File No: LTD/2042

October 2018

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

White Vanilla

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 and Energy.

This Public Report is 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
LTD/2042	Takasago International (Singapore) Pte Ltd	White Vanilla	Yes	< 1 tonne per annum	Fragrance ingredient

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified chemical is 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 recommended hazard classification is presented in the following table.

Hazard classification	*Hazard statement*
Serious Eye Damage/Eye Irritation (Category 2A)	H319 – Causes serious eye irritation

The environmental hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS) is presented below. Environmental classification under the GHS is not mandated in Australia and carries no legal status but is presented for information purposes.

Hazard classification	*Hazard statement*
Acute (Category 3)	H402 - Harmful to aquatic life

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

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

Environmental risk assessment
On the basis of the PEC/PNEC ratio, the notified chemical is not considered to pose an unreasonable risk to the environment.

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- The notified chemical should be classified as follows:
  – Serious Eye Damage/Eye Irritation (Category 2A): H319 – Causes serious eye irritation

  The above should be used for products/mixtures containing the notified chemical, if applicable, based on the concentration of the notified chemical present.

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 during reformulation processes:
  - Enclosed, automated processes, where possible
  - Adequate local exhaust ventilation

- 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 chemical during reformulation processes:
  - Avoid contact with eyes and skin

- 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 chemical during reformulation processes:
  - Respiratory protection if inhalation exposure may occur

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

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

- If products and mixtures containing the notified 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.

Disposal

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

Storage

- The handling and storage of the notified chemical should be in accordance with the Safe Work Australia Code of Practice for *Managing Risks of Hazardous Chemicals in the Workplace* (SWA, 2012) or relevant State or Territory Code of Practice.

Emergency procedures

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

Regulatory Obligations

Secondary Notification
This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified 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 importation volume exceeds one tonne per annum notified chemical;

- the concentration of the notified chemical exceeds or is intended to exceed 0.05% in cosmetic or household products;
- further information on the repeated does toxicity of the notified chemical becomes available;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from a fragrance ingredient, or is likely to change significantly;
- the amount of chemical being introduced has increased, or is likely to increase, significantly;
- the chemical has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the chemical 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.

Safety Data Sheet
The SDS of the notified chemical provided by the notifier was reviewed by NICNAS. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Takasago International (Singapore) Pte Ltd (ABN: 29 099 666 832)
Level 5, 815 Pacific Highway
CHATSWOOD NSW 2067

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

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, molecular weight, analytical data, degree of purity, impurities, additive/adjuvants, use details, import volume and identity of manufacturer.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed for hydrolysis as a function of pH, adsorption/desorption and flammability.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Canada (2017)
China (2017)
Japan (2015)
Philippines (2015)
USA (2015)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
White Vanilla

MOLECULAR WEIGHT
< 500 g/mol

ANALYTICAL DATA
Reference NMR, FTIR, GC-FID, GC-MS, UV-Vis spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 95%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: white to pale yellow powder

Property	Value	Data Source/Justification
Melting Point	76.4 °C	Measured
Boiling Point	Decomposes prior to boiling, from 220 °C at 102 kPa	Measured
Density	1,310 kg/m^3 at 20 °C	Measured
Vapour Pressure	2.7×10^{-6} kPa at 25 °C	Measured
Water Solubility	6.1 g/L at 20 °C	Measured
Hydrolysis as a Function of pH	Not determined	

Partition Coefficient (n-octanol/water)	log Pow = 0.702 at 22 °C	Measured
Adsorption/Desorption	K_{oc} = 57.5 at 25 °C	Calculated (ACD/Labs 1994-2018)
Dissociation Constant	pKa = 10.1 at 25 °C	Measured
Particle Size	Inhalable fraction (< 100 μm): 24.8% Respirable fraction (< 10 μm): 6.96% Respirable fraction (< 5.5 μm): 1.68%	Measured
Flash Point	209 ± 2 °C at 101.3 kPa	Measured
Flammability	Not determined	Not expected to be highly flammable based on the measured flash point
Autoignition Temperature	324 ± 5 °C	Measured
Explosive Properties	Not determined	Contains no functional groups that imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that imply oxidative properties

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

Reactivity
The notified 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 notified 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.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will not be manufactured in Australia. It will be imported into Australia as a component of fragrance formulations (at < 1% concentration) or in finished consumer products (at ≤ 0.05% concentration).

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

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

PORT OF ENTRY
Major cities throughout Australia

TRANSPORTATION AND PACKAGING
Fragrance formulations containing the notified chemical will be imported in 200 L drums and finished consumer products will be imported in containers suitable for retail sale. The products will be transported locally by road. After reformulation, the finished products will be packaged in containers suitable for retail sale and distributed by road.

USE
The notified chemical will be used as a fragrance ingredient in cosmetic and household products at ≤ 0.05 concentration.

OPERATION DESCRIPTION

Reformulation
The reformulation processes for incorporating the notified chemical into end-use products will likely vary depending on the specific type of cosmetic and household products formulated. This may involve both automated and manual processes including transferring and blending the notified chemical with other formulations. However, a typical blending operation will be highly automated and occur in a fully enclosed/contained environment, followed by automated filling using sealed delivery systems into containers of various sizes.

End-use

Household products
Finished household cleaning products containing the notified chemical at ≤ 0.05% concentration will be used by consumers and professional cleaners. The products may be used in either closed systems with episodes of controlled exposure, for example automatic washing machines or open processes, and manually applied by sponge, mop, spray or brush followed by wiping or rinsing.

Cosmetics
Finished cosmetic products containing the notified chemical at ≤ 0.05% concentration will be used by consumers and professionals (such as hairdressers and workers in beauty salons). Depending on the nature of the product, application of products may be done by hand, sprayed or through the use of an applicator.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and storage	1-2	50
Mixing	≤ 8	240
Quality control	0.5	240
Cleaning and maintenance	≤ 8	240
Professional end users	1-8	240

EXPOSURE DETAILS

Transport and storage workers
Transport and storage workers may come into contact with the notified chemical at < 1% concentration only in the unlikely event of accidental rupture of containers.

Reformulation workers
During reformulation, dermal, ocular and possible inhalation exposure of workers to the notified chemical (at < 1% concentration) may occur during weighing, transfer, blending, quality control analysis and cleaning/maintenance of equipment. Exposure is expected to be minimised through the use of local exhaust ventilation and enclosed and automated systems, and through the use of personal protective equipment (PPE) such as impervious gloves, safety glasses, protective clothing and respiratory protection.

Professional end users
Exposure to the notified chemical at ≤ 0.05 % concentration in end-use products may occur in professions where the services provided involve the application of cosmetic products to clients or the use of cleaning products in the cleaning industry. The principal route of exposure is expected to be dermal, while ocular and inhalation exposure is also possible. Such professionals may use PPE to minimise repeated or prolonged exposure and ensure that good hygiene practices are 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.

6.1.2. Public Exposure
There will be widespread and repeated exposure of the public to the notified chemical at ≤ 0.05 % concentration through the use of a variety of cosmetic and household products. The principal route of exposure will be dermal, while ocular and inhalation exposure is also possible, particularly if products are applied by spray.

Data on typical use patterns of cosmetic and household products (SCCS, 2012; Cadby *et al.*, 2002; ACI, 2010; Loretz *et al.,* 2006) in which the notified chemical may be used are shown in the following tables. 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 dermal absorption (DA) of 100% was assumed for the notified chemical for calculation purposes. For the inhalation exposure assessment, a 2-zone approach was applied (Steiling *et al.*,

2014; Rothe *et al*., 2011; Earnest, Jr, 2009). An adult inhalation rate of 20 m^3/day (enHealth, 2012) was used and it was conservatively assumed that the fraction of the notified chemical inhaled is 50%. For calculation purposes, a lifetime average female body weight (BW) of 64 kg (enHealth, 2012) was used.

Cosmetic products (Dermal exposure)

Product type	Amount (mg/day)	C (%)	RF (unitless)	Daily systemic exposure (mg/kg bw/day)
Body lotion	7,820	0.05	1	0.0611
Face cream	1,540	0.05	1	0.0120
Hand cream	2,160	0.05	1	0.0169
Deodorant (non-spray)	1,500	0.05	1	0.0117
Fine fragrances	750	0.05	1	0.0059
Hair styling products	4,000	0.05	0.1	0.0031
Shower gel	18,670	0.05	0.01	0.0015
Hand wash soap	20,000	0.05	0.01	0.0016
Shampoo	10,460	0.05	0.01	0.0008
Conditioner	3,920	0.05	0.01	0.0003
Total				**0.1148**

C = concentration of the notified chemical; RF = retention factor
Daily systemic exposure = (Amount × C × RF × DA)/BW

Household products (Indirect dermal exposure - from wearing clothes)

Product type	Amount (g/use)	C (%)	Product Retained (PR) (%)	Percent Transfer (PT) (%)	Daily systemic exposure (mg/kg bw/day)
Laundry liquid	230	0.05	0.95	10	0.0017
Fabric softener	90	0.05	0.95	10	0.0007
Total					**0.0024**

Daily systemic exposure = (Amount × C × PR × PT × DA)/BW

Household products (Direct dermal exposure)

Product type	Frequency (use/day)	C (%)	Contact Area (cm^2)	Product Use C (g/cm^3)	Film Thickness (cm)	Time Scale Factor	Daily systemic exposure (mg/kg bw/day)
Laundry liquid	1.43	0.05	1980	0.01	0.01	0.007	0.0000
Dishwashing liquid	3	0.05	1980	0.009	0.01	0.03	0.0001
All-purpose cleaner	1	0.05	1980	1	0.01	0.007	0.0011
Total							**0.0012**

Daily systemic exposure = (Frequency × C × Contact Area × Product Usage × Film Thickness on skin × Time Scale Factor × DA)/BW

Aerosol products (Inhalation exposure)

Product type	Amount (g/day)	C (%)	Inhalation Rate (m^3/day)	Exposure Duration (Zone 1) (min)	Exposure Duration (Zone2) (min)	Fraction Inhaled (%)	Volume (Zone 1) (m^3)	Volume (Zone 2) (m^3)	Daily systemic exposure (mg/kg bw/day)
Hair spray	9.89	0.05	20	1	20	50	1	10	**0.0016**

Daily systemic exposure = [(Amount × C × Inhalation Rate × Fraction Inhaled × 0.1) / (BW × 1440)] × [Exposure Duration (Zone 1)/Volume (Zone 1) + Exposure Duration (Zone 2)/Volume (Zone 2)]

The worst case scenario estimation using these assumptions is for a person who is a simultaneous user of all products listed in the above tables that contain the notified chemical. This would result in a combined internal dose of 0.12 mg/kg bw/day. It is acknowledged that inhalation exposure to the notified chemical from use of other cosmetic and household products (in addition to hair spray) may occur. However, it is considered that the combination of the conservative (screening level) hair spray inhalation exposure assessment parameters, and the aggregate exposure from use of the dermally applied products, which assumes a conservative 100% absorption

rate, is sufficiently protective to cover additional inhalation exposure to the notified chemical from use of other spray cosmetic and household products with lower exposures.

6.2. Human Health Effects Assessment

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

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 > 2000 mg/kg bw; low toxicity
Skin irritation – *in vitro*, Epidermis	non-irritating
Skin irritation – Human closed patch test	non-irritating at 0.5% and 5% concentration
Eye irritation – *in vitro*, BCOP	not corrosive or severely irritating at 20%
Eye irritation – *in vitro*, EpiOcular	irritating
Mouse, skin sensitisation – LLNA	no evidence of sensitisation
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – *in vitro* mammalian cell micronucleus assay	non genotoxic

Toxicokinetics

No toxicokinetics data were submitted for the notified chemical. Based on the molecular weight (< 500 g/mol) of the notified chemical, there is potential for the chemical to cross biological membranes. However, absorption is expected to be limited based on the partition coefficient (log Pow = 0.702 at 22 °C) of the notified chemical.

Acute toxicity

The notified chemical was found to be of low acute oral toxicity in rats.

No information was submitted for the notified chemical on acute dermal and acute inhalation toxicity.

Irritation

Based on a study conducted on the EpiSkin reconstructed human epidermis model, the notified chemical was not considered to be irritating to the skin. In a human patch test, two solutions containing 0.5% and 5% notified chemical were found to be non-irritating.

No prediction of eye irritation could be made for a solution containing 20% notified chemical (gave an *in vitro* irritancy score of > 3 and ≤ 55) in an *in vitro* bovine cornea opacity and permeability (BCOP) test. However, 20% concentration was not corrosive to eyes. In another *in vitro* eye irritation test using the EpiOcular method (OECD TG 492), the notified chemical was categorised as an eye irritant (UN GHS Category 1 or 2) as the cell viability scores indicated that the chemical was not in the category for non-classification according to the TG.

Sensitisation

The notified chemical was not a skin sensitiser in mice when tested at up to 20% concentration in a local lymph node assay (LLNA).

Mutagenicity/Genotoxicity

The notified chemical was negative in a bacterial reverse mutation test and in an *in vitro* mammalian cell micronucleus test.

Health hazard classification

Based on the available information, the notified chemical is 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 recommended hazard classification is presented in the following table.

Hazard classification	***Hazard statement***
Serious Eye Damage/Eye Irritation (Category 2A)	H319 – Causes serious eye irritation

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

Reformulation

During reformulation, worker exposure will be limited through the use of engineering controls (such as enclosed, automated systems and local exhaust ventilation) and appropriate PPE (eye protection and respiratory protection if inhalation exposure may occur), as anticipated by the notifier. Therefore, provided that control measures are in place to minimise worker exposure, under the occupational settings described, the risk to the health of workers from reformulation of the notified chemical is not considered to be unreasonable.

End-Use
Workers involved in professions where the services provided involve the application of cosmetic and household products containing the notified chemical to clients (*e.g.* hairdressers, beauty salon workers and cleaners) or the use of household products in the cleaning industry may be exposed to the notified chemical at ≤ 0.05% concentration. PPE may be employed by workers to minimise repeated exposure, and good hygiene practices are expected to be in place. If PPE is used, the risk to such workers is expected to be of a similar or lesser extent than that for consumers using the various products containing the notified chemical.

6.3.2. Public Health
Members of the public will experience widespread and frequent exposure to the notified chemical at ≤ 0.05% concentration through daily use of cosmetic and household products. The main route of exposure is expected to be dermal an inhalation, with some potential for accidental ocular or oral exposure.

Eye irritation
The notified chemical is an eye irritant; however, risk of eye irritation effects is not expected at the proposed low use concentrations (≤ 0.05%).

Repeated dose toxicity
The repeated dose toxicity effects of the notified chemical have not been determined. However, exposure is expected to be limited by the low concentrations of the notified chemical in end use products (≤ 0.05%).

Therefore, based on the information available, the risk to the public associated with the use of the notified chemical at ≤ 0.05% concentration in cosmetic and household products is not considered to be unreasonable. In the absence of data on the repeated dose toxicity potential of the notified chemical, use of the notified chemical is supported only under limited exposure conditions, which are reflected in the low concentrations of the notified chemical in end-use products.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE
The notified chemical is to be imported into Australia as part of chemical mixtures that will be formulated into a range of cosmetics and household products (e.g. laundry detergent). Except in the case of accidental spills and leaks, there is unlikely to be significant release of the notified chemical to the environment from either transport to or within Australia, or storage within factory facilities. B However, the formulation process is expected to occur within a fully enclosed environment. Waste containing the notified chemical generated during reformulation (such as wash waters and residues in empty import containers) will either be released to sewers or disposed of to landfill according to local government regulations. Any accidental spill will likely be collected with absorbent cloth and disposed of to landfill according to local government regulations.

RELEASE OF CHEMICAL FROM USE
The notified chemical will be used in cosmetic and household products. After application, the notified chemical is expected to be released to sewer. Direct release into surface water is expected to be minimal.

RELEASE OF CHEMICAL FROM DISPOSAL
It is likely that only a small amount (< 5%) of any formulation will remain in a product container after final use. Residues of the notified chemical in empty containers are likely to either share the fate of the container and be disposed of to landfill, or be released to the sewer system when containers are rinsed before recycling through an approved waste management facility.

7.1.2. Environmental Fate

The submitted biodegradable study indicates that the chemical is degradable in domestic sewage (> 96% biodegradation in 28 days). For details of the study, please see Appendix C. Further, a log Pow value of 0.702 suggests that bioaccumulation in aquatic organisms is unlikely.

7.1.3. Predicted Environmental Concentration (PEC)

The calculation for the predicted environmental concentration (PEC) is summarised in the table below. It is assumed that 100% of the total import volume of the notified chemical is released to the sewer, release is nationwide over 365 days per year, and there is no removal of the notified chemical during sewage treatment processes.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	1000	kg/year
Proportion expected to be released to sewer	100	%
Annual quantity of chemical released to sewer	1000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	2.7	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	24.4	million
Removal within STP	0	%
Daily effluent production:	4,877	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.02	µg/L
PEC - Ocean:	< 0.01	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m^2/year (10 ML/ha/year). The notified 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 0.02 µg/L may potentially result in a soil concentration of approximately 0.13 µg/kg (0.02 × 1000/150).

As the notified chemical is readily biodegradable it is not expected to accumulate over time in soil.

7.2. Environmental Effects Assessment

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

Endpoint	*Result*	*Assessment Conclusion*
Daphnia toxicity (acute)	EC50 (48 h) = 24 mg/L	Harmful to invertebrates

Under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009), the notified chemical is formally classified as 'Acute category 3' and 'Harmful to aquatic life'.

7.2.1. Predicted No-Effect Concentration

The predicted no-effects concentration (PNEC) has been calculated from the most sensitive acute endpoint for aquatic invertebrates and an assessment factor of 100.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
Daphnia	24	mg/L
Assessment Factor	1000	
Mitigation Factor	1	
PNEC:	24	µg/L

7.3. Environmental Risk Assessment

Risk Assessment	***PEC µg/L***	***PNEC µg/L***	***Q***
Q - River:	0.02	24	< 0.01

Q - Ocean:	< 0.01	24	< 0.01

The Risk Quotients (Q = PEC/PNEC) for discharge of treated effluents containing the notified chemical have been calculated to be < 1 for both river and ocean compartments. This indicates that, based on the amount of the notified chemical to be imported each year and its use pattern, it is unlikely to reach ecotoxicologically significant concentrations in surface waters. The notified chemical is not expected to bioaccumulate. Therefore, the notified chemical is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point/Freezing Point 76.4 ± 0.5 °C

Method	OECD TG 102 Melting Point/Melting Range EC Council Regulation No 440/2008 A.1 Melting/Freezing Temperature
Remarks	Determined by differential scanning calorimetry
Test Facility	Envigo (2017a)

Boiling Point Decomposes from 220 °C at 102.0 kPa, prior to boiling

Method	OECD TG 103 Boiling Point EC Council Regulation No 440/2008 A.2 Boiling Temperature
Remarks	Determined by differential scanning calorimetry
Test Facility	Envigo (2017a)

Density 1,310 kg/m^3 at 20 °C

Method	OECD TG 109 Density of Liquids and Solids EC Council Regulation No 440/2008 A.3 Relative Density
Remarks	Determined using a gas comparison pycnometer
Test Facility	Envigo (2017a)

Vapour Pressure 2.7×10^{-6} kPa at 25 °C

Method	OECD TG 104 Vapour Pressure EC Council Regulation No 440/2008 A.4 Vapour Pressure
Remarks	Vapour pressure balance
Test Facility	Envigo (2017b)

Water Solubility 6.1 g/L at 20 °C

Method	OECD TG 105 Water Solubility EC Council Regulation No 440/2008 A.6 Water Solubility
Remarks	Flask method
Test Facility	Envigo (2017a)

Partition Coefficient (n-octanol/water) log Pow = 0.702 at 22 °C

Method	OECD TG 107 Partition Coefficient (n-octanol/water) EC Council Regulation No 440/2008 A.8 Partition Coefficient
Remarks	Shake-flask method
Test Facility	Envigo (2017a)

Dissociation Constant pKa = 10.1 at 25 °C

Method	OECD TG 112 Dissociation Constants in Water
Test Facility	Envigo (2017a)

Particle Size
< 100 µm: 24.8%
< 10 µm: 6.96%
< 5.5 µm: 1.68%

Method	EC Guidance Document on the Determination of Particle Size Distribution, Fibre Length and Diameter Distribution of Chemical Substances
Remarks	Determined using a sieving apparatus and a cascade impactor
Test Facility	Envigo (2017a)

Flash Point 209 ± 2 °C at 101.3 kPa

Method	EC Council Regulation No 440/2008 A.9 Flash Point
Remarks	Closed cup method
Test Facility	Envigo (2017c)

Autoignition Temperature 324 ± 5 °C

Method	EC Council Regulation No 440/2008 A.15 Auto-Ignition Temperature (Liquids and Gases) EC Council Regulation No 440/2008 A.16 Relative Self-Ignition Temperature for Solids
Test Facility	Envigo (2017c)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 420 Acute Oral Toxicity - Fixed Dose Method
Species/Strain	Rat/Wistar (RccHan:WIST)
Vehicle	Arachis oil
Remarks - Method	No significant protocol deviations

RESULTS

Main Study

Group	*Number and Sex of Animals*	*Dose (mg/kg bw)*	*Mortality*
1	1 F	300	0/1
2	1 F	2,000	0/1
3	4 F	2,000	0/4

Discriminating Dose	> 2,000 mg/kg bw
Signs of Toxicity	Hunched posture was noted on Day 1 for two animals treated at 2,000 mg/kg bw, which was recovered within 4 hours.
Effects in Organs	No abnormalities were observed at necropsy.
Remarks - Results	The animals showed expected body weight gains over the observation period.
CONCLUSION	The notified chemical is of low acute toxicity via the oral route.
TEST FACILITY	Envigo (2017d)

B.2. Irritation – skin (*in vitro* reconstructed human epidermis test)

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 439 *In vitro* Skin Irritation: Reconstructed Human *Epidermis* Test Method EpiSkin™ Reconstituted Human Epidermis Model
Vehicle	None (moistened with sterile distilled water)
Remarks - Method	In a pre-test the test substance was not shown to have the ability to directly reduce MTT (3-[4,5-dimethylthiazol-2-yl]-2,5-diphenyl-tetrazolium bromide). The test substance (10 mg moistened with 5 µL sterile distilled water which was topically applied to the epidermal surface) was applied to the tissues in triplicate. Following exposure periods of 15 minutes at room temperature, the tissues were rinsed, treated with MTT and then incubated at 37 °C for approximately 42 hours. Negative control (Dulbecco's phosphate buffered saline with Ca^{2+}/Mg^{2+}) and positive control (5% aqueous solution of sodium dodecyl sulfate) were run concurrently with the test substance.

RESULTS

Test Material	*Mean OD_{562} of Triplicate Tissues*	*Relative Mean Viability (%)*	*SD of Relative Mean Viability*
Negative control	1.098	100	4.1
Test substance	1.008	91.8	11.4
Positive control	0.101	9.2	0.8

OD = optical density; SD = standard deviation

Remarks - Results	The test substance was categorised as non-irritating accordingly to the test guidelines, based on the > 50% relative mean tissue viability of the test substance-treated tissues. The negative control and positive control gave satisfactory results, confirming the validity of the test system.
CONCLUSION	The notified chemical was considered to be non-irritating to the skin under the conditions of the test.
TEST FACILITY	Envigo (2017e)

B.3. Skin irritation – human volunteers

TEST SUBSTANCE	Notified chemical (0.5% and 5% in vehicle)
METHOD	Human closed patch test
Study Design	Patches containing 0.03 mL test substance were applied. Patches were removed after 24 hours and the application sites were evaluated at 60 minutes and 24 hours.
Study Group	14 F, 6 M; age range 22 – 59 years
Vehicle	White petrolatum
Remarks - Method	Occluded. The study was performed in compliance with *"Implementation of skin irritation and sensitization tests and skin measurement and evaluation,"* Chapter 1: Skin irritation test, Section 3: Human patch test (pp 29). The reference for this study guideline was not available.
RESULTS	
Remarks - Results	20 qualified test subjects were selected for this study. All subjects completed the study. No visible skin reactions were observed for any test subject.
CONCLUSION	The test substance was non-irritating under the conditions of the test.
TEST FACILITY	IGHD (2013)

B.4. Irritation – eye (*in vitro* bovine corneal opacity and permeability test)

TEST SUBSTANCE	Notified chemical (20% in vehicle)
METHOD	OECD TG 437 Bovine Corneal Opacity and Permeability Test Method for Identifying Ocular Corrosives and Severe Irritants
Vehicle	0.9% sodium chloride
Remarks - Method	No significant protocol deviations. Vehicle control and positive control (20% imidazole) were run concurrently with the test substance.

RESULTS

Test Material	*Mean Opacities of Triplicate Tissues*	*Mean Permeabilities of Triplicate Tissues*	*IVIS*
Vehicle control	2.0	0.018	2.3
*Test substance**	4.3	0.029	4.8
*Positive control**	69.7	1.381	90.4

IVIS = *in vitro* irritancy score
*Corrected for background values

Remarks - Results	An IVIS score of 4.8 was reported for the test substance, indicating it is not a Category 1 Eye Irritant. No prediction of eye irritation can be made for IVIS scores > 3 and ≤ 55, based on the test guidelines. The vehicle control and positive control gave satisfactory results, confirming the validity of the test system.
CONCLUSION	The test substance (notified chemical at 20% concentration) is not a Category 1 Eye Irritant under the conditions of the test.
TEST FACILITY	Envigo (2017f)

B.5. Irritation – eye (*in vitro* EpiOcular test)

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 492 Reconstructed Human Cornea-like Epithelium (RhCE) Test Method for Identifying Chemicals Not Requiring Classification and Labelling for Eye Irritation or Serious Eye Damage
Vehicle	None
Remarks - Method	The method of this study followed the version of OECD TG 492 adopted in July 2015. In a preliminary test the test substance had reactivity with MTT (3-[4,5-dimethylthiazol-2-yl]-2,5-diphenyl-tetrazolium bromide). Therefore, the study was performed in parallel on viable tissues (in tissue-binding test) and frozen tissues (in interference test). The test substance (50 mg) was applied to the tissues in duplicate. Following exposure periods of 6 hours ± 15 minutes (at 37 °C), the tissues were rinsed, treated with MTT and then incubated at 37 °C for 180 ± 10 minutes. Negative control (distilled water) and positive control (methyl acetate) were run concurrently with the test substance.

RESULTS

Test Material	*Mean OD_{570} of Duplicate Tissues*	*Relative Mean Cell Viability (%)*
Negative Control	0.881	100
Test Substance	0.066	7.5
Positive Control	0.061	6.9

OD = optical density

Remarks - Results	In both tissue-binding and interference tests, the cell viability in the test group was ≤ 60%. Therefore, correction of cell viability was not conducted and the test substance was categorised as an irritant (UN GHS Category 1 or 2) according to the test guidelines. However, the June 2018 revision of OECD TG 492 indicated that no prediction can be made for results which gave cell viability ≤ 60%. This is different to the judgement criteria used in the guidelines followed by this study. The vehicle control and positive control gave satisfactory results, confirming the validity of the test system.
CONCLUSION	The notified chemical cannot be considered to be a non-irritant to eyes under the conditions of the test.

TEST FACILITY CERI (2017)

B.6. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE Notified chemical

METHOD OECD TG 429 Skin Sensitisation: Local Lymph Node Assay
Species/Strain Mouse/CBA/J
Vehicle Acetone/olive oil (4:1)
Preliminary study Yes – tested at 5%, 10% and 20%
Positive control Conducted in parallel with the test substance using α-hexylcinnamaldehyde (25%)
Remarks - Method The concentration selection for the main test was based on the results from a preliminary test carried out at 5%, 10% and 20%.

RESULTS

Concentration (% w/w)	*Number and Sex of Animals*	*Proliferative Response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance			
0 (vehicle control)	4	1263.5	1.0
5	4	1467.5	1.2
10	4	9.31.6	0.7
20	4	950.2	0.8
Positive Control			
25	4	5502.7	4.4

EC3 Not determined as the test substance didn't elicit a SI ≥ 3 at any dose levels tested
Remarks - Results No treatment-related mortalities occurred during the study. No animals showed abnormal clinical signs or erythema on the ear lobes. Body weights and body weight gains were unaffected by treatment.

The mean lymph node weights of the animals in treatment groups were similar to that in the vehicle control and lower than that in the positive control.

The negative control and positive control gave satisfactory results, confirming the validity of the test system.

CONCLUSION There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical under the conditions of the test.

TEST FACILITY PIIF (2013)

B.7. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical

METHOD OECD TG 471 Bacterial Reverse Mutation Test
Species/Strain *Salmonella typhimurium*: TA1535, TA1537, TA98, TA100,
Escherichia coli: WP2uvrA
Metabolic Activation System S9 mix from phenobarbital/β-naphthoflavone induced rat liver
Concentration Range in Main Test a) With metabolic activation: 4.88 – 5,000 µg/plate
b) Without metabolic activation: 4.88 – 5,000 µg/plate
Vehicle Dimethyl sulfoxide
Remarks - Method Dose selection for the main tests was based on the results form a dose-finding study performed at 4.88 – 5000 µg/plate.

Vehicle and positive controls were run concurrently with the test substance. Positive controls were i) without metabolic activation: 2-(2-furyl)-3-(5-nitro-2-furyl)acrylamide (TA98, TA100, WP2uvrA), sodium azide (TA1535), 9-aminoacridine (TA1537); ii) with metabolic activation: 2-aminoanthracene.

RESULTS

Metabolic Activation	*Test Substance Concentration (μg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 5,000	> 5,000	> 5,000	Negative
Test 2		> 5,000	> 5,000	Negative
Present				
Test 1	> 5,000	> 5,000	> 5,000	Negative
Test 2		> 5,000	> 5,000	Negative

Remarks - Results

No significant increases in the frequency of revertant colonies were noted for any of the bacterial strains, with any dose of the test substance, in the presence or absence of metabolic activation.

The vehicle and positive controls gave satisfactory responses, confirming the validity of the test system.

CONCLUSION

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

TEST FACILITY

CMIC (2013)

B.8. Genotoxicity – *in vitro* mammalian cell nucleus test

TEST SUBSTANCE

Notified chemical

METHOD

OECD TG 487 *In vitro* Mammalian Cell Micronucleus Test

Species/Strain: Chinese Hamster (CH)

Cell Type/Cell Line: CHL/IU lung fibroblast cell line)

Metabolic Activation System: S9 mix from phenobarbital/β-naphthoflavone induced rat liver

Vehicle: Dimethyl sulfoxide

Remarks - Method: Dose selection for the main experiments was based on the results from 2 preliminary tests carried out at 2.63 – 168 μg/mL concentration for 6 hours short-term treatment and 24 hours continuous treatment, respectively.

Vehicle control and positive control (mitomycin C and benzopyrene) were run concurrently with the test substance.

Metabolic Activation	*Test Substance Concentration (μg/mL)*	*Exposure Period*	*Expression Time*	*Harvest Time*
Absent				
Test 1	42*, 84*, 168*	6 h	18 h	24 h
Test 2	21*, 25*, 29.7*, 35.4*, 42.1*, 50*	24 h	0 h	24 h
Present				
Test 1	42*, 84*, 168*	6 h	18 h	24 h

*Cultures selected for micronucleus analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (μg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 168	> 168	> 168	Negative
Test 2	> 42	> 29.7	> 50	Negative
Present				
Test 1	> 168	> 168	> 168	Negative

Remarks - Results

In both main tests, no statistically significant increases in the frequencies of micronucleated or multinucleated cells were noted in the presence or absence of metabolic activation.

The positive and vehicle controls gave satisfactory responses, confirming the validity of the test system.

CONCLUSION

The notified chemical was not clastogenic to CHL/IU cells treated *in vitro* under the conditions of the test.

TEST FACILITY

UBE (2015)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 C Ready Biodegradability
Inoculum	Activated sludge
Exposure Period	28 days
Remarks - Method	The test solutions were as follows: (i) water + test item; (ii) sludge + test item; (iii) sludge + aniline; (iv) negative control. In each case the volume of the test solution was 300 mL, and the concentration of the test item / aniline 100 mg/L. The temperature of incubation was 25°C. The extent of degradation, expressed as a percentage, was determined by the measurement of biological oxygen demand (BOD), dissolved organic carbon (DOC), and HPLC of the test item.

RESULTS

For 28 days:

	Percent biodegradation by BOD (average)	*Percent degradation by DOC (average)*	*Percent degradation by HPLC (average)*
test item	*98*	*96*	*99*
aniline	*98*		

Remarks - Results	The validity criteria for the test were met.
CONCLUSION	The percentage degradation of the test item by BOD, DOC and HPLC was 98%, 96% and 99%, respectively, while for aniline it was 98% (BOD). The test item is readily biodegradable.
TEST FACILITY	CERI (2014)

C.2.1. Chronic toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 202 *Daphnia* sp. Acute Immobilisation Test and Reproduction Test ENV/MC/CHEM (98)17 - Static EC Council Regulation No 440/2008
Species	*Daphnia magna*
Exposure Period	48 hours
Water Hardness	250 mg $CaCO_3$/L
Remarks - Method	A preliminary range finding test was performed using a negative control and nominal test item concentrations of 0.1, 1.0, 10 and 100 mg/L. For each test concentration and a negative control, 10 *Daphnia* were used. Immobilisation of *Daphnia* was only observed for the concentration of 100 mg/L. Chemical analysis of the test item preparations showed a variation of no more than 5% of the nominal. Based on the results of the range finding test, a definitive test was performed with nominal concentrations of 10, 18, 32, 56 and 100 mg/L. For each test concentration and a negative control, four replicates of five *Daphnia* were used. Again, chemical analysis of the test item preparations showed a variation of no more than 5% of the nominal. A positive control test with a reference substance, potassium dichromate, was performed approximately six months prior to the main test, using four concentrations: 0.32, 0.56, 1.0, 1.8 and 3.2 mg/L.

RESULTS

Nominal concentration mg/L	*Total number of D. magna*	*Number Immobilised*	
		24 h	*48 h*
0	20	0	0
10	20	0	0
18	20	0	0
32	20	1	20
56	20	19	20
100	20	20	20

EC50	24 mg/L at 48 hours (95% confidence limit: 22-26 mg/L). Probit analysis, but this equivalent to the geometric mean of the sequential concentrations with no response and 100% response.
NOEC	18 mg/L at 48 hours
Remarks - Results	The validity criteria for the test were met. The dissolved oxygen concentrations after 48 h for the control and test vessels were 3 mg/L. For the positive control, the 48 h EC50 was 0.64 mg/L, but no indication of whether this was within the expected range was provided.
CONCLUSION	The notified chemical is harmful to *Daphnia*.
TEST FACILITY	Envigo (2017g)

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