amount* (*g/day*)	*C* (*%*)	*Exposure Duration Zone 1* (*min*)	*Exposure Duration Zone 2* (*min*)	*Volume Zone 1* (m^3)	*Volume Zone 2* (m^3)	*Daily systemic exposure* (*mg/kg bw/day*)
Hairspray	9.89	15	1	20	1	10	0.442

Total Daily systemic exposure = Daily systemic exposure in Zone 1 [(amount x C x inhalation rate x exposure duration (zone 1) x fraction inhaled)/(volume (zone 1) x body weight)] + Daily systemic exposure in Zone 2 [(amount x C x inhalation rate x exposure duration (zone 2) x fraction inhaled)/(volume (zone 2) x body weight)]
Note - conversion factors of 0.1 [to account for C/Bioavailability as a % and unit conversion (g to mg) ((1/100 x 1/100) x 1000)] and 1440 [to account for mins to day conversion, i.e. 1440 mins/day]

The worst case scenario estimation using these assumptions is for a person who is a simultaneous user of all products listed in the above table that contain the assessed chemical. This would result in a combined internal dose of 4.021 mg/kg bw/day.

6.2. Human Health Effects Assessment

While the study dossiers on the assessed chemical were not provided by the applicant, the results from toxicological investigations conducted on the assessed chemical are summarised in the table below. These results were taken from a report on 'Safety Evaluation of Food Additives', prepared by the sixty-ninth meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) (JECFA, 2009). AICIS has not evaluated

individual studies referenced in the above document and the toxicology information was adopted as such from the above document.

The data submitted to the JECFA on the toxicity of phytosterol esters consisted of a series of publications. While the complete dossier containing the original test reports were submitted by the sponsor shortly before the JECFA meeting, the dossier could not be considered exhaustively by the JECFA. However, the original test reports with data, which were previously evaluated by the Scientific Committee on Food (SCF, 2000), this report was available to the JECFA. Phytosterol esters in the SCF report were derived from vegetable distillates (mainly soya bean). As concentrations were not indicated for studies below, these concentrations were probably assumed to be the neat mixtures of these chemicals.

Endpoint	***Result and Assessment Conclusion***
Acute oral toxicity – rat*	LD50 > 2000 mg/kg bw; low toxicity
Acute dermal toxicity – rat*	LD50 > 2000 mg/kg bw; low toxicity
Skin irritation and corrosion – rabbit	Minimally irritating
Eye irritation – rabbit	Minimally irritating
Sensitisation – guinea pig	Non sensitising
Repeat dose oral toxicity – rat, 90 days	NOAEL = 3900 mg/kg bw/day
Repeat dose oral toxicity – rat, 13 weeks	NOAEL = 3000 mg/kg bw/day
Genotoxicity – *in vitro* Reverse mutation	Non genotoxic
Genotoxicity – *in vitro* Chromosomal aberration test	Non genotoxic
Genotoxicity – *in vitro* Gene mutation test	Non genotoxic
Genotoxicity – *in vivo* Micronucleus induction	Non genotoxic
Genotoxicity – *in vivo* Unscheduled DNA synthesis	Non genotoxic
Reproductive and developmental toxicity – rat	NOAEL = 2700 mg/kg bw/day

* Analogue

Toxicokinetics, Metabolism and Distribution
After oral intake, phytosterol fatty acid ester are readily hydrolysed by intestinal esterases. Free phytosterols are absorbed from the gastrointestinal tract to a much lower extent than cholesterol, of which 55-60% is taken up. Published data reviewed by the SCF (2002) indicated that in humans, approximately 5% of β-sitosterol and 15% of campesterol are absorbed in the gastrointestinal tract. While unabsorbed phytosterols are excreted predominantly unchanged with the faeces, excretion of absorbed phytosterols predominately takes place via the bile in the faces.

Acute Toxicity
Wood-derived and vegetable oil-derived mixtures of an analogue, phytostanol esters, were shown to have low acute oral toxicity in a study in rats carried out according to OECD TG 401, 423 (1998) and also shown to have low acute dermal toxicity in a study in rats carried out according to OECD TG 402 (1998).

Skin and eye Irritation
In a skin irritation/corrosion study in albino rabbits (OECD TG 404, 1998) wood-derived mixtures of the analogue, phytostanol esters, did not cause any skin effects and were considered non-irritating to skin. However, vegetable oil-derived mixture of the analogue, phytostanol esters, caused very slight erythema after 1 hour of treatment with 2000 mg/kg bw, which was completely reversible within 24 hours of treatment.

In an *in vivo* eye irritation test (OECD TG 405, 1998), wood-derived and vegetable oil-derived mixture of an analogue, phytostanol esters, caused slight and moderate discharge, respectively, which was reversible within 24 hours of treatment. Both mixtures were considered minimally irritating to rabbit eyes.

Sensitisation
In maximisation tests (OECD TG 406, 1998), guinea-pigs induced with wood-derived and vegetable oil derived mixtures of the analogue phytostanol esters did not cause signs of skin sensitisation after the challenge phase.

Repeated Dose Toxicity
In a 90-day study in rats, phytosterol esters was fed to Wistar rats (20 rats/group/sex) at 0%, 0.16%, 1.6%, 3.3%, and 8.1% (w/w) (corresponding to 0, 0.2%, 1%, and 5% of phytostanol esters in the feed) for 13 weeks (UK, Home office guidelines, not specified). These concentrations in feed were equal to 0, 0.08, 0.78, 1.6, and 3.9 g phytosterol/kg bw/day for males and 0, 0.09, 0.87, 1.8, and 4.2 g phytosterol/kg bw/day for females. The Committee determined a no-observed-effect-level (NOAEL) of 8.1% phytosterol/kg bw/day in this study (highest

tested dose), equivalent to a dose of 3.9 g phytosterol/kg bw/day for males, on the basis of the minimal changes noted and the absence of any histopathological findings.

In a 13 week study in rats, phytostanols (isolated from soya bean and esterified with fatty acids from olive oil) were administered by gavage at 0, 1, 3 & 9 g/kg bw/day to 16, 10, 10 and 16 Sprague-Dawley rats, respectively (OCED TG not stated). Decreased body weight was noted in males and females at the highest dose. Histopathological examination showed an increased incidence of cardiomyopathy at the highest dose in males, but not in females. No other changes of biological importance were noted. Based on the effects observed at the highest dose level, the lowest-observed-adverse-effect-level (LOAEL) in this study was determined to be 9 g/kg bw/day and the no-observed-adverse-effect-level (NOAEL) was 3 g/kg bw/day.

Genotoxicity
Phytosterols and phytosterol esters were investigated in a battery of in vitro (reverse mutations in bacteria, chromosomal aberrations in peripheral lymphocytes, and gene mutations in mouse lymphoma cells) and in vivo assays (the bone marrow micronucleus assay in rats and the rat liver assay for the unscheduled DNA synthesis). These studies were carried out according to the OECD Tests guidelines 471, 473, 474, 476, and 486 (1997). Phytosterols and phytosterol esters did not show any genotoxic activity in any of these tests.

Toxicity for Reproduction
In a two generation reproductive toxicity study (OECD TG 416, 1999), phytosterol esters was fed to Wistar rats (28 rats/dose/sex) at levels of 0, 1.6%, 3.2%, and 8.1% (w/w), equal to doses of 0, 0.5-2.3, 0.9-4.5 and 2.3-12.6 g/kg bw/day. Females were treated during a 10-week premating period, the mating period (up to 3 weeks), and gestational until weaning. Males were treated only during the premating period. Food consumption, food efficiency, and body weight gain of F0 and F1 males and females at the highest dose were slightly, but significantly, decreased. Low food consumption may have contributed to decreases in body weight gain. While the viability index of pubs at PND 4 for F0 and F1 pups was slightly decreased, no differences in pup mortality were observed when analysed on litter basis, and pup weights of both generations were unaffected. The NOAEL was 8.1% phytosterol esters in the diet, equal to 2.7 g/kg bw/day, expressed as phytosterols (average exposure during premating and gestation for F0 and F1 females).

Health Hazard Classification
Based on the available information, the assessed chemical is not recommended for classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

6.3. Human Health Risk Characterisation
Based on the studies evaluated by the FAO/WHO (2009), the assessed chemical is expected to be of low acute oral and dermal toxicity and minimally irritating to the skin and eye. The assessed chemical is not a skin sensitiser. Dermal absorption of the assessed chemical is likely to be limited due to large molecular weight (> 500), high partition coefficient (log Pow > 12), and insolubility in water. As the vapour pressure of assessed chemical is low, inhalation exposure is therefore not expected to be significant. Based on the available information, systemic effects are not expected from the use of the assessed chemical.

6.3.1. Occupational Health and Safety
Workers may experience dermal, ocular and potentially inhalation exposure to the notified polymer up to > 90% concentration during formulation processes. As stated by the applicant, the use of enclosed processes and PPE (impervious gloves, goggles, protective clothing and respiratory protection, if significant inhalation exposure is expected) should minimise the potential for exposure to workers. Similarly, potential exposure to the compounders and the laboratory scientists will also be minimised through the use of PPE.

Workers involved in professions where the services provided involve the application of cosmetic products to clients (e.g. beauty and hair salon workers) may be exposed to the assessed chemical at ≤ 15% concentrations. Such professionals may use PPE to minimise repeated exposure, and good hygiene practices are expected to be in place. If PPE is used, the exposure of such workers is expected to be of a similar or lesser extent than that experienced by consumers using the various cosmetic products containing the assessed chemical. Therefore, the risk to workers who use products containing the assessed chemical is expected to be of a similar or to a lesser extent than consumers who use such products on a regular basis. For details of the public health risk assessment see section 6.3.2 below.

Under the conditions of the occupational settings described, the assessed chemical is not considered to pose an unreasonable risk to the health of workers.

6.3.2. Public Health

Members of the public may experience repeated exposure to the assessed chemical through the use of cosmetic products containing the assessed chemical at ≤ 15% concentrations. The main route of exposure is expected to be dermal, with some potential for accidental ocular or inhalation exposure. As the assessed chemical does not possess any irritating and skin sensitisation potentials, the risk to the public from the use of cosmetic products is expected to be minimal.

The repeated dose toxicity potential was estimated by calculation of the margin of exposure (MoE) of the assessed chemical using the worst case exposure scenario from use of multiple products containing the assessed chemical (4.021 mg/kg bw/day) (see Section 6.1.2). Using a NOAEL of 3000 mg/kg bw/day, derived from a repeated dose toxicity study on the assessed chemical, the MOE was estimated to be 746. A MOE value ≥ 100 is considered acceptable to account for intra- and inter-species differences, and to account for long-term exposure. Therefore, the MOE value is considered acceptable.

Based on the information available, the assessed chemical is not considered to pose an unreasonable risk to public health when used in the proposed manner.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The assessed chemical is not manufactured in Australia and will only be imported for reformulation into cosmetic products. In general, the reformulation processes are expected to involve blending operations that will normally be automated and occur in an enclosed system. Release of the assessed chemical to the environment in the event of accidental spills or leaks during reformulation, storage and transport is expected to be disposed of to landfill in accordance with local government regulations. Empty containers containing the assessed chemical will be rinsed and then be recycled or disposed of through an approved waste management facility.

RELEASE OF CHEMICAL FROM USE

The assessed chemical will be primarily washed into the sewers during use of the various end-use cosmetic products.

RELEASE OF CHEMICAL FROM DISPOSAL

Wastes and residues of the assessed chemical in empty end-use containers are likely to either share the fate of the containers and be disposed of to landfill or be released to sewer when containers are rinsed before recycling through an approved waste management facility.

7.1.2. Environmental Fate

Following its use in cosmetic products, the majority of the assessed chemical will enter the sewers and be treated at sewage treatment plants (STPs) before the potential release to surface waters nationwide.

A ready biodegradation study on an analogue (the majority isomer in the mixture) determined that the assessed chemical is readily biodegradable (80% degradation after 28 days). Although only 49% of the degradation occurred in the 10 day window, the assessed chemical is still considered readily biodegradable as it is a mixture. For further details on the biodegradability study, refer to Appendix A.

The assessed chemical is expected to be efficiently removed at STPs due to its ready biodegradability. Approximately 7% of the assessed chemical is expected to be released to surface waters. A proportion of the assessed chemical may be applied to land when effluent is used for irrigation or when sewage sludge is used for soil remediation, or disposed of to landfill. The assessed chemical residues in landfill and soils are expected to be immobile based on its modelled soil adsorption coefficient.

The assessed chemical satisfies criteria to be categorised as bioaccumulative based on its estimated partition coefficient (log P_{ow} > 4.2). However, the ready biodegradation of the chemical indicates a low potential to bioaccumulate.

In the aquatic and soil compartments, the assessed chemical is expected to degrade through biotic and abiotic processes to form water and oxides of carbon.

7.1.3. Predicted Environmental Concentration (PEC)

The use pattern will result in most of the assessed chemical being washed into the sewer. The predicted environmental concentration (PEC) has been calculated assuming the realistic worst-case scenario with 100% release of the assessed chemical into sewer systems nationwide over 365 days per annum. The extent to which the assessed chemical is removed from the effluent in STP processes based on the properties of the assessed chemical has not been considered for this scenario, and therefore no removal of the assessed chemical during sewage treatment processes, is assumed. The 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	1,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	1,000.000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	2.74	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	24.386	Million
Removal within STP	0%	Mitigation
Daily effluent production:	4,877	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.56	µg/L
PEC - Ocean:	0.06	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m^2/year (10 ML/ha/year). The assessed 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 0.562 µg/L may potentially result in a soil concentration of approximately 3.75 $\times 10^{-3}$ mg/kg. Assuming accumulation of the assessed chemical in soil for 5 and 10 years under repeated irrigation, the concentration of assessed chemical in the applied soil in 5 and 10 years may be approximately 1.87 $\times 10^{-2}$ mg/kg and 3.75 $\times 10^{-2}$ mg/kg, respectively.

7.2. Environmental Effects Assessment

No measured ecotoxicological data were submitted for the assessed chemical and this is not required for a limited application. The applicant has supplied estimated toxicity endpoints for the analogue chemical (the majority isomer in the mixture) using QSAR modelling software. All estimated endpoints are above the estimated water solubility of the assessed chemical which indicate that the assessed chemical is likely to have no acute toxic effects at the limit of its water solubility.

7.2.1. Predicted No-Effect Concentration

A PNEC was not calculated for this assessed chemical. The estimated ecotoxicity endpoints provided for the assessed chemical are all above the chemical's maximum solubility. No toxic effects are expected at the maximum solubility limit.

7.3. Environmental Risk Assessment

A Risk quotient cannot be calculated for the assessed chemical. The assessed chemicals saturates in water saturates before toxic effects are expected to be observed. Based on the ready biodegradability and the expected low aquatic toxicity of the assessed chemical, the assessed chemical is not expected to pose an unreasonable risk to the environment.

APPENDIX A: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

A.1. Environmental Fate

A.1.1. Ready Biodegradability

TEST SUBSTANCE	Assessed Chemical
METHOD	OECD TG 301 B Ready Biodegradability: CO2 Evolution Test
Inoculum	Activated Sludge
Exposure Period	29 days
Auxiliary Solvent	None
Analytical Monitoring	$ThCO_2$
Remarks – Method	As per OECD guidelines. Test substance: Aniline.

RESULTS

Test Substance		*Aniline*	
Day	*% Degradation*	*Day*	*% Degradation*
2	2.8	2	3.2
9	30.0	9	74.7
14	48.7	14	80.2
23	68.1	23	86.5
29	80.1	29	86.3

Remarks – Results	All Validity criteria were met. Degradation of reference substance was > 60% on day 14, the CO_2 emitted by the blank controls was < 40 mg/L and the inorganic carbon in the medium was < 5%. Because the test item is a mixture the 10-day window has not been taken into account. Degradation surpassed 60% within 28 days. Therefore, the test item is considered as "readily biodegradable" within 28 days.
CONCLUSION	The test substance is readily biodegradable.
TEST FACILITY	LAUS GmbH (Muckle, 2016)

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