File No: STD/1467

May 2013

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)**

# PUBLIC REPORT

## Fatty acids, olive-oil, lauryl esters (INCI name: Lauryl Olivate)

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (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 Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of Sustainability, Environment, Water, Population and Communities.

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:


| | |
|---|---|
| Street Address: | Level 7, 260 Elizabeth Street, SURRY HILLS NSW 2010, AUSTRALIA. |
| Postal Address: | GPO Box 58, SYDNEY NSW 2001, AUSTRALIA. |
| TEL: | + 61 2 8577 8800 |
| FAX | + 61 2 8577 8888 |
| Website: | www.nicnas.gov.au |


**Director**
**NICNAS**

# TABLE OF CONTENTS

# 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 |
|---|---|---|---|---|---|
| STD/1467 | Ingredients Plus Pty Ltd | Fatty acids, olive-oil, lauryl esters (INCI name: Lauryl Olivate) | ND* | ≤ 15 tonnes per annum | Component of rinse-off and leave-on cosmetic products |

*ND = not determined

# CONCLUSIONS AND REGULATORY OBLIGATIONS

**Hazard classification**
Based on the limited toxicity data available the notified chemical cannot be classified 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 expected to pose an unreasonable risk to the environment.

**Recommendations**

REGULATORY CONTROLS

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.

- 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 dermal exposure.

- 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:
  - Impervious gloves and 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.

Disposal

- The notified chemical should be disposed of to landfill.

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 concentration of the chemical exceeds or is intended to exceed 5% in cosmetic products.

or

(2) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from a component of rinse-off and leave-on cosmetic products, or is likely to change significantly;
- the amount of chemical being introduced has increased from 15 tonnes per annum, 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.

*(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)
Ingredients Plus Pty Ltd (ABN: 25 112 469 619)
Unit 8, 9-11 South Street
Rydalmere NSW 2116

NOTIFICATION CATEGORY
Standard: Chemical other than polymer (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: spectral data, residual monomers/impurities and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: all physico-chemical (exceptions: melting point, boiling point, water solubility and autoignition temperature), toxicological and ecotoxicological endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

## 2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Sensolene Care DD

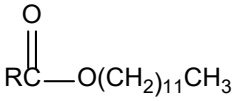
CAS NUMBER
92113-71-8

CHEMICAL NAME
Fatty acids, olive-oil, lauryl esters

OTHER NAME(S)
Lauryl Olivate (INCI name)
Dodecyl Olivate

MOLECULAR FORMULA
Unspecified

STRUCTURAL FORMULA



Where R is derived from the fatty acids of olive oil

MOLECULAR WEIGHT
> 400 Da

ANALYTICAL DATA
IR and GC spectra were provided.

## 3. COMPOSITION

DEGREE OF PURITY ≥ 98%

## 4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Yellow soft wax

| Property | Value | Data Source/Justification |
|---|---|---|
| Melting Point/Freezing Point | 30 ± 3 °C | Measured |
| Boiling Point | 360 to > 450 °C at 100.9-101.5 kPa | Measured |
| Density | Not determined | Expected to be < 1000 kg/m$^3$ at 25 °C |
| Vapour Pressure | Not determined | Based on the structure/molecular |

| | | |
|---|---|---|
| | | weight of the chemical, expected to be low. |
| Water Solubility | ≤ $7.1 \times 10^{-3}$ g/L at 20 °C | Measured |
| Hydrolysis as a Function of pH | Not determined | The notified chemical contains hydrolysable functional groups, however, hydrolysis is expected to be slow in the environmental pH range (4-9) |
| Partition Coefficient | Not determined | The notified chemical is expected to partition from water to oil, based on its hydrophobic structure |
| Adsorption/Desorption | Not determined | The notified chemical is expected to be adsorbed to soil, sediment and sludge based on its hydrophobic structure |
| Dissociation Constant | Not determined | The notified chemical does not contain dissociable functionality |
| Particle Size | Not determined | Waxy solid |
| Flash Point/flammability | Not determined | Not expected to be classified as a flammable substance |
| Autoignition Temperature | 378 ± 5 °C | Measured |
| Explosive Properties | Not determined | Notified chemical does not contain functional groups that would imply explosive properties |
| Oxidising Properties | Not determined | Notified chemical does not contain functional that would imply 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 physical-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 be imported at 100% concentration and as a component of finished products at ≤ 5% concentration.

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

| *Year* | *1* | *2* | *3* | *4* | *5* |
|---|---|---|---|---|---|
| *Tonnes* | 1-3 | 3-10 | 3-10 | 3-10 | 10-15 |

PORT OF ENTRY
Sydney, by wharf

IDENTITY OF MANUFACTURER/RECIPIENTS
Ingredients Plus Pty Ltd

TRANSPORTATION AND PACKAGING
The notified chemical (at 100% concentration) will be imported in 19 L steel pails or 209 L steel drums. It will be transported by road or rail from the port of entry to the storage warehouse and then distributed to reformulation sites.
Where the notified chemical is imported as a component of finished products, it will be imported in the

consumer packaging, packed in bulk cartons. It will then be transported to the distributor sites and from there to various warehousing facilities or directly to retail outlets around Australia for retail sale.

USE
The notified chemical is intended to be used as an emollient ingredient in cosmetic products (e.g. creams, lotions and hair care products), at ≤ 5% concentration.

OPERATION DESCRIPTION
The procedures for incorporating the notified chemical (100% concentration) into end-use products will likely vary depending on the nature of the cosmetic products formulated, and may involve both automated and manual transfer steps. However, in general, it is expected that the reformulation processes will involve blending operations that will be highly automated and occur in a fully enclosed environment, followed by automated filling of the reformulated products into containers of various sizes.

The finished products containing the notified chemical (at ≤ 5% concentration) may be used by consumers and professionals such as hairdressers and workers in beauty salons. Depending on the nature of the product, these could be applied in a number of ways, such as by hand or using an applicator.

## 6. HUMAN HEALTH IMPLICATIONS

### 6.1. Exposure Assessment

#### 6.1.1. Occupational Exposure
Transportation and storage workers will only be exposed to the notified chemical (at 100% concentration or as a component of end-use products) in the unlikely event of an accident.

During cosmetic formulation processes (including quality control, transfer, cleaning and maintenance tasks), dermal and ocular exposure may occur. Exposure is expected to be minimised by the use of adequate ventilation, enclosed mixing vessels, a high degree of process automation and the use of personal protective equipment (PPE), including goggles, impervious gloves and appropriate industrial clothing. Due to the estimated low vapour pressure of the notified chemical, inhalation exposure is not expected.

Exposure of workers to the notified chemical in end-use products may occur in professions where the services provided involve the application of cosmetic products to clients e.g. in hair and beauty salons. Such professionals may use PPE to minimise repeated exposure, and good hygiene practices are expected to be in place. If PPE is used, exposure to such workers is expected to be of a similar or lesser extent than that of consumers.

#### 6.1.2. Public Exposure
There will be widespread and repeated exposure of the public to the notified chemical, at up to a maximum concentration of 5%, through the use of rinse-off and leave-on cosmetic products. The main route of exposure will be dermal; however, ocular exposure is also possible.

### 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* |
|---|---|
| Human, skin irritation (100%) | Non-irritating |
| Human, skin sensitisation – RIPT (100%) | No evidence of sensitisation |

While only limited studies have been conducted on the notified chemical (as summarised in the above table), extensive information has been published on the toxicity that is associated with alkyl esters and/or fatty acids and alcohols (see for example: CIR, 2013; CIR, 2012; CIR, 2011; CIR, 1985; CIR, 1982; OECD, 2006). Some of this information is discussed below.

*Toxicokinetics, metabolism and distribution.*
The potential for dermal absorption of the notified chemical is expected to be limited by the low water solubility (≤ $7.1 \times 10^{-3}$ g/L at 20 °C) and relatively high molecular weight. Following oral administration, the notified

chemical is expected to be hydrolysed into the component alcohol and free fatty acids.

*Acute toxicity.*
No acute toxicity data is available on the notified chemical. Based on the structure of the notified chemical, it is not expected to present a concern for acute toxicity effects. This is supported by information on other alkyl esters (e.g. CIR, 2013; CIR, 2012; CIR, 1985; CIR, 1982), which in general, suggests that the esters are of low acute toxicity.

*Irritation and sensitisation.*
Based on the structure of the notified chemical, at most, slight skin and/or eye irritation effects would be expected, with the levels of irritation not expected to warrant classification of the chemical as a skin or eye irritant. Similarly, based on the absence of structural alerts (and expected limited dermal absorption), skin sensitisation is not expected. This is supported by studies conducted on the notified chemical, where it was found to be non-irritating and non-sensitising to human skin and further supported by study results for similar chemicals (e.g. CIR, 2013; CIR, 2011).

*Repeated Dose Toxicity.*
No repeat dose toxicity information is available on the notified chemical. However, information is available on other alkyl esters, for example:

In a chronic two-year feeding study with octadecanoic acid, butyl ester (butyl stearate; CAS no. 123-95-5) at concentrations of 1.25% and 6.25% in the diet, exposed rats showed no significant difference from control animals with respect to growth, survival, blood counts or other haematological parameters (Smith, 1953). The study author also noted that under the conditions employed, specific gross or microscopic pathologic changes were not provoked.

Overall, the available information on alkyl esters and/or the component fatty acids and alcohols (see for example, CIR, 2013; CIR, 2012; and OECD, 2006), coupled with the continued dietary consumption of fatty acids/esters, indicates that the notified chemical is not expected to present a notable concern for toxicity following repeated administration.

*Mutagenicity/Genotoxicity.*
Based on the structure of the notified chemical it is not expected to present a concern for genotoxic effects. This is supported by the results reported from in vitro and in vivo studies on alkyl esters and/or the component fatty acids and alcohols (e.g. CIR, 2012; and OECD, 2006).

***Health hazard classification***
Based on the limited toxicity data provided, the notified chemical cannot be classified 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
*Reformulation*
Dermal and ocular exposure of workers to the notified chemical (at ≤ 100% concentration) may occur during reformulation processes. Given that the exposure of workers is expected to be minimised through the use of automated processes, ventilated environments, and wearing PPE, the risk to workers from 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 (at ≤5% concentration) 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 (for details of the public health risk assessment, see Section 6.3.2.).

### 6.3.2. Public Health

At the proposed usage concentration of ≤ 5% notified chemical in rinse-off and leave-on cosmetic products, acute toxicity effects are not expected. The main routes of exposure will be dermal; however, ocular exposure is also possible during the use of the cosmetic products. Dermal absorption of the notified chemical is expected to be limited. Adverse systemic effects from repeated use of the notified chemical at the proposed concentration are not expected. It is noted that alkyl esters are commonly used cosmetic ingredients, with higher usage concentrations having been reported (CIR, 2013).

Therefore, when used in the proposed manner, the risk associated with use of the notified chemical at ≤ 5% concentration in rinse-off and leave-on cosmetic products is not considered to be unreasonable.

## 7. ENVIRONMENTAL IMPLICATIONS

### 7.1. Environmental Exposure & Fate Assessment

### 7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical will be imported in bulk as a component of finished cosmetic products and will also be imported at 100% concentration for blending. Release from blending is expected to be very low. The rinsates from empty import containers are expected to be disposed of according to local regulations and industry standard operating practices. Accidental spills are expected to be contained and disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

The notified chemical will be used as a component in skin care and hair care products. Therefore, it is expected that the majority of the imported quantity of notified chemical will eventually be washed off the skin and hair and ultimately released to the sewer.

RELEASE OF CHEMICAL FROM DISPOSAL

Residue of the notified chemical in the empty end-use containers 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

The majority of the notified chemical is expected to be released to sewer during use in cosmetic products. During waste water treatment processes in sewage treatment plants (STPs), most of the notified chemical is expected to be removed from waste waters to sludge due to its hydrophobic structure. The notified chemical that partitions and/or adsorbs to sludge will be removed with the sludge for disposal to landfill or used in soil remediation. The quantity of notified chemical that is released to surface waters is expected to be very low due to its very low water solubility. However, if it reaches receiving waters, it is expected to partition and/or adsorb to suspended solids and organic matter.

An analogue substance (fatty acids, C16-18 and C18-unsatd., 2-ethylhexyl esters; CAS no. 85049-37-2), is considered applicable as read across to the notified chemical with regards to biodegradability due to their identical generic molecular structure. The analogue substance is biodegraded in 28 days (85%; IUCLID, 1996). Hence, the notified chemical is expected to biodegrade in a similar manner as its analogue. Since the notified chemical has low water solubility and rapid degradability, it is not expected to be significantly bioavailable in receiving waters. Hence the bioavailable fraction of the notified chemical in the receiving waters is expected to be low. Although the notified chemical is likely to bioaccumulate due to its hydrophobic structure, it may be negligible due to its low water solubility and rapid degradability.

### 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 cosmetic products, it is assumed that 100% of the notified chemical will be released to sewer on a nationwide basis over 365 days per year. It is also assumed that there is no removal of the notified chemical during STP processes.

| ***Predicted Environmental Concentration (PEC) for the Aquatic Compartment*** | | |
|---|---|---|
| Total Annual Import/Manufactured Volume | 15,000 | kg/year |
| Proportion expected to be released to sewer | 100% | |

| | | |
|---|---|---|
| Annual quantity of chemical released to sewer | 15,000 | kg/year |
| Days per year where release occurs | 365 | days/year |
| Daily chemical release: | 41.10 | 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: | 9.09 | µg/L |
| PEC - Ocean: | 0.91 | 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 9.09 µg/L may potentially result in a soil concentration of approximately 60.6 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 303 µg/kg and 606 µg/kg, respectively. However, it is expected that the majority of the notified chemical will be removed from STP influent by adsorption to sludge and degradation processes. Hence, the resulting concentration of notified chemical in soil may be less than the predicted concentration

### 7.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on an analogue substance are summarised in the table below. The analogue substance (fatty acids, C16-18 and C18-unsatd., 2-ethylhexyl esters; CAS no. 85049-37-2), was used as read across to the notified chemical due to their identical generic molecular structure. As the reported analogue endpoints exceed the water solubility limit of the notified chemical, the data suggest that aquatic toxicology would not be expected at water saturated levels. The notified chemical is not anticipated to be bioavailable as it is expected to have a high log Kow value. Therefore, no effects on aquatic biota are predicted for the notified chemical at its water saturation concentration (ECOSAR (v1.00), US EPA, 2009).

| *Endpoint* | *Result(mg/L)* | *Assessment Conclusion* |
|---|---|---|
| *Brachydanio rerio* (Fish; LL50, 48 h) | 3200 (IUCLID, 1996). | Not expected to be harmful to fish at its solubility limit |
| *Daphnia magna*. (Daphnia sp.; EL50, 24 h) | 17 (IUCLID, 1996). | Not expected to be harmful to aquatic invertebrates at its solubility limit |
| *Scenedesmus subspicatus* (Algae; EL50, 96 h ) | 40 (IUCLID, 1996). | Not expected to be harmful to algae at its solubility limit |

Classification should be based only on toxic responses observed in the soluble range. The predicted values for the notified chemical to the three test species are much higher than the solubility limit. Hence, it is not expected to be harmful to non-target aquatic organism at its solubility limit in the aquatic environment. Therefore, under the Globally Harmonised System (GHS) (United Nations, 2009), the notified chemical is not expected to be harmful to aquatic vertebrates, invertebrates and algae on an acute basis and is not formally classified under the GHS.

#### 7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) has not been calculated for the notified chemical as it is not expected to be harmful to aquatic organisms up to its limit of solubility.

### 7.3. Environmental Risk Assessment

Based on the analogue data, the notified chemical is expected to be rapidly biodegradable in the environment. Additionally, it has low potential to be bioavailable due to its low water solubility. The notified polymer is not expected to be harmful to aquatic organisms up to the limit of its solubility. Therefore, the notified chemical is not expected to pose an unreasonable risk to the environment based on the assessed use pattern.

## APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

**Melting Point/Freezing Point** 30 ± 3°C

| | |
|---|---|
| Method | OECD TG 102 Melting Point/Melting Range.<br>EC Council Regulation No 440/2008 A.1 Melting/Freezing Temperature. |
| Remarks | Determined by using the pour point method, where the test item was poured into a test jar, enclosed in a glass jacket. The sample was heated to 46 ºC and subsequently cooled, then starting at 42 °C (intervals of 3 °C), the sample was tilted to a horizontal position for a period of 5 seconds to observe signs of flow. |
| Test Facility | Harlan (2012a) |

**Boiling Point** 360 to > 450°C at 100.9-101.5 kPa

| | |
|---|---|
| Method | OECD TG 103 Boiling Point.<br>EC Council Regulation No 440/2008 A.2 Boiling Temperature. |
| Remarks | Determined by differential scanning calorimetry (DSC). |
| Test Facility | Harlan (2012a) |

**Water Solubility** ≤ 7.1× 10-3 g/L at 20 °C

| | |
|---|---|
| Method | OECD TG 105 for Testing of Chemicals (Flask Method). |
| Remarks | Six samples of notified chemical (2.0210, 1.9966, 1.9882, 0.2205, 0.2088 and 0.2328 g) and purified water (200 mL) with three blank samples (purified water only) in nine separate flasks, were shaken for approximately 24 hours (one blank, one low and one high loading samples), 48 hours (one blank, one low and one high loading samples), and 72 hours (one blank, one low and one high loading samples), at 30 °C. After shaking, the samples were left to stand for 24 hours at 20 °C. The samples were then filtered through a 0.2 µm nalgene membrane filter and analysed without further treatment for total organic carbon (TOC). The pH of each sample was measured. As the test item is a complex mixture, samples with two loading rates were used (differing by a factor of 10) for the solubility test according to the test guideline. No correction factor was used as the sample blank results were, in general, approximately below the detection limit.<br><br>The individual result for each loading rate was also variable. It is also reported in the study that the water solubility (extractability) of the notified chemical is loading rate dependent. The sample-to-sample variability was considered to be most likely due to the complex nature of the test item. |
| Test Facility | Harlan (2012a) |

**Autoignition Temperature** 378 ± 5 °C

| | |
|---|---|
| Method | EC Council Regulation No 440/2008 A.15 Auto-Ignition Temperature (Liquids and Gases). |
| Remarks | Determined by heating aliquots of the test material in a flask and observing any ignition. |
| Test Facility | Harlan (2012b) |

## APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

**Skin irritation – human volunteers**

| | |
|---|---|
| TEST SUBSTANCE | Notified chemical |
| METHOD | 48 hour closed patch test under occlusion |
| Study Design | The test substance was applied to the subjects (dorsal skin area) and was left in contact with the skin surface for 48 hours. The cutaneous reactions were analysed 15 minutes, 1 hour and 24 hours after patch removal.<br><br>A chamber containing a blotting paper disk soaked with distilled water was applied and used as a negative control. |
| Study Group | 10M, 15F; age range 18-60 years |
| Vehicle | None |
| Remarks - Method | Occluded. The test substance was applied using a Finn Chamber, a 7 mm diameter aluminium disc. |
| RESULTS | |
| Remarks - Results | All 25 subjects completed the study. No adverse reactions were noted. |
| CONCLUSION | The notified chemical was non-irritating under the conditions of the test. |
| TEST FACILITY | Farcoderm (2011a) |

**Skin sensitisation – human volunteers**

| | |
|---|---|
| TEST SUBSTANCE | Notified chemical |
| METHOD | Repeated insult patch test with challenge |
| Study Design | Induction Procedure: 9 patches were applied to the dorsal skin area (3 patches per week for 3 weeks) and remained in place for 24 hours. These patches were applied in the same skin area.<br>Rest Period: 14 days<br>Challenge Procedure: a patch was applied for 24 hours in a skin area that was different to the skin area used for the induction phase. Sites were graded 24, 48 and 72 hours post patch removal. |
| Study Group | 19F, 6M; age range 18-60 years |
| Vehicle | None |
| Remarks - Method | Occluded. The test substance was applied using a Finn Chamber, a 7 mm diameter aluminium disc. |
| RESULTS | |
| Remarks - Results | All 25 subjects completed the study.<br><br>Slight erythema was noted in 5 subjects (induction observations 1-2, 5-6, 7-8 and 9 in 2, 1, 1 and 1 subjects, respectively).<br><br>There were no adverse responses noted for any of the subjects 24, 48 and 72 hours post challenge patch removal. |
| CONCLUSION | The notified chemical was non-sensitising under the conditions of the test. |
| TEST FACILITY | Farcoderm (2011b) |

# BIBLIOGRAPHY

CIR (2013) Amended Safety Assessment of Alkyl Esters as used in Cosmetics. Washington DC 20036-4702.

CIR (1985) Final Report on the Safety Assessment of Butyl Stearate, Cetyl Stearate, Isobutyl Stearate, Isocetyl Stearate, Isopropyl Stearate, Myristyl Stearate and Octyl Stearate. Journal of the American College of Toxicology. Volume 4, Number 5.

CIR (1982) Final Report on the Safety Assessment of Octyl Palmitate, Cetyl Palmitate and Isopropyl Palmitate. International Journal of Toxicology 1:13.

CIR (2011) Plant-Derived Fatty Acid oils as Used in Cosmetics. Washington DC 20036-4702.

CIR (2012) Safety Assessment of Stearyl Heptanoate and Related Stearyl Alkanoates as Used in Cosmetics. Washington DC 20036-4702.

Farcoderm (2011a) Report on a Human Patch Test, 48 Hour Closed Patch Test Under Occlusion (Study No. SI.01.C_2010/1828, March, 2011). Pavia, Italy, Farcoderm srl (Unpublished report submitted by the notifier).

Farcoderm (2011b) Human Dermatological Investigation, Repeated Patch Test to Detect the Skin Sensitisation Potency of a Cosmetic Raw Material (Study No. SI.01.C_2011/03, March, 2011). Pavia, Italy, Farcoderm srl (Unpublished report submitted by the notifier).

Harlan (2012a) Sensolene DD: Determination of General Physico-Chemical Properties (Study No. 41201587, October, 2012). Derby, U.K, Harlan Laboratories Limited.

Harlan (2012b) Sensolene DD: Determination of Auto-Ignition Temperature (Liquids and Gases) (Study No. 41201588, November, 2012). Derby, U.K, Harlan Laboratories Limited.

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

OECD (2006) SIDS Initial Assessment Profile. Long Chain Alcohols (C6-22 primary aliphatic alcohols).

Smith CC (1953) Toxicity of butyl stearate, dibutyl sebacate, dibutyl phthalate and methoxyethyl oleate. AMA Arch. Ind. Hyg. Occup. Med. 7: 310-318.

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 >.

US EPA (2009) Estimations Programs Interface Suite™ for Microsoft® Windows, v 4.00. United States Environmental Protection Agency. Washington, DC, USA, <http://www.epa.gov/oppt/exposure/pubs/episuite.htm> Accessed 2010, Sep 16.