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

**FULL PUBLIC REPORT**

**Sodium PEG-7 olive oil carboxylate**

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Street Address:	334 - 336 Illawarra Road MARRICKVILLE NSW 2204, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 8577 8888.
Website:	<a href="http://www.nicnas.gov.au">www.nicnas.gov.au</a>

**Director  
Chemicals Notification and Assessment**

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## **FULL PUBLIC REPORT**

### **Sodium PEG-7 olive oil carboxylate**

#### **1. APPLICANT AND NOTIFICATION DETAILS**

**APPLICANT(S)**

Unilever Australia Limited (ABN 66 004 050 828) of 219 North Rocks Road North Rocks NSW 2151.

**NOTIFICATION CATEGORY**

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

**EXEMPT INFORMATION (SECTION 75 OF THE ACT)**

No details are claimed exempt from publication.

**VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)**

Variation to the schedule of data requirements is claimed as follows:

Melting point/Boiling point, Vapour Pressure, Water Solubility, Hydrolysis as Function of pH, Partition Coefficient, Adsorption/Desorption, Dissociation Constant, Particle size, Flash Point, Flammability Limits, Autoignition Temperature, Explosive Properties, Reactivity.

**PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)**

None.

**NOTIFICATION IN OTHER COUNTRIES**

None.

#### **2. IDENTITY OF CHEMICAL**

**CHEMICAL NAME**

Fatty acids, olive oil, esters with polyethylene glycol mono(carboxymethyl) ether, sodium salts.

**OTHER NAME(S)**

C16-18 saturated and C18 unsaturated fatty acid esters, olive oil, poly(oxy-(1,2-ethanediyl)), carboxylic acid sodium salts.

Polyethylene glycol, C16-18 saturated and C18 unsaturated fatty acid esters, olive oil, carboxylic acid sodium salts.

Sodium PEG-7 olive oil carboxylate.

**MARKETING NAME(S)**

Olivem 400 (35% notified chemical)

Dove Essential Nutrients Clarifying Toner (1.2% notified chemical)

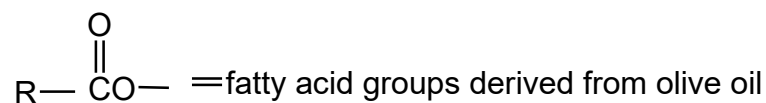
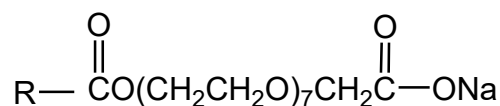
**CAS NUMBER**

226416-05-3

**MOLECULAR FORMULA**

C<sub>34</sub>H<sub>63</sub>O<sub>11</sub>Na (typical)

**STRUCTURAL FORMULA**



#### MOLECULAR WEIGHT

668

Components: 670 (as oleic acid ester- 81% of mixture), 644 (as palmitic acid ester- 8% of mixture) 668 (as linoleic acid ester- 7% of mixture) and 672 (as stearic acid ester- 2% of mixture). Minor amounts of squalene ester- 1% of mixture, and linolenic acid ester- 1% of mixture, are also present.

#### SPECTRAL DATA

ANALYTICAL METHOD	Infrared (IR) Spectroscopy
	Major peaks at 3447, 3426, 2925, 2857, 2128 (broad), 1737, 1635, 1461, 1352, 1324, 1299, 1252, 1107, 951, 887, 836, 721 $\text{cm}^{-1}$
Remarks	Full report not provided. The IR Spectra was done on a sample of Olivem 460 evaporated to remove water. Olivem 460 is a 60% solution of the notified chemical in water.
TEST FACILITY	B&T Srl (2003)

### 3. COMPOSITION

#### DEGREE OF PURITY

>95%

#### HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

<i>Chemical Name</i>	Acetic acid, chloro-, sodium salt		
<i>CAS No.</i>	3926-62-3	<i>Weight %</i>	<0.001%
<i>Hazardous Properties</i>	At Concentrations equal to or more than 25%: Toxic (T): R25 - Toxic if swallowed; R38 - Irritating to skin. At Concentrations equal to or more than 20% and less than 25%: Harmful (Xn): R22 - Harmful if swallowed; R38 - Irritating to skin. At Concentrations equal to or more than 3% and less than 20%: Harmful (Xn): R22 - Harmful if swallowed.		
<i>Chemical Name</i>	1,4-Dioxane		
<i>CAS No.</i>	123-91-1	<i>Weight %</i>	<0.001%
<i>Hazardous Properties</i>	At Concentrations equal to or more than 20%: Harmful (Xn): R40 - Possible risk of irreversible effects; R36/37 - Irritating to eyes and respiratory system. At Concentrations equal to or more than 1% and less than 20%: Harmful (Xn): R40 - Possible risk of irreversible effects.		
<i>Chemical Name</i>	Oxirane		
<i>CAS No.</i>	75-21-8	<i>Weight %</i>	<0.001%

#### *Hazardous Properties*

At Concentrations equal to or more than 5%:

Toxic (T): R45 - May cause cancer; R46 - May cause heritable genetic damage;  
R23 - Toxic by inhalation; R36/37/38 - Irritating to eyes, respiratory system and skin.

At Concentrations equal to or more than 0.5% and less than 5%:

Toxic (T): R45 - May cause cancer; R46 - May cause heritable genetic damage;  
R20 - Harmful by inhalation.

At Concentrations equal to or more than 0.1% and less than 0.5%:

Toxic (T): R45 - May cause cancer; R46 - May cause heritable genetic damage.

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight)

<i>Chemical Name</i>	Sodium chloride		
<i>CAS No.</i>	7647-14-5	<i>Weight %</i>	2.5% maximum

ADDITIVES/ADJUVANTS

Unknown.

## 4. INTRODUCTION AND USE INFORMATION

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

Import (as a 1.2% finished cosmetic facial toner and/or as a 35% aqueous solution – Olivem 400).

COMPOSITION OF OLIVEM 400

<i>Chemical Name</i>	<i>CAS No.</i>	<i>Weight %</i>
Sodium PEG-7 olive oil carboxylate (notified chemical)	226416-05-3	34-36*
Water	7732-18-5	64-66*
Preservative (0.2% Euxyl K446)		
2-Propanol, 1,1'-oxybis-	110-98-5	0.16
Pentanedinitrile, 2-bromo-2-(bromomethyl)-	35691-65-7	0.02
1,3-Propanediol, 2-bromo-2-nitro-	52-51-7	0.02

\* Determination of water-dry weight by gravimetric method (B&T Srl 2000).

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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	0.250	0.280	0.300	0.300	0.300

USE

As an anionic surfactant in a cosmetic facial toner.

## 75. PROCESS AND RELEASE INFORMATION

### 5.1. Distribution, Transport and Storage

PORT OF ENTRY

Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS

Unilever Australia Limited

TRANSPORTATION AND PACKAGING

The notified chemical will be transported as a component of a finished cosmetic facial toner initially in 200 mL plastic bottles (Dove Essential Nutrients Clarifying Toner) suitable for retail sale. They will be packed in cardboard cartons with 12 cartons per shipper. The shippers will be transported by road in a container from the wharf to the notifier's site in North Rocks, then to three retail chains for distribution.

## 5.2. Operation Description

The notified chemical will be imported as a finished product, and thus no reformulation or repackaging will occur in Australia. However, at some later time when local manufacture becomes viable, there may be significant use in locally formulated cosmetic products.

For local production, a compounder will weigh and manually add required quantities of Olivem 400 (35% aqueous solution) and other ingredients into a mixing tank (6 tonnes capacity) under adequate local ventilation. Following quality control analyses by a chemist, the resulting mixture will be transferred to the packing line for filling into plastic retail bottles, typically 200 mL. These mixing and dispensing processes will be automated and occur in a closed system or in one designed not to create aerosols or a dust hazard. The finished toner products containing 1.2% notified chemical will then be stored or delivered to retailers' central depots for distribution to consumers.

Consumers will moisten a cotton ball with the toner and wipe over the face one to two times a day. It is expected that the toner will be left on for up to 8 hours, then be washed off at the end of each day and end up in the sewer system.

## 5.3. Occupational exposure

### *Number and Category of Workers*

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration</i>	<i>Exposure Frequency</i>
Transport, Storage and Warehouse workers	12	4 h/day	12
Compounder	1	8 h/day	12
Chemist	1	3 h/day	12
Packers (Dispensing and Capping)	2	8 h/day	12

### *Exposure Details*

When the notified chemical is imported in end use cosmetic facial toners, occupational exposure to the notified chemical will be limited to handling of the closed packages during transport, storage, retail distribution and sale. A large number of workers in these sectors will handle the product containing the notified chemical for brief periods, with no exposure expected except in the case of an accident. Should a spill occur, it is expected to be contained and absorbed with inert material (sand or vermiculate), and placed into properly labelled containers for disposal in accord with the MSDS and official regulations.

During use of Olivem 400 in local formulation, a quality assurance (QA) chemist may be potentially exposed to the notified chemical when sampling and testing samples containing it. However, they will handle only small quantities and will wear appropriate personal protective equipment.

Dermal and ocular exposure due to splashes and spillages can occur during weighing, mixing, packaging and equipment cleaning procedures at a reformulation plant. The notifier indicates that adequate ventilation will be in place to prevent workers from breathing vapour, mist or dust. Operators of the reformulation plant will wear splash proof goggles, chemically resistant gloves, safety shoes, aprons, or other protective clothing, and appropriate respirators when required. In addition, the entire reformulation and packaging process for cosmetic products is generally automated, enclosed, and expected to be performed by well-trained staff. Copies of the MSDS will be readily accessible in all work areas.

## 5.4. Release

### RELEASE OF CHEMICAL AT SITE

The notified chemical will not be manufactured or reformulated in Australia. It will be imported as a component in a finished cosmetic facial toner at a level less than 2%. Transportation and storage of the notified chemical in its product formulation is not likely to constitute a major hazard, as the material is likely to be in small individual containers (200 mL bottles), or in packaging designed to withstand impact. Accidental spills and release during periods of transportation and storage should be relatively easily recovered and disposed of. Losses from local formulation of the 35% solution imported in unspecified containers are expected to low, <5% or a maximum of 15 kg per annum.

#### RELEASE OF CHEMICAL FROM USE

Since the notified chemical will be used as a surfactant in cosmetic formulations, almost all of the import volume or 300 kg per annum will be released to sewer from washing off the skin. The remaining 1% or 3 kg will remain in the empty product containers and will be disposed of into domestic rubbish and ultimately landfill. While direct release is likely to be to the aquatic compartment, it is difficult to determine which environmental medium the chemical will finally reside in without considering the fate of the substance. The nature of surfactants indicates they should associate with sludge due to hydrophobic moieties or remain in solution due to hydrophilic moieties, depending on the composition of the waste. Consequently, once in the sewage treatment plant, the chemical may end up in receiving waters or associated with sludge where it could be incinerated, or in some cases, applied to agricultural land.

#### 5.5. Disposal

The majority of the notified chemical will ultimately be disposed of to sewer in a diffuse manner as it is rinsed off the face after application. Spilt material will be removed with wet mops and larger spills may be contained by absorbents such as sand, placed into containers and disposed in landfill.

#### 5.6. Public exposure

Wide dispersive use with intermittent dermal contact and possibly accidental ocular contact with the toner is expected to occur among public consumers. For purposes of estimating exposure, calculations are based on use information of non rinse-off products (eg 0.8 g/application and 2 applications per day) as outlined in the Annex 5 of the *Notes of Guidance for Testing of Cosmetic Ingredients for their Safety Evaluation* (SCCNFP 2000), and assumptions that these toners are used extensively and contain a maximum of 1.2% notified chemical. The total daily exposure of an individual to the notified chemical is estimated to be  $0.8 \text{ g} \times 2 \times 1.2\% = 0.02 \text{ g}$ . At this level, systemic exposure via skin absorption would not be a concern.

### 6. PHYSICAL AND CHEMICAL PROPERTIES

Presented below are the physicochemical properties of Olivem 400 which contains not less than 34% notified chemical in water. No information was provided on the notified chemical itself.

**Appearance at 20°C and 101.3 kPa** Clear pale yellow liquid with a slight characteristic odour

METHOD	Gardner Method - Determination of Colour
Remarks	Full report not provided. A colour depth and gradation of Olivem 400 solution was determined using the Gardner colorimetric scale. Results: 3 max.
TEST FACILITY	B&T Srl (2003a)

**Melting Point/Boiling Point** Not determined

Remarks	Olivem 400 is a liquid above 5°C and expected to boil at ~100°C.
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**Density** 1050-1105 kg/m<sup>3</sup> at 20°C

METHOD	Pycnometer Method - Determination of Density
Remarks	Full report not provided. The relative density of Olivem 400 was determined by comparing weights of the two pycnometers filled with Olivem 400 and distilled water.
TEST FACILITY	B&T Srl (1997a)

**Viscosity** 1000 cPs maximum at 25°C

METHOD	Capillary Viscometer Method - Determination of Viscosity
Remarks	Full report not provided. The kinematic viscosity of Olivem 400 was determined by measuring the flowing times (by gravity) of 25 mL product through a calibrated Ubbelohde viscometer.
TEST FACILITY	B&T Srl (1999)



<b>Vapour Pressure</b>	Not determined
Remarks	Vapour pressure of Olivem 400 is expected to be low based on its high molecular weight and overshadowed by the vapour pressure of water of ~2.34 kPa at 20°C.
<b>Water Solubility</b>	Not determined
Remarks	Notified chemical is supplied as a 35% aqueous solution, and thus its solubility in water is expected to be at least 350 g/L.
<b>pH</b>	5.0-7.0 at 20°C
Remarks	The pH was determined for a 5% Olivem 400 solution, or 1.75% notified chemical in water.
TEST FACILITY	B&T Srl (1997b)
<b>Hydrolysis as a Function of pH</b>	Not determined
Remarks	The notified chemical is supplied as a solution with a pH range of 5-7. While the notified chemical contains an ester group it is not likely to be susceptible to hydrolysis within the environmental pH range (4-9).
<b>Partition Coefficient (n-octanol/water)</b>	log Pow = 1.75 (estimated)
Remarks	This value was calculated using KowWin. A reliable partition coefficient is generally difficult to determine for a surfactant. Based on its high water solubility the notified chemical is likely to have a low partition coefficient (in agreement with the calculated value) but this may be offset by its surface activity, which could also affect any measurement of the partition coefficient.
TEST FACILITY	B&T Srl (2003b)
<b>Adsorption/Desorption</b>	Not determined
Remarks	No data were provided for the adsorption/desorption behaviour of the notified chemical. The notified chemical is a surfactant and its adsorption/desorption is likely to be complicated by its surface active properties. Based on the high water solubility and expected low partition coefficient the notified chemical should not bind strongly to the organic matter in the soil and may potentially be mobile. However, surface activity would increase the binding of the chemical to soils and sediments.
<b>Dissociation Constant</b>	Not determined
Remarks	No data were provided for the dissociation constant of the notified chemical. The notified chemical is the sodium salt of an ethoxylated carboxylic acid and would be expected to remain mostly dissociated under ambient environmental conditions.
<b>Particle Size</b>	Not applicable
Remarks	Notified chemical is supplied as a 35% aqueous solution.
<b>Flash Point</b>	Not determined
Remarks	Not expected to be flammable (aqueous solution).
<b>Flammability Limits</b>	Not determined
Remarks	Not expected to be flammable (aqueous solution).
<b>Autoignition Temperature</b>	Not determined

Remarks Not expected to self ignite (aqueous solution).

**Explosive Properties** Not determined

Remarks Not expected to be explosive on structural grounds.

**Reactivity** Stable under normal conditions

Remarks Not expected to have oxidising properties or other unusual activity.

## 7. TOXICOLOGICAL INVESTIGATIONS

<i>Endpoint and Result</i>	<i>Assessment Conclusion</i>
Eye irritation – in vitro	slightly irritating
Skin irritation – human	slightly irritating

### 7.1. Eye irritation – in vitro

TEST SUBSTANCE 35% notified chemical (Olivem 400)

METHOD INVITTOX Protocol no. 37 Red Blood Cell Test System –

Cell Type/Cell Line

Vehicle

Exposure Period

Test Concentration

Remarks - Method

ERGATT/FRAME Data Bank of In vitro Techniques in Toxicology 1992  
Human red blood cells (RBCs)

Phosphate buffered isotonic saline pH 7.4 (PBS)

10 min

Haemolysis test: 1% to 8% Olivem or 0.35% to 2.8% notified chemical in PBS (eight equidistant concentrations)

Denaturation test: 0.1% Olivem or 0.035% notified chemical in PBS

The test used RBCs obtained from healthy volunteers to quantify adverse effects of surfactants on the cytoplasmic membranes (haemolysis) and to proteins released from the cell (denaturation). The relation between haemolysis and protein denaturation, known as Lysis/Denaturation (L/D) ratio, is then calculated (based on changes in the photometrical absorbance of oxyhaemoglobin) to determine the irritation index, which may be compared with acute eye irritation data.

<i>In Vivo Eye Irritation</i>	<i>In Vitro L/D</i>
Non irritant	>100
Slightly irritant	>10
Moderately irritant	>1
Irritant	>0.1
Very irritant	<0.1

RESULTS The eye irritation index calculated as the L/D ratio = 24 (slightly irritating).

Remarks - Results

The relative percentage of oxyhaemoglobin release for each concentration, and hence the half maximal effective concentration (H50) from the dose-response curve was calculated based on spontaneous and total haemolyses monitored against PBS and distilled water respectively. The denaturation index (DI%) was calculated based on the absorbance ratios of the test substance (Ri), of standard oxyhaemoglobin (R1 = 1.05±0.005) and of 3.47 mM/L sodium lauryl sulphate in PBS (R2). The formula  $DI\% = 100 \times (R1 - Ri) / (R1 - R2)$ , where  $(R1 - R2) = 100\%$  oxyhaemoglobin denaturation, and the absorbance ratios = absorbances at 575 nm divided by those at 540 nm. The relationship between H50 and DI% was then used to calculate the L/D ratio.

CONCLUSION	The notified chemical is slightly irritating to the eye.
TEST FACILITY	Ager Srl (1999a)

## 7.2. Skin irritation – human volunteers

TEST SUBSTANCE	35% notified chemical (Olivem 400)
METHOD	Human Primary Skin Irritation Test (modified Draize Test) (Kligman & Wooding 1967; Mathias 1987; and SCCNFP 1999)
Study Design	The test sample was absorbed onto a paper inserted into chambers, which were applied as single doses on intact back skin for 48 h, under occlusive conditions. The primary dermal irritation index is calculated as the sum of individual scores for erythema and oedema, divided by the number of volunteers, then averaged for both evaluation times (48 and 72 h).
Study Group	20 volunteers of either sex aged from 18-65 years
Vehicle	None, applied as supplied
Remarks - Method	Prior starting the test, the preclinical safety assessment of the test product had been ascertained, based on its formulation and the conformity of the test sample to the <i>European Cosmetics Directive 76/768 and amendments</i> .
RESULTS	
Remarks - Results	Allergenic reactions were not observed in any volunteer. The irritation index was 0.2 after 15 min and 0.05 after 24 h patches removal (ie 48 h and 72 h since application respectively). Primary irritation index = 0.1 (slightly irritating). The test results were analysed at Laboratori di Analisi Fabre Srl, Monza.
CONCLUSION	A human patch test was conducted using Olivem 400 (35%notified chemical) under occlusive dressing. The notified chemical is slightly irritating under the conditions of the test.
TEST FACILITY	Ager Srl (1999b)

## 8. ENVIRONMENT

### 8.1. Environmental fate

#### 8.1.1. Ready biodegradability

No biodegradability studies or test results have been provided for the notified chemical, despite a claimed biodegradability of >90% in the MSDS. This claim should therefore be treated with caution. MSDS's for a number of "analogues" have been provided which are all "readily biodegradable". However, the structures do not closely resemble the notified chemical (generally either straight chain fatty acids or polyethylene glycols with only one "analogue" in the esterified form as for the notified chemical).

#### 8.1.2. Bioaccumulation

A bioaccumulation study was not conducted. Based on the estimated value for the partition coefficient (Log P = 1.75) the notified chemical is not expected to bioaccumulate significantly. However, a measured degree of caution must be drawn to the above statement because the notified chemical is a surfactant and assumptions made based on the partition coefficient may potentially be complicated due to its surface acting properties. The MSDS for the related substance, PEG-100 stearate, says it is “expected to be of low toxicity to aquatic life”.

## **8.2. Ecotoxicological investigations**

No ecotoxicological data were submitted. MSDS's for a number of “analogues” have been provided which show a broad range of toxicity towards fish with values ranging from 5-100 mg/L. However, the correlation of these results to the notified chemical should be treated with caution, because the analogue structures do not closely resemble the notified chemical (generally either straight chain fatty acids or polyethylene glycols with only one in the esterified form as for the notified chemical).

# **9. RISK ASSESSMENT**

## **9.1. Environment**

### **9.1.1. Environment – exposure assessment**

Olivem 400 will be used as a surfactant in facial toner, and thus the vast majority of notified chemical would be expected to be released to the environment via consumer use through rinsing the chemical off the skin and into the sewerage system. In the sewer, it is anticipated that some would adsorb to sewage sludge due to the expected surface active nature of the chemical. The sludge will be either sent to landfill or incinerated.

The high water solubility and predicted biodegradability (based on analogue data) of the notified chemical indicate that it is unlikely that the chemical will bioaccumulate (Connell 1989).

The worst case scenario Predicted Environmental Concentrations (PEC) for the notified chemical is 0.21 µg/L. This value assumes all 300 kg of the chemical is released into the sewer over a 365 day period, with no removal of the polymer by adsorption or degradation, giving a daily release of approximately 0.82 kg. The PEC also assumes release occurs throughout the country, with a sewer output based on 20 million people using water at an average volume of 200 L per day per person.

$$\text{i.e., PEC} = 300 \times 10^6 / (20 \times 10^6 \times 200 \times 365) = 2.05 \times 10^{-4} \text{ mg/L}$$

The PEC in inland waterways of a worst case is 0.21 µg/L, while further dilution (10-fold) occurs in oceans and the value is 0.02 µg/L.

### **9.1.2. Environment – effects assessment**

While no data were provided on environment effects, the use and properties of this chemical indicate high exposure to the aquatic environment. Some analogue data for ecotoxicological studies were provided, however none of the analogues closely resemble the notified compound. Therefore, the predicted no effects concentration (PNEC) cannot be derived.

### **9.1.3. Environment – risk characterisation**

The notified chemical will be used as an ingredient of facial care formulations, and almost all will eventually be released into domestic sewage systems as a consequence of product use. It is expected that most of the material would eventually partition to sediment and slowly degrade to water and oxides of carbon through biological processes.

Assuming a worst-case situation where the entire import volume of 300 kg is released to sewer and remains in the aqueous compartment, the PEC would be expected to be low (0.21 µg/L for freshwater) for the aquatic environment, assuming nationwide use. No toxicity data are available to derive a PNEC and subsequently a risk quotient. However for the low quantities imported the safety margin is expected to be acceptable.

## **9.2. Human health**

#### **9.2.1. Occupational health and safety – exposure assessment**

When the notified chemical is introduced as a constituent of ready-to-use cosmetics in consumer packages, occupational exposure would be limited to handling of spillages during an accident. The MSDS indicates collection and disposal of the spills will be in accordance with the official regulations.

During local reformulation, although the blending, dispensing and packaging processes are mainly automated and will occur in an enclosed system, several groups of workers may receive transient dermal, inhalation and ocular exposure to the notified chemical during routine operations. Exposure may occur from inadvertent leaks and spills during weighing and loading ingredients, packaging from the blending vessel into consumer packages, and cleaning equipment. QA sampling and maintenance of transfer lines/pumps will be conducted under exhaust ventilation so inhalation exposure is unlikely. The plant personnel will wear chemical resistant gloves, goggles, coveralls and respirators (where appropriate) to minimise exposure to the notified chemical and other components of the facial toner formulations. Employers are responsible for maintaining the level of atmospheric nuisance dust and organic vapours below the relevant NOHSC exposure standards (NOHSC 1995). In addition, the engineering controls, industrial hygiene and good work practices will help further limit worker exposure to the notified chemical.

#### **9.2.2. Public health – exposure assessment**

End users of the facial toner product, possibly several thousands, may be exposed to the notified chemical at 1.2%. The total daily exposure of an individual is estimated to be 0.02 g with dermal and ocular contact likely to be the main route of exposure. However, given the small amounts used per application and the low concentration of the notified chemical in the product, the public exposure is determined to be low.

#### **9.2.3. Human health – effects assessment**

The notified chemical is a slight eye irritant in vitro. It is also a slight skin irritant at 35% solution in a human test. With a high molecular weight, dermal absorption of the chemical is anticipated to be low. Therefore, the notified chemical would not pose a significant health hazard when used in the proposed manner. However, long-term exposure to anionic surfactants has been linked to swelling of the skin in a conditioned allergic reaction. This swelling is temporary, although it tends to increase the susceptibility of the skin to permeation by other substances (KCPC 2004).

#### **9.2.4. Occupational health and safety – risk characterisation**

The notified chemical will be used at cosmetic formulation sites where operatives are familiar in using such products and good handling procedures and housekeeping are the norm. Therefore, the OHS risk presented by the notified chemical is expected to be low, given the engineering controls, the good work practices and safety measures including use of appropriate personal protective equipment by workers.

The notified chemical may be present in formulations containing hazardous ingredients. If these formulations are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2002), workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

#### **9.2.5. Public health – risk characterisation**

Given the notified chemical will only be used at a low concentration of 1.2% in a toner product, and its high molecular weight will preclude systemic absorption, the risk to public health is determined to be low.

### **10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS**

#### **10.1. Hazard classification**

Based on the available data there is insufficient information to substantiate that the notified chemical is not a hazardous substance. However, Olivem 400 (35% notified chemical) is not likely to be classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

#### **10.2. Environmental risk assessment**

On the basis of the widespread and low use level, the chemical is not considered to pose a risk to the environment at the proposed import volume.

#### **10.3. Human health risk assessment**

##### **10.3.1. Occupational health and safety**

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

##### **10.3.2. Public health**

There is No Significant Concern to public health when used in the proposed manner.

### **11. MATERIAL SAFETY DATA SHEET**

#### **11.1. Material Safety Data Sheet**

The MSDS of the [product containing the notified chemical](#) provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 2003). It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

#### **11.2. Label**

The label for the [product containing the notified chemical](#) provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC 1994). The accuracy of the information on the label remains the responsibility of the applicant.

### **12. RECOMMENDATIONS**

#### **CONTROL MEASURES**

##### **Occupational Health and Safety**

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical as introduced in a 35% solution:
  - Enclosed and automated processes at the blending and packaging sites;
  - Adequate ventilation for the plant operators and local exhaust ventilation for quality control personnel.
- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced in the lubricant additive package:
  - Adequate training for staff in handling surfactant components;
  - Implementation of general health surveillance and monitoring programs as required.
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced in the lubricant additive package:
  - Industrial standard protective clothing and gloves;
  - Safety glasses with side-shields/chemical goggles;
  - Vapour respirators if required.

Guidance in selection of personal protective equipment can be obtained from

Australian, Australian/New Zealand or other approved standards.

- A copy of the MSDS should be easily accessible to employees.
- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

#### Disposal

- The notified chemical should be disposed of by recovering the product if possible and disposing to landfill.

#### Emergency procedures

- Spills/release of the notified chemical should be prevented from spreading or entering into drains, ditches or rivers by using sand, earth or other appropriate barriers. Small spills may be diluted with water, whilst larger spills should be adsorbed with inert material (sand or vermiculate) and disposed of in accordance with local, state and federal authorities.

### 12.1. Secondary notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under Section 64(2) of the Act:
  - if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

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