File No: LTD/1959

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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

6,10-Dodecadienal, 3,7,11-trimethyl-, (3*S*,6*E*)-

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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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/1959	Takasago International (Singapore) Pte Ltd	6,10-Dodecadienal, 3,7,11-trimethyl-, (3*S*,6*E*)-	Yes	≤ 1 tonne per annum	A 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*
Sensitisation, Skin (Category 1B)	H317 – May cause an allergic skin reaction

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 1)	H400 - Very toxic to aquatic life
Chronic (Category 1)	H410 - Very toxic to aquatic life with long lasting effects

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 and the reported use pattern, 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:
  - Sensitisation, Skin (Category 1): H317 – May cause an allergic skin reaction

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

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:
  - 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:
  - Avoid contact with skin and eyes
  - Avoid inhalation

- 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:
  - Coveralls
  - Impervious gloves
  - Eye protection
  - 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.

Public Health

- The following measures should be taken to minimise public exposure to the notified chemical:
  - The notified chemical should only be used at ≤ 0.05% in cosmetic and household products.

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.

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 and household products.

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 and products containing the notified chemical provided by the notifier were 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: analytical data, degree of purity, impurities, additives/adjuvants and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
REACH (2016)

2. IDENTITY OF CHEMICAL

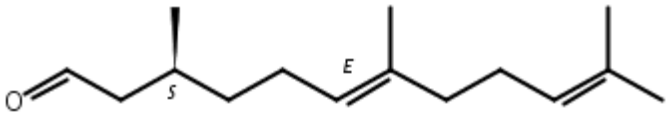
MARKETING NAME(S)
L-2H-Farnesal

CAS NUMBER
194934-66-2

CHEMICAL NAME
6,10-Dodecadienal, 3,7,11-trimethyl-, (3*S*,6*E*)-

MOLECULAR FORMULA
$C_{15}H_{26}O$

STRUCTURAL FORMULA



MOLECULAR WEIGHT
222.37 Da

ANALYTICAL DATA
Reference NMR, IR, GC, GC-MS, UV, and Dual-GC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 95 %

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Clear colourless liquid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	< -20 °C	Measured
Boiling Point	287 ± 1 °C at 101.7 kPa	Measured
Density	865 kg/m^3 at 20 °C	Measured
Vapour Pressure	3.9×10^{-4} kPa at 25 °C	Measured
Water Solubility	2.87 × 10^{-4} g/L at 20 °C	Measured
Hydrolysis as a Function of pH	$t_{1/2}$=2.58 h at pH=4, 25°C $t_{1/2}$=57.8 h at pH=7, 25°C $t_{1/2}$=80.6 h at pH=9, 25°C	Measured
Partition Coefficient (n-octanol/water)	log P_{OW} = 6.21 at 20 °C	Measured
Adsorption/Desorption	Log Koc = 4.07	Estimated. KOCWIN v2.00, US EPA 2011
Dissociation Constant	Not determined	The notified chemical does not contain functional groups that are expected to dissociate under environmental conditions.
Flash Point	136 ± 2 °C at 99.7 kPa	Measured
Flammability	Not determined	Not expected to be flammable (Flash point is 136 °C at 99.7 kPa)
Autoignition Temperature	228 ± 5 °C	Measured
Explosive Properties	Not determined	Based on its structural formula, the chemical is not expected to have explosive properties
Oxidising Properties	Not determined	Based on its structural formula, the chemical is not expected to have oxidising 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 in finished products or in fragrance mixtures.

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
The notified chemical will be imported to various ports around Australia.

IDENTITY OF MANUFACTURER/RECIPIENTS
A number of importers located in Australia.

TRANSPORTATION AND PACKAGING
The imported finished products in suitable packaging and fragrance mixtures in drums up to 200 L, containing the notified chemical at ≤ 0.05% and ≤ 5% respectively, will be transported by road to the notifier's warehouses or to the formulation sites. The fragrance mixtures containing the notified chemical will be reformulated and repackaged in Australia into final consumer products. The final consumer products will be transported by road to the retailers' sites.

USE
The notified chemical will be used as a fragrance ingredient in a variety of finished consumer goods such as fine perfumes, cosmetics, personal cleaning, household and laundry products. The notified chemical will be used at a concentration of ≤ 0.05% in perfumery products and ≤ 0.03% in cosmetic, personal cleaning, household and laundry products.

OPERATION DESCRIPTION
The procedures for incorporating the imported preparations (at ≤ 5% concentration) into end-use products will likely vary depending on the type of product formulated, and may involve both automated and manual transfer steps. It is expected that the reformulation processes will involve blending operations that will be highly automated and occur in a fully enclosed/contained environment, followed by automated filling (using sealed delivery systems) of the reformulated end-use products into containers of various sizes.

The end-use products containing the notified chemical (at ≤ 0.05% concentration) may be used by consumers and professionals such as hairdressers, workers in beauty salons or cleaners. Depending on the nature of the product, these could be applied 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 (10-20 workers)	1-2	50
Mixers (10-20 workers)	Up to 8	240
QC samplers (1-2 workers)	0.5	240
Cleaners/maintenance (5-10 workers)	Up to 8	240
End users (professionals) > 1000	1-8	200

EXPOSURE DETAILS
Transport and storage
Transport, storage and warehouse workers may come into contact with the notified chemical as a component of the imported fragrance mixtures at ≤ 5% concentrations or finished / end-use products at ≤ 0.05% concentrations, only in the event of accidental rupture of containers. If such an event occurs, workers may be exposed through dermal, ocular or inhalation exposure.

Formulation of end products
During reformulation, dermal, ocular and perhaps inhalation exposure of workers to the notified chemical at ≤ 0.05% concentration may occur during handling of drums, during weighing and transfer stages, blending, quality control analysis and cleaning and maintenance of equipment. The notifier states that exposure is expected to be minimised through the use of mechanical ventilation and/or enclosed systems, and through the use of PPE such as protective clothing, eye protection and suitable gloves.

Beauty care and cleaning professionals
Exposure to the notified chemical in end-use products may occur in professions where the services provided involve the application of cosmetic products (at ≤ 0.05% concentration) to clients or the use of household products (at ≤ 0.03% concentration) in the cleaning industry. The principal route of exposure will be dermal,

while ocular and inhalation exposure is also possible. Such professionals may use some PPE to minimise repeated exposure and good hygiene practices are expected to be in place. If PPE is used, exposure of such workers is expected to be of a similar or less 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 the cosmetic and household products. The main route of exposure will be dermal, while ocular and inhalation exposure is also possible, particularly if products are applied by spray.

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
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Mouse, skin sensitisation – Local lymph node assay	evidence of sensitisation
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vivo Micronucleus in mice	non genotoxic

Toxicokinetics, metabolism and distribution

No toxicokinetic data on the notified chemical were submitted. For dermal absorption, molecular weights below 100 Da. are favourable for absorption and molecular weights above 500 Da. do not favour absorption (ECHA, 2014). Dermal uptake is likely to be low if the water solubility is below 1 mg/L and the rate of penetration may be limited by the rate of transfer between the stratum corneum and the epidermis if log P values are above 4 (ECHA, 2014). In addition evidence of skin sensitisation or irritation increase the probability of dermal absorption occurring (ECHA, 2014). Despite the low water solubility (2.87×10^{-4} g/L) and high partition coefficient (log Pow of 6.21), based on the low molecular weight (222.37 Da), of the notified chemical, and the evidence of irritation and sensitisation absorption across biological membranes may occur.

Acute toxicity

The notified chemical is of low acute oral toxicity based on a study conducted in rats. No information was provided on acute dermal and inhalation toxicity.

Irritation and sensitisation

The notified chemical was slightly irritating to the skin and eyes. The notified chemical showed evidence of skin sensitisation in a LLNA study with an EC3 of 27.5%.

Repeated dose toxicity

No information was provided on the repeated dose toxicity of the notified chemical.

Mutagenicity/Genotoxicity

The notified chemical was non-mutagenic in a bacterial reverse mutation assay and not clastogenic in an *in vivo* mammalian erythrocyte 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***
Sensitisation, Skin (Category 1B)	H317 – May cause an allergic skin reaction

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

Based on the available information the critical health effect of the notified chemical is skin sensitisation with the chemical also being a slight skin and eye irritant. The toxicity of the notified chemical following repeated exposure is also unknown.

Transport, Storage and Reformulation

During transport, storage and reformulation workers may be at risk of sensitisation when handling the notified chemical at ≤ 5% concentration. It is anticipated by the notifier that engineering controls such as enclosed and automated processes and local ventilation will be implemented where possible, and appropriate PPE will be used to limit workers exposure.

Therefore, under the occupational settings described, the risk to the health of workers from use of the notified chemical is not considered to be unreasonable.

End-use

Cleaners and beauty care professionals will handle the notified chemical in a variety of cosmetic and household products at ≤ 0.05% concentrations. Such professionals may use PPE to minimise repeated exposure, and good hygiene practices are expected to be in place. If PPE is used, exposure of such workers is expected to be of a similar or lesser extent than that experienced by consumers using products containing the notified chemical (for details of the public health risk assessment, see Section 6.3.2).

6.3.2. Public Health

Members of the public may be repeatedly exposed to the notified chemical during the use of a variety of cosmetic and household products at ≤ 0.05% concentrations. The main route of exposure is expected to be dermal with some potential for accidental ocular or oral exposure.

The notified chemical was slightly irritating to the skin and eyes. However, given the low proposed use concentration (≤ 0.05%), irritation effects are not expected.

A significant risk associated with use of the notified chemical is its potential to cause sensitisation by skin contact. Methods for the quantitative risk assessment of dermal sensitisation have been the subject of significant discussion (see for example, Api *et al*., 2008 and RIVM, 2010). Using fine fragrance as an example product that may contain the notified chemical at a maximum concentration of 0.05%, as a worst case scenario, the Consumer Exposure Level (CEL) for the notified chemical is estimated to be 1.88 µg/cm^2/day (Cadby *et al*., 2002). When tested in an LLNA study, the notified chemical was a skin sensitiser with an EC3 value of 27.5%. Consideration of each of the studies and application of appropriate safety factors, allowed the derivation of an Acceptable Exposure Level (AEL) of 19.82 µg/cm^2. In this instance, the factors employed included an interspecies factor (3), intraspecies factor (10), a matrix factor (3.16), a use/time factor (3.16) and database factor (1), giving an overall safety factor of ~300.

As the AEL > CEL, the risk to the public of the induction of sensitisation that is associated with the use of fine fragrances (a worst case example of a leave-on cosmetic product) is not considered to be unreasonable. Based on the significantly lower expected exposure level from other leave-on cosmetic products, rinse-off products and household products, by inference, the risk of induction of sensitisation associated with the use of these products is also not considered to be unreasonable. It is acknowledged that consumers may be exposed to multiple products containing the notified chemical, and a quantitative assessment based on aggregate exposure has not been conducted.

The toxicity of the notified chemical following repeated exposure is unknown. However, no signs of systemic toxicity were noted in the acute oral toxicity study at doses of up to 2,000 mg/kg bw and therefore the risk of adverse effects following dermal exposure at concentrations of ≤ 0.05% is not considered to be unreasonable.

Therefore, the risk to the public associated with use of the notified chemical in a variety of cosmetic and household products at ≤ 0.05% concentrations assessed 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 chemical will be imported into Australia as a component in finished products or in fragrance mixtures for reformulation into finished cosmetic formulations, personal cleaning, and household and laundry products. There is unlikely to be any significant release of the notified chemical to the environment from transport and storage, except in the case of accidental spills and leaks. In the event of spills, the products containing the notified chemical is expected to be collected with absorbents, and disposed of to landfill in accordance with local government regulations.

The reformulation process will involve blending operations that will be highly automated, and is expected to occur within a fully enclosed environment. Therefore, significant release of the notified chemical from this process to the environment is not expected. The process will be followed by automated filling of the formulated products into containers of various sizes suitable for retail and end-use. Wastes containing the notified chemical generated during reformulation include equipment wash water, residues in empty import containers and spilt materials. It is estimated by the notifier that up to 1% of the import volume of the notified chemical may be released from reformulation processes. These will be collected and released to sewers, or disposed of to landfill in accordance with local government regulations. Empty import containers are expected to be recycled or disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

The notified chemical is expected to be released to the aquatic compartment through sewers during its use in various cosmetic formulations and household products across Australia.

RELEASE OF CHEMICAL FROM DISPOSAL

A small proportion of the notified chemical may remain in end-use containers once the consumer products are used up. Wastes and 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

Following its use in Australia, the majority of the notified chemical is expected to be released to sewers on a nationwide basis. The submitted biodegradation study indicates that the notified chemical is expected to be rapidly degraded in sewage treatment plants (STPs). For the details of the environmental fate study please refer to Appendix C. The submitted studies have also shown that the notified chemical was not stable in water. The notified chemical is readily hydrolysable under the environmental conditions (pH=4-9, $t_{1/2}$ ~0.1-3.4 days).

The half-life of the notified chemical in air is calculated to be 0.61 h based on reactions with hydroxyl radicals (AOPWIN v1.92, US EPA 2011). Therefore, in the event of release to the atmosphere, the notified chemical is not expected to persist in the atmospheric compartment.

In STPs the notified chemical is expected to be efficiently removed (based on its low water solubility and high partition coefficients) from effluent by adsorption to sludge. Therefore, only a small portion of the notified chemical may be released to surface waters. A proportion of the notified 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 notified chemical residues in landfill and soils are expected to have low mobility based on its calculated soil adsorption coefficient (Log K_{OC} =4.07). In the aquatic and soil compartments, the notified 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 calculation for the Predicted Environmental Concentration (PEC) is summarised in the table below. Based on the reported use in cosmetics and household cleaning products, it is assumed that 100% of the total import volume of the notified chemical is released to the sewer, and there is no removal within sewage treatment plants (STPs) under a worst case scenario. The release is assumed to be nationwide over 365 days per year.

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	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)	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:	0.61	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 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 0.61 µg/L may potentially result in a soil concentration of approximately 4.04 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 20.2 µg/kg and 40.4 µg/kg, respectively.

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*
Fish Toxicity (96 h)	LC50 > 0.22 mg/L (WAF[§])	Not harmful to fish up to the limit of its solubility in test medium
Daphnia Toxicity (48 h)	EC50=0.36 mg/L (WAF[§])	Not harmful to aquatic invertebrates up to the limit of its solubility
Algal Toxicity (72 h)	EC50=0.18 mg/L (WAF[§]) NOEC=0.034 mg/L(WAF[§])	Very toxic to algae

[§] Water accommodated fraction

Based on the acute ecotoxicological endpoints, the notified chemical is expected to be very toxic to algae. Therefore, the notified chemical is classified as “Acute Category 1: Very Toxic to aquatic life” according to the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations 2009). On the basis of acute toxicity data, ready biodegradability, high Pow value and NOEC values, the notified chemical is formally classified as ‘Chronic Category 1: Very toxic to aquatic life with long-lasting effects”.

7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentrations (PNEC) for the notified chemical have been derived and compared from both the most sensitive acute endpoint (EC50) and chronic endpoint (NOEC) for algae. The PNEC value derived from NOEC value for algae and assessment factor of 50 had the lowest value and was used in further risk assessment.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
NOEC (Alga)	0.034	mg/L
Assessment Factor	50	
Mitigation Factor	1.00	
PNEC:	0.68	µg/L

7.3. Environmental Risk Assessment

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

Risk Assessment	*PEC µg/L*	*PNEC µg/L*	*Q*
Q - River:	0.61	0.68	**0.891**
Q - Ocean:	0.06	0.68	**0.089**

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 indicating that the notified chemical is unlikely to reach ecotoxicologically significant concentrations in surface waters based on its maximum annual importation quantity. The notified chemical is readily (bio) degradable and not expected to bioaccumulate. On the basis of the PEC/PNEC ratio and assessed use pattern, the notified chemical is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point/Freezing Point < -20 °C

Method	OECD TG 102 Melting Point/Melting Range. EC Council Regulation No 440/2008 A.1 Melting/Freezing Temperature.
Remarks	Determination of crystallisation point.
Test Facility	Envigo (2015a)

Boiling Point 287 ± 1 °C at 101.7 kPa

Method	OECD TG 103 Boiling Point. EC Council Regulation No 440/2008 A.2 Boiling Temperature.
Remarks	Determination by differential scanning calorimetry (DSC).
Test Facility	Envigo (2015a)

Density 865 kg/m3 at 20 °C

Method	OECD TG 109 Density of Liquids and Solids. EC Council Regulation No 440/2008 A.3 Relative Density.
Remarks	Determination by using a pycnometer method.
Test Facility	Envigo (2015a)

Vapour Pressure 3.9×10^{-4} kPa at 25 °C

Method	OECD TG 104 Vapour Pressure. EC Council Regulation No 440/2008 A.4 Vapour Pressure.
Remarks	Determination by using the vapour pressure balance method.
Test Facility	Harlan (2015a)

Water Solubility 2.87×10^{-4} 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 (2015a)

Hydrolysis as a Function of pH

Method	OECD TG 111 Hydrolysis as a Function of pH. EC Council Regulation No 440/2008 C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH.

pH	*T (°C)*	*$t_{½}$ hours*
4	25	2.58
7	25	57.8
9	25	80.6

Remarks	A 1% co-solvent of acetonitrile (MeCN) was used to aid the solubility. The standard and sample solutions were analysed by Gas Chromatography.
Test Facility	Envigo (2016)

Partition Coefficient (n-octanol/water) log P_{OW} = 6.21 at 20 °C

Method	OECD TG 117 Partition Coefficient (n-octanol/water). EC Council Regulation No 440/2008 A.8 Partition Coefficient.
Remarks	HPLC Method
Test Facility	Envigo (2015a)

Flash Point 136 ± 2 °C at 99.7 kPa

Method	EC Council Regulation No 440/2008 A.9 Flash Point.
Remarks	Closed Cup Equilibrium method.
Test Facility	Harlan (2015b)

Autoignition Temperature 228 ± 5 °C

Method	EC Council Regulation No 440/2008 A.15 Auto-Ignition Temperature (Liquids and Gases).
Remarks	Determination by heating aliquots of the test substance in a flask and observing for any ignition.
Test Facility	Harlan (2015b)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 420 Acute Oral Toxicity – Fixed Dose Procedure. EC Council Regulation No 440/2008 B.1 bis Acute toxicity (oral) fixed dose method.
Species/Strain	Rat/Wistar (Female)
Vehicle	Arachis oil BP
Remarks - Method	No significant protocol deviations

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	1F	300	0/1
2	1F	2000	0/1
3	4F	2000	0/4

LD50	> 2000 mg/kg bw
Signs of Toxicity	No signs of systemic toxicity were observed.
Effects in Organs	No abnormalities were noted at necropsy.
Remarks - Results	No deaths were noted.

CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	Harlan (2015c)

B.2. Irritation – skin

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion. EC Council Regulation No 440/2008 B.4 Acute Toxicity (Skin Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	2 males
Vehicle	None
Observation Period	14 Days
Type of Dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations

RESULTS

Lesion	*Mean Score* Animal No.*		*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2			
Erythema/Eschar	2.0	1.7	2	> 72 h	0
Oedema	1.7	0.7	2	< 72 h	0

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

Remarks - Results	Well-defined erythema, very slight oedema and moderate desquamation were observed at 3-minute and 1-hour application sites. Well-defined erythema and slight oedema were observed at the 4-hour application sites. Slight or moderate desquamation was noted at the treated skin sites at the 7-day observation. All treated skin sites appeared normal at the 14-Day observation. No corrosive effects were noted.

CONCLUSION The notified chemical is slightly irritating to the skin.

TEST FACILITY Harlan (2015d)

B.3. Irritation – eye

TEST SUBSTANCE Notified chemical

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
EC Council Regulation No 440/2008 B.5 Acute Toxicity (Eye Irritation).
Species/Strain Rabbit/New Zealand White (Hsdlf:NZW)
Number of Animals 2 males
Observation Period 72 h
Remarks - Method No significant protocol deviations

RESULTS

Lesion	*Mean Score* Animal No.*		*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2			
Conjunctiva: redness	0.7	0.7	2	< 72 h	0
Conjunctiva: chemosis	0.3	0.3	2	< 48 h	0
Conjunctiva: discharge	0	0.3	2	< 48 h	0
Corneal opacity	0	0	0	0	0
Iridial inflammation	0	0	0	0	0

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

Remarks - Results Moderate conjunctival irritation was noted in both animals at the 1 hour observation. This had declined to minimal irritation at the 24 and 48 hour observations, with both eyes appearing normal at the 72 hour observation.

CONCLUSION The notified chemical is slightly irritating to the eye.

TEST FACILITY Envigo (2015b)

B.4. 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 [SPF] (24 females)
Vehicle DMF
Preliminary study No
Positive control 25% α-Hexylcinnamaldehyde (HCA).
Remarks - Method No significant protocol deviations

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 F	733.0	-
25%	4 F	1831.5	2.5
50%	4 F	4648.8	6.3
100%	4 F	5023.0	6.9
Positive Control	4 F	2300.1	3.1

EC3 27.5%
Remarks - Results No animal showed abnormal clinic signs or erythema during the

observation period. Body weight changes were similar in the control and treated groups. The ear thickness of the treated mice group at 50 and 100% of the test substance and the positive control were increased during the sensitising period. The weights of the lymph nodes in all test substance treated mice groups and the positive control group were higher than that in the vehicle control group.

CONCLUSION There was evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical.

TEST FACILITY BSRC (2013)

B.5. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria.
Pre incubation procedure

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100, *E. coli*: WP2uvrA
Metabolic Activation System	Phenobarbital (PB) and 5,6-benzoflavone (BF)
Concentration Range in Main Test	a) With metabolic activation: 2.44-5000 µg/plate b) Without metabolic activation: 0.610-5000 µg/plate
Vehicle	DMSO
Remarks - Method	No significant protocol deviations

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	≥ 19.5	≥ 9.77	> 5000	negative
Test 2		≥ 9.77	> 5000	negative
Present				
Test 1	≥ 78.1	≥ 39.1	≥ 5000	negative
Test 2		≥ 39.1	≥ 5000	negative

Remarks - Results

Throughout the tests, the test substance did not induce any increases in the number of revertant colonies to at least twice as many as that of the negative control for any bacterial strains at any dose levels either with or without metabolic activation.

Cytotoxicity to bacteria by the test substance was observed at and above dose levels of 19.5 µg/plate in TA100, TA1535, and TA1537 strains without metabolic activation and in TA1535 and TA1537 strains with metabolic activation in the dose determination test. In test 1 and 2 cytotoxicity to bacteria was observed at and above the dose levels of 9.77 µg/plate in TA100, TA1535 and TA1537 strains without metabolic activation, and at and above dose levels of 39.1 µg/plate in TA98 strain without metabolic activation and in TA1535 and TA1537 strains with metabolic activation.

Precipitation of the test substance was observed at 5000 µg/plate with metabolic activation in the dose determination test, test1 and 2.

The positive and negative controls produced satisfactory responses, thus confirming the activity of the S9-mix and the sensitivity of the bacterial strains.

CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	UBE (2013)

B.6. Genotoxicity – in vivo

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 474 Mammalian Erythrocyte Micronucleus Test.
Species/Strain	Mice/Crl: CDI (ICR)
Route of Administration	Oral – gavage
Vehicle	Corn oil
Remarks - Method	No significant protocol deviations

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
I (vehicle control)	5 M	0	24 h
II (low dose)	5 M	250	24 h
III (mid dose)	5 M, 5 M	500, 1000	24 h, 24 h
IV (high dose)	5 M	2000	24 h
V (positive control, M)	5 M	2	24 h

M=mitomycin C.

RESULTS	
Doses Producing Toxicity	No mortality was observed in any of the groups during the treatment period, and no remarkable clinical findings were noted in any of the groups during the observation period. A slight decrease in body weight was observed in the 2000 mg/kg group on the next day following the administration of the test substance.
Genotoxic Effects	Incidence of micronucleated polychromatic erythrocyte (MNPCE) (0.118 ±0.069%) in the negative control group and (0.078 ± 0.018, 0.108 ± 0.022 and 0.092 ± 0.058%) in the treated groups at the 2000, 1000 and 500 mg/kg respectively. The polychromatic erythrocytes (PCE) ratio of the test substance treatment groups showed no statistical significant difference compared to the negative control group.
Remarks - Results	A Kastenbaum-Bowman conditional binominal test which was performed on two groups of 6 animals (males) each at 1000 and 2000 mg/kg respectively showed no significant difference in MNPCE frequencies between the negative control (23/4000) and the test substance treatment groups (15 to 21/4000) but displayed a significant difference to the positive control group (708/4000). The Cochran-Armitage trend analysis confirmed that there was no dose-response relationship regarding the frequencies of MNPCE in the test substance treatment groups.
CONCLUSION	The notified chemical was not clastogenic under the conditions of this in vivo Mammalian Erythrocyte Micronucleus Test.
TEST FACILITY	DIMS (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: Modified MITI Test (I).
Inoculum	The activated sludge
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Theoretical oxygen demands (TOD).
Remarks - Method	HPLC and LC-MS methods were performed to conduct quantitative and qualitative analyses of the test item and converted products.

RESULTS

Test substance		*Aniline*	
Day	*% Degradation (BOD)*	*Day*	*% Degradation (BOD)*
7	52	7	77
14	78	14	90
21	85	21	91
28	86 (100*)	28	91

* was calculated based on the percentage residue in the test solution (6%)

Remarks – Results	The preliminary results indicated that the notified chemical might be volatile and DOC measurements were not applicable. The % residue of the notified chemical in the water solution was 6%. Therefore, the primary degradation was also calculated based on the residual amount of the test substance at the end of the test and amount of the test substance added. The pH of the test solution and the test media was not measured. The reference compound, aniline, reached the pass levels of biodegradation by days 7 and 14 indicating the suitability of the inoculum. The toxicity control exceeded 25% biodegradation (required by guideline) showing that toxicity was not a factor inhibiting the biodegradability of the test substance. The degree of degradation of the test substance after 28 days was 86%.
CONCLUSION	The notified chemical is readily biodegradable
TEST FACILITY	Chemicals Evaluation and Research Institute (2013)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test – Semi-static. EC Council Regulation No 440/2008 C.1 Acute Toxicity for Fish – Semi-static.
Species	Rainbow Trout (*Oncorhynchus mykiss*)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	140 mg/L as $CaCO_3$

Analytical Monitoring	Gas Chromatography
Remarks – Method	The notified chemical was stirred in test water at > 100 mg/L for 24 hours and undissolved fraction was removed by filtration. A solution was diluted to produce 32% v/v saturated solution. The treatment solutions were renewed every 24 hours.

RESULTS

Concentration		*Number of Fish*	*Cumulative Mortality (%)*
Nominal (% v/v saturated solution)	*Actual Geometric mean measured concentrations (mg/L)*		*96 h*
Control	Control	7	0
32	0.22	7	0

LC50	> 0.22 mg/L at 96 hours.
NOEC	0.22 mg/L
Remarks – Results	The actual concentrations of the test substance in freshly prepared treatment solutions were measured at the beginning of 0 hour and 72 hour exposure periods and that for 24 hour-old solutions were measured at the end of 24 hour and 96 hour exposure periods. The end points were calculated based on the geometric mean of measured concentrations.

CONCLUSION The notified chemical is not harmful to fish up to the limit of its solubility in test medium.

TEST FACILITY Envigo (2015c)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified chemical

METHOD OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – Semi-static.
EC Council Regulation No 440/2008 C.2 Acute Toxicity for Daphnia - .

Species	*Daphnia magna*-Semi-static.
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	Gas Chromatography
Remarks - Method	The notified chemical was stirred in test water at > 100 mg/L for 24 hours and undissolved fraction was removed by filtration. A saturated solution was diluted to produce 2.6, 6.4, 16 and 40 % v/v solutions. Semi-static conditions were employed in the test to maintain dissolved test item concentrations; and daphinds were transferred from 24-hour old test media into the fresh test media.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal (% v/v saturated solution)	*Actual Geometric mean measured concentrations (mg/L)*		*24 h*	*48 h*
Control	Control	20	0	5
2.6	0.010	20	0	10
6.4	0.018	20	0	0

16	0.080	20	5	5
16	0.080	20	5	5
40	0.29	20	0	10
100	0.74	20	60	100

EC50	0.36 mg/L at 48 hours
NOEC	0.29 mg/L
Remarks - Results	All validity criteria for the test were satisfied. A decline in measured test concentrations was observed in the old media at 24 and 48 hours in the range of 25% to 71% of nominal concentrations. The toxicity data were reported based on geometric mean measured concentrations.
CONCLUSION	The notified chemical is not harmful to aquatic invertebrates up to the limit of its water solubility
TEST FACILITY	Envigo (2015d)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 201 Alga, Growth Inhibition Test. EC Council Regulation No 440/2008 C.3 Algal Inhibition Test.
Species	*Pseudokirchneriella subcapitata*
Exposure Period	72 hours
Concentration Range	Nominal: 1.0, 1.8, 3.2, 5.6, and 10 mg/L Actual: 0.095, 0.21, 0.31, 0.42, 0.96 mg/L (time-weighted mean measured test concentrations)
Auxiliary Solvent	None
Water Hardness	Unknown
Analytical Monitoring	Gas Chromatography
Remarks - Method	No significant deviations from the test guidelines were reported. All validity criteria for the test were satisfied.

RESULTS

Biomass		*Growth*	
EC50 *mg/L at 72 h*	*NOEC* *mg/L*	*EC50* *mg/L at 72 h*	*NOEC* *mg/L*
0.066 (95% CL 0.053– 0.082)	0.034	0.18 (95% CL 0.17–0.18)	0.034

Remarks - Results	The test concentrations declined significantly during the 72-hour test period reaching below the limit of quantification. The test substance was unstable during the test; therefore, the tested endpoints were based on the geometric mean measured test concentrations.
CONCLUSION	The notified chemical is very toxic to algae
TEST FACILITY	Envigo (2015e)

BIBLIOGRAPHY

Api AM, Basketter DA, Cadby PA, Cano MF, Ellis G, Gerberick GF, Griem P, McNamee PM, Ryan CA and Safford R (2008) Dermal Sensitisation Quantitative Risk Assessment (QRA) for Fragrance Ingredients, Regulatory Toxicology and Pharmacology, 52:3-23.

BSRC (2013) Mouse Local Lymph Node Assay of (3S,6E)-3,7,11-trimethyl-6,10-dodecadienal. (Study No. E554 (432-023), March, 2013). Shizuoka, Japan, Public Interest Incorporated Foundation, Biosafety Research Centre. (Unpublished report submitted by the notifier).

Cadby, PA., Troy, WR., Vey, MGH. (2002) Consumer Exposure to Fragrance Ingredients: Providing Estimates for Safety Evaluation. Regulatory Toxicology and Pharmacology, 36:246-52.

Chemicals Evaluation and Research Institute (2013). Biodegradation Study of Dihydrofarnesal (Study No. 16027, November, 2013). Kurume, Japan, Chemicals Evaluation and Research Institute (Unpublished report submitted by the notifier).

DIMS (2015) Micronucleus Test of Dihydrofarnesal in Mice, (Study No. 15181, December, 2015).Aichi, Japan, DIMS Institute of Medical Science, Inc. (Unpublished report submitted by the notifier).

ECHA (2014) Guidance on Information Requirements and Chemical Safety Assessment Chapter R.7c: Endpoint specific guidance, November 2014, version 2.0. European Chemicals Agency, http://echa.europa.eu/documents/10162/13632/information_requirements_r7c_en.pdf.

Envigo (2015a) I-Dihydrofarnesal: Determination of General Physico-Chemical Properties. (Study No. 41402856, October, 2015). Derbyshire UK, Envigo Research Limited (Unpublished report submitted by the notifier).

Envigo (2015b). I-Dihydrofarnesal: Acute Eye Irritation in the Rabbit. (Study No. 41402861, September, 2015). Derbyshire, UK, Envigo Research Limited (Unpublished report submitted by the notifier).

Envigo (2015c). L-Dihydrofarnesal: Acute Toxicity to Rainbow Trout (Study No. 41402862, December, 2015). Shardlow, Derbyshire, UK, Envigo Research Limited (Unpublished report submitted by the notifier).

Envigo (2015d). L-Dihydrofarnesal: Daphnia sp., 48-Hour Acute Immobilization Test (Study No. 41402863, December, 2015). Shardlow, Derbyshire, UK, Envigo Research Limited (Unpublished report submitted by the notifier).

Envigo (2015e). L-Dihydrofarnesal: Algal Growth Inhibition Test (Study No. 41402864, December, 2015). Shardlow, Derbyshire, UK, Envigo Research Limited (Unpublished report submitted by the notifier).

Envigo (2016). L-Dihydrofarnesal: Determination of Hydrolysis as a Function of pH (Study No. 41501314, May, 2016). Derbyshire, UK, Envigo Research Limited (Unpublished report submitted by the notifier).

Harlan (2015a) I-Dihydrofarnesal: Determination of Vapor Pressure. (Study No. 41402857, September, 2015). Derbyshire UK, Harlan Laboratories Ltd (Unpublished report submitted by the notifier).

Harlan (2015b) I-Dihydrofarnesal: Determination of Flash Point and Auto-Ignition Temperature (Liquids and Gases). (Study No. 41402858, August 2015). Derbyshire UK, Harlan Laboratories Ltd (Unpublished report submitted by the notifier).

Harlan (2015c) I-Dihydrofarnesal: Acute Oral Toxicity in the Rat – Fixed Dose Method. (Study No. 41402859, August, 2015). Derbyshire, UK, Harlan Laboratories Ltd. (Unpublished report submitted by the notifier).

Harlan (2015d) I-Dihydrofarnesal: Acute Dermal Irritation in the Rabbit. (Study No. 41402860, September, 2015). Derbyshire, UK, Harlan Laboratories Ltd. (Unpublished report submitted by the notifier).

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

NTC (National Transport Commission) 2007 Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG code), 7th Edition, Commonwealth of Australia.

RIVM (2010) Observations on the Methodology for Quantitative Risk Assessment of Dermal Allergens, Report 320015003/2010, National Institute for Public Health and the Environment.

SWA (2015) Code of Practice: Spray Painting and Powder Coating, Safe Work Australia, http://www.safeworkaustralia.gov.au/sites/swa/about/publications/pages/spray-painting-and-powder-coating.

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

UBE (2013) Bacterial Reverse Mutation Test of dihydrofarnesal. (Study No. USA-R-13087, May, 2013). Yamaguchi, Japan, UBE Scientific Analysis Laboratory, Inc. (Unpublished report submitted by the notifier).

United Nations (2009) Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 3rd revised edition. United Nations Economic Commission for Europe (UN/ECE), <http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html >.