File No: LTD/1795

March 2015

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Jojoba, ext., hydrogenated
(INCI Name: Hydrogenated Jojoba Oil)

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment.

For the purposes of subsection 78(1) of the Act, this Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This Public Report is also available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

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Director
NICNAS

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SUMMARY

The following details will be published in the NICNAS *Chemical Gazette:*

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1795	L'Oreal Australia Pty Ltd	Jojoba, ext., hydrogenated (INCI name Hydrogenated Jojoba Oil)	ND*	≤ 1 tonne per annum	Cosmetic Ingredient

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified chemical is not recommended for classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

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

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical [as introduced:
  - Avoid skin and eye contact

- 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 as introduced:
  - safety glasses
  - gloves
  - coveralls

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

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

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures

consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Public Health

- Product formulators should exercise due care when using the notified chemical in cosmetic products given its potential ability to enhance the dermal penetration of other chemicals in the formulation.

- Introducers should aim to minimise the level of cyanoglycosides impurities, if these are identified in the notified chemical.

Disposal

- Where reuse or recycling are not available or practical, dispose of the 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 containment, physical 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 is intended to exceed 15% in makeup products, 10% in rinse off cosmetics and 5% in other leave on and aerosol cosmetic products;
- the material introduced is other than the hydrogenated product of Jojoba seed oil.

or

(2) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from a component of cosmetics, or is likely to change 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.

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

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
L'Oreal Australia Pty Ltd (ABN: 40 004 191 673)
564 St Kilda Road,
Melbourne VIC 3004

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: other names, analytical data, and identity of recipients.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed for all physico-chemical endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

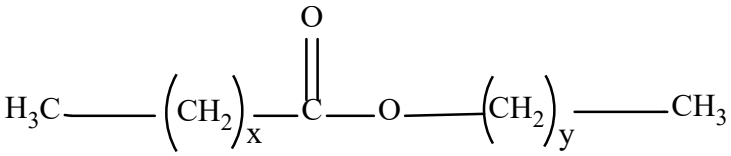
MARKETING NAME(S)
Hydrogenated Jojoba Oil (INCI name)

CAS NUMBER
92457-12-0

CHEMICAL NAME
Jojoba, ext., hydrogenated

MOLECULAR FORMULA
Unspecified

STRUCTURAL FORMULA



x and y are each in the range 16-26.
The notified chemical is a mixture of saturated long chain esters of high molecular weight. It is the product of reduction of Simmondsia Chinensis (Jojoba) Seed Oil, which is composed almost completely (97%) of wax esters of monounsaturated straight-chain acids and alcohols of high molecular weight (CIR, 2008).

MOLECULAR WEIGHT
>500 Da

ANALYTICAL DATA
Reference gas/liquid chromatography IR spectra were provided.

Identity of Analogue

CHEMICAL NAME
Jojoba Oil (INCI name Simmondsia Chinensis (Jojoba) Seed Oil)
[The same CAS number also covers Jojoba Seed Wax (CIR, 2008)]

CAS NUMBER
61789-91-1

3. COMPOSITION

DEGREE OF PURITY
UVCB (variable composition)

IDENTIFIED IMPURITIES
Impurities were not identified in the analytical studies on the notified chemical. CIR (2008) reports that jojoba seed oil contains 1% total free acids, 1% total free alcohols and small quantities of sterols (< 0.5%). These components are expected to also be present in the notified chemical.

ADDITIVES/ADJUVANTS
None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: White to yellow waxy flakes

Property	Value	Data Source/Justification
Melting Point/Freezing Point	67.0 - 71.0 °C	Measured
Boiling Point	> 400 °C at 101.3 kPa	Estimated, as the boiling point for jojoba oil (analogue) is 398°C and the boiling point is expected to be higher for the notified chemical which has been saturated.
Density	860-870 kg/m^3 at 25 °C	(M)SDS
Vapour Pressure	Not determined	Expected to be very low as chemical is solid with an estimated high boiling point.
Water Solubility	Not determined	The notified chemical is expected to have low water solubility based on its chemical structure
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionality. However, the notified chemical is not expected to be significantly hydrolysed under normal environmental conditions (pH 4 – 9).
Partition Coefficient (n-octanol/water)	Not determined	Expected to partition to n-octanol based on its low water solubility
Adsorption/Desorption	Not determined	Expected to partition to soil/sediment based on its low water solubility
Dissociation Constant	Not determined	Does not contain dissociable functionality
Particle Size	Not determined	Notified chemical consists of wax flakes
Flash Point	>296 °C	(M)SDS
Autoignition Temperature	Not determined	Expected to be high, based on flash point
Explosive Properties	Not determined	Contains no structural alerts for explosive properties
Oxidising Properties	Not determined	Contains no structural alerts for oxidising properties

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 for the Classification and Labelling of Chemicals (GHS), as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will not be manufactured within Australia. The notified chemical will be imported into Australia in neat form and as a component of finished cosmetic products up to 15% 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
Melbourne and Sydney

TRANSPORTATION AND PACKAGING
The notified chemical will be imported in neat form and as a component of finished cosmetic products (at up to 15% concentration) in containers suitable for retail sale in ≤500 mL plastic/HDPE bottles or tubes. The finished cosmetic products are packaged in shipper cartons, which in turn are arranged in pallets inside sea containers.

USE
The notified chemical will be used as an ingredient of cosmetic products (makeup products at up to 15% concentrations, rinse off products at up to 10% concentration and other leave-on products and aerosols at up to 5% concentration).

OPERATION DESCRIPTION
The notified chemical will be imported in neat form and as a component of finished cosmetic products (up to 15%) into Australia.

Dockside and warehouse workers will transport the notified chemical and finished products containing the notified chemical from the wharf to the central distribution centres and place the pallets of products into the warehouse. Warehouse workers will be involved in transferring pallets in the central warehouse and operating a picking operation for stock to distributors at the retailer's central distribution depots.

In the case of the formulation process taking place in Australia, quantities of the products containing the notified chemical will be sampled and tested by a chemist for QA purposes. Production compounders will weigh an appropriate amount of the raw material into a separate container then add the amount directly into a flame proof mixing tank. Mixing and dispensing will be carried out in a closed system with flame proof mixers and pumps designed not to create aerosols or a dust hazard and earthed for static discharges.

Products containing the notified chemical (up to 15%) may be used in professions where the services involve the application of cosmetic products to clients (e.g. workers in beauty salons).

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration*	*Exposure Frequency*

	(hours/day)	*(days/year)*
Transport and Storage	4	12
Professional compounder	8	12
Chemist	3	12
Packers (Dispensing & Capping)	8	12
Store Persons	4	12
End Users	8	365

EXPOSURE DETAILS
The notified chemical will not be manufactured in Australia. The notified chemical will be imported in neat form and in finished cosmetic products at up to 15%.

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

Reformulation
During formulation process, chemists may come into an accidental skin or eye contact with the notified chemical during sampling and testing for QA purposes. Workers may be involved in weighing, mixing and dispensing (compounders) may experience dermal, ocular and inhalation exposure from drips, spills, splashes and vapour when weighing the material and adding to mixing tanks. Workers are expected to use safety glasses with shields, gloves, apron or coverall during formulation process. Adequate ventilation and appropriately located exhaust hoods will be also used in the workplace.

End-use
Exposure to the notified chemical in end-use products (at up to 15% concentration) may occur in professions where the services provided involve the application of cosmetic and personal care products to clients (e.g. hair dressers, workers in beauty salons). The principal route of exposure will be dermal, while ocular and inhalation exposure is also possible. Such professionals may use some PPE to minimise repeated exposure, but this is not expected to occur in all workplaces. However, good hygiene practices are expected to be in place. If PPE is used, exposure of such workers is expected to be of a similar or lesser extent than that experienced by consumers using products containing the notified chemical.

6.1.2. Public Exposure
Public exposure to the notified chemical is expected to be widespread and frequent through daily use of personal care products containing the notified chemical at concentrations up to 15%. Exposure to the notified chemical will vary depending on individual use patterns and the concentration of use. The principal route of exposure will be dermal. Ocular and ingestion (from the use of lip products) exposure may also occur. Inhalation exposure is deemed negligible, given the characteristics of the notified chemical.

Exposure can be calculated using data on typical use patterns of cosmetic product categories in which the notified chemical may be used (SCCS, 2012; Cadby et al., 2002). For the purposes of the exposure assessment, Australian use patterns for the various product categories are assumed to be similar to those in Europe. An adult bodyweight of 60 kg was used for calculation purposes.

The worst case scenario estimation using these assumptions is for a person who is a simultaneous user of all products that contain the notified chemical. This would result in a combined internal dose of 7.09 mg/kg bw/day. Specific use details of the notified chemical are considered exempt information.

6.2. Human Health Effects Assessment

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

Endpoint	*Chemical*	*Result and Assessment Conclusion*
Rat, acute oral toxicity	Analogue	LD50 >5000 mg/kg bw; low toxicity
Rat, acute dermal toxicity	Analogue	LD50 >2000 mg/kg bw; low toxicity
Rabbit, skin irritation	Analogue	slightly irritating

Rabbit, eye irritation	Analogue	non-irritating
Marmots, skin sensitisation – (10%).	Analogue	no evidence of sensitisation
Human, skin sensitisation – RIPT (10%)	Notified Chemical	no evidence of sensitisation
Guinea pigs, repeat dose dermal toxicity – 20 weeks.	Analogue	NOAEL 500 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	Derivatives of Analogue	non mutagenic

Toxicokinetics, metabolism and distribution.
The notified chemical has a molecular weight >500 Da and expected relatively high partition coefficient. This would limit the potential for the chemical to be absorbed via the dermal route (ECHA, 2012). However the Analogue is reported to enhance the skin penetration of some other substances (CIR, 2008).

Acute toxicity.
No acute oral, dermal or inhalation toxicity data for the notified chemical were provided. However, information on analogue indicated high oral and dermal LD50s (>5000 and >2000 mg/kg bw, respectively) (CIR, 2008). Information is not available on acute inhalation toxicity.

Irritation and sensitisation.
No skin or eye irritation data for the notified chemical were provided. Information on analogue in CIR (2008) indicates that it has low potential for skin and eye irritation.

A product containing the notified chemical at 10% did not produce any responses indicative of irritation or sensitisation in a Human Repeated Insult Patch test (HRIPT). CIR (2008) reported several patch tests using Analogue. No allergic reactions were seen in some studies. In two studies, limited transient reactions on challenge were considered by the study authors to not be indicative of sensitisation. A mixture containing mainly Analogue was negative in a maximisation study in albino marmots.

Repeated dose toxicity.
No data on repeated dose toxicity for the notified chemical were provided. However, in a subchronic dermal toxicity study, 0, 250 or 500 mg/kg bw/day of analogue was applied 6 days/week for 20 weeks on the shaved skin of 32 DH guinea pigs (4M and 4F/group). The established NOAEL was 500 mg/kg bw/day, as no differences were observed in body weights, organ weights (liver, heart, kidneys and testes) between treated and control groups and no lesions in tissues from the organs such as adrenal gland, thyroid gland, kidney, urinary bladder, spleen, liver, pancreas, heart, brain, stomach, intestines and skin were observed in all groups (CIR, 2008).

Mutagenicity/Genotoxicity.
No data on genotoxicity for the notified chemical were provided. However, an Ames test (strains: S. typhimurium (TA98, TA100, TA1535, TA1537 and TA1538 and E. coli) on a mixture of jojoba oil (Analogue) derivatives showed no sign of toxicity and no mutagenicity at concentrations up to 100 mg/plate (CIR, 2008).

Health hazard classification
Based on the available information, the notified chemical is not recommended for classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
Transport and storage
Workers may experience dermal and accidental ocular exposure to the notified chemical (at up to 100% concentration) during transport or storage.

Reformulation
Workers may experience dermal, ocular and inhalation exposure to the neat notified chemical during formulation processes. This exposure may occur during handling of the chemical, cleaning and/or maintenance of the equipment. Exposure may also extend to compounders and laboratory staff involved in the formulation of the end products containing the notified chemical and the sampling and quality control testing of these products.

The use of enclosed process and PPE (safety glasses with shields, gloves, apron or coverall), and adequate ventilation and appropriately located exhaust hoods if significant inhalation exposure is expected) is expected to be used during formulation processes.

Based on the use of measures used to mitigate exposure and the overall low toxicity of the notified chemical, the risk to workers from transport/storage and use 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 products containing the notified chemical to clients (*e.g.*, hairdressers and beauty salon workers) may be exposed to the notified chemical. The risk to these workers is expected to be of a similar or lesser extent than that experienced by consumers using products containing the notified chemical.

Such professionals may use PPE to minimise repeated exposure, and good hygiene practices are expected to be in place. For hairdressing salons, good ventilation would be recommended if hair spray is routinely used in a confined space. If PPE is used, the exposure of such workers is expected to be of a similar or lesser extent than that experienced by consumers using the various cosmetic products containing the notified chemical. Based on the information available, the risk to workers associated with use of the notified chemical is not considered to be unreasonable.

6.3.2. Public Health
Members of the public will experience widespread and frequent exposure to the notified chemical through daily use of cosmetic products of leave on makeup products at up to 15% concentrations, rinse off products at up to 10% concentrations and other leave on products and aerosols at up to 5% concentration.

The potential systemic exposure to the public from the use of the notified chemical in cosmetic products was estimated to be 7.09 mg/kg bw/day. Using a NO(A)EL of 500 mg/kg bw/day, which was derived from a dermal repeated dose toxicity study on the analogue chemical, the margin of exposure (MOE) was estimated to be 71. A MOE value greater than or equal to 100 is considered acceptable to account for intra- and inter-species differences. However the calculated MOE is based on the highest dose tested in the repeated dose study and the NOAEL is expected to be higher. The assumed dermal absorption of 50% is also likely to represent a conservative assumption, given the molecular weight >500 Da and expected relatively high partition coefficient of the notified chemical. Furthermore, the assumption that an adult consumer will use daily a large number of make-up, rinse-off and leave-on cosmetics containing the notified chemical at up to 15% concentration, is conservative, and likely to overestimate exposure under realistic use scenarios. Therefore, the MOE is considered to be acceptable.

It is noted that the notified chemical may enhance dermal absorption of other chemicals (CIR, 2008), therefore care should be taken in formulating it into the end-use products.

According to WHO (2006) and US EPA (1996) Jojoba Oil may contain cyanoglycosides as impurities (e.g., simmondsin, simmondsin-2-ferulate or related conjugated organonitriles including demethyl simmondsin and didemethylsimmondsin), which are of toxicological concern. The notified chemical is produced from Jojoba Oil. While there is uncertainty whether such impurities may be present in the notified chemical, this information is of relevance to introducers.

Based on the information, the risk to the public associated with the use of the notified chemical in cosmetics at up to 15% in leave-on make-up products, up to 10% in rinse off products, and up to 5% in aerosols and other leave-on products is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical will not be manufactured in Australia. It will be imported in neat form for formulation into cosmetic products or as a component of finished cosmetics. There is unlikely to be any significant release to the environment from storage and transport, except in the case of accidental spills. Accidental spills are unlikely, given the imported product will be containerised. If spills do occur, the product containing the notified chemical is expected to be collected with inert material and disposed of to landfill.

The formulation process will involve blending operations that will be highly automated and is expected to occur in a fully enclosed environment. Therefore, a 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. Wastes, which contain the notified chemical, generated during reformulation include equipment washings, empty import containers and spilt materials. The wastes may be collected and released to sewers for the worst case scenario.

RELEASE OF CHEMICAL FROM USE
The notified chemical is a component in rinse-off and leave-on cosmetic products. The formulated product will be applied to body parts and will either be removed with tissues and disposed of to domestic garbage, or washed off the body with ultimate release to the sewer.

RELEASE OF CHEMICAL FROM DISPOSAL
Wastes and residue of the notified chemical in empty containers (3%) is likely either to share the fate of the container and be disposed of to landfill, or to be washed to sewer when containers are rinsed before recycling.

7.1.2. Environmental Fate

No environmental fate data was submitted. Following its use in cosmetic products, the majority of the notified chemical is expected to enter the sewer before potential release to surface waters on a nationwide basis. The majority of the notified chemical will enter the sewer system as a result of the use of the notified chemical. Based on its low water solubility, some of the notified chemical is expected to partition to sludge. The notified chemical has low potential to bioaccumulate and it is not expected to be significantly bioavailable in the aquatic environment due to its low water solubility. In surface waters, the notified chemical is expected to disperse and degrade through biotic and abiotic processes to form water and oxides of carbon. A proportion of notified chemical may be applied to land when treated sewage effluent is used for irrigation or when sewage sludge is used for soil remediation, or disposed of to landfill. Notified chemical residues in landfill and soil are not expected to be mobile based on its low water solubility, and are expected to degrade to form water and oxides of carbon.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has been calculated assuming a worst case scenario of 100% release of the notified chemical into sewer systems nationwide and no removal from STPs.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment

Total Annual Import/Manufactured Volume	1,000	kg/year
Proportion expected to be released to sewer	100.000%	
Annual quantity of chemical released to sewer	1,000.000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	2.74	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	0%	Mitigation
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

No ecotoxicity data for the notified chemical were submitted. The ecotoxicity effects of the notified chemical were predicted using Ecological Structure Activity Relationship (ECOSAR v1.11, US EPA 2012). The conservative toxicity results are summarised in the table below.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	96 h LC50 = 1.73×10^{-8} mg/L	Not toxic at the solubility limit
Daphnia Toxicity	48 h EC50 = 6.11×10^{-9} mg/L	Not toxic at the solubility limit
Algal Toxicity	72 h EC50 = 1.89×10^{-10} mg/L	Not toxic at the solubility limit

Classification should be based only on toxic responses observed in the soluble range. Furthermore, the actual toxicity of the notified chemical to aquatic life may be overestimated by ECOSARs estimation used here as surface waters tend to have higher total organic content (TOC) and dissolved organic content (DOC) than what is used in standard aquatic toxicity testing media. Classification should be based on actual toxicity endpoints and, therefore, the notified chemical cannot be formally classified under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009).

7.2.1. Predicted No-Effect Concentration

A predicted no-effect concentration (PNEC) was not calculated since the notified chemical is predicted to be non-toxic to fish, invertebrates, algae at its solubility limit.

7.3. Environmental Risk Assessment

A risk quotient (RQ) value has not been calculated as no PNEC data was generated. Based on the assessed use pattern, the notified chemical is not likely to be present in ecotoxicologically significant concentrations in the aquatic environment. In the aquatic environment it is unlikely to bioaccumulate based on its low water solubility. Therefore, on the basis of the assessed use pattern, the notified chemical is not expected to pose an unreasonable risk to the environment.

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Skin sensitisation – human volunteers

TEST SUBSTANCE	Notified chemical (10% in product)
METHOD	Repeated insult patch test with challenge
Study Design	Induction Procedure: A series of nine occlusive patches over three week period containing approximately 0.2 g of the test substance were applied. The patches kept dry for 24 hours then removed. A24 hours period no test substance was applied followed the weekday patch removals a 48 hours Rest Period: 14 days Challenge Procedure: The challenge patch was applied to only virgin site for 24 hours. Observation was performed after 48, 72 and 96 hours post patching.
Study Group	142 F, 60 M; age range 18 to 70 years
Vehicle	
Remarks - Method	Occluded. The test substance was spread on a webril/adhesive patch.
RESULTS	
Remarks - Results	202/228 subjects completed the study. 26 subjects discontinued due to personal reasons (not due to the test material reaction). During the induction phase, no reactions were exhibited. At the challenge phase, one subject exhibited a low-level transient reaction.
CONCLUSION	The test substance was non-sensitising under the conditions of the test.
TEST FACILITY	Harrison Research Laboratories (2002)

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