File No LTD/1124

9 March 2004

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Glycine, N-(1-oxooctyl)-

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 the Environment and Heritage.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at:

Library
National Occupational Health and Safety Commission
25 Constitution Avenue
CANBERRA ACT 2600
AUSTRALIA

To arrange an appointment contact the Librarian on TEL + 61 2 6279 1161 or + 61 2 6279 1163.

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

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:	www.nicnas.gov.au

Director
Chemicals Notification and Assessment

TABLE OF CONTENTS

FULL PUBLIC REPORT

Glycine, N-(1-oxooctyl)-

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Johnson & Johnson Pacific Pty Ltd (ABN 73 001 121 446)
Level 3, 1 Bay Street
Broadway NSW 2007

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)
No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

CHEMICAL NAME
Glycine, N-(1-oxooctyl)-

OTHER NAME(S)
Capyloyl Glycine

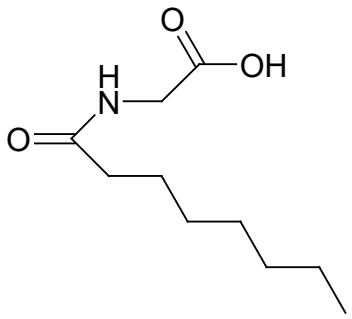
MARKETING NAME(S)
Lipacide C8G
Component of Sepicontrol A5
Component of NEUTROGENA SKINCLEARING® Gel

CAS NUMBER
14246-53-8

MOLECULAR FORMULA
$C_{10}H_{19}NO_3$

MOLECULAR WEIGHT
201.37

STRUCTURAL FORMULA



SPECTRAL DATA

ANALYTICAL METHOD	Infrared (IR) spectroscopy
Remarks	Major peaks at 3312, 2924, 2850, 1698, 1547, 1466, 1413, 1337, 1277, 1234, 1206, 1038, 945 and 679 cm^{-1}
TEST FACILITY	Test report not provided.

3. COMPOSITION

DEGREE OF PURITY
>98%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight)
None

ADDITIVES/ADJUVANTS
None

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will not be manufactured, reformulated or packaged in Australia. It will be imported as a component of finished personal care products at a maximum concentration of 2%.

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

Year	*1*	*2*	*3*	*4*	*5*
KIlograms	100	900	1000	1500	2500

USE
The notified chemical will be used as a component of facial gels.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
Johnson & Johnson Pacific Pty Ltd (ABN 73 001 121 446)
Level 3, 1 Bay Street
Broadway NSW 2007

TRANSPORTATION AND PACKAGING
The notified chemical will be imported as a component of finished personal care products in 15 mL plastic tubes packed in individual consumer packaging. The individual packages are shrink wrapped and packaged into a carton. The products will be stored at the notifier's contract warehouse prior to transportation by road to the distribution warehouses for retail outlets, who will supply the products to retail outlets for consumer use.

5.2. Operation Description

No reformulation or packaging of the products containing the notified chemical will occur in Australia. The ready to use personal care product will be distributed to retail outlets to be used as facial gels.

5.3. Occupational exposure

Warehouse workers will handle products containing the notified chemical while contained in their outer carton. Retail workers will handle the products in their retail packaging. Worker exposure to the notified chemical may occur during transport and storage of the product containing up to 2% of the notified chemical if the packaging is breached.

5.4. Release

RELEASE OF CHEMICAL AT SITE
The notified chemical will not be manufactured or reformulated in Australia.

RELEASE OF CHEMICAL FROM USE
The notified chemical will be imported into Australia as a component of cosmetic products. The main source or release will be to sewer following washing after application. Some residual product will be retained in packaging, and will go into domestic rubbish and ultimately into landfill. This is not expected to exceed more than 1% of the import volume, and disposal will be dispersed around the country.

5.5. Disposal

Unused chemical not released through a sewage treatment plant will most likely be disposed of to landfill.

5.6. Public exposure

The notified chemical will be imported as a component of finished personal care products. Public exposure during transport and storage is unlikely unless the packaging is breached. Public exposure will result through use of personal care products containing a maximum of 2% notified chemical. Consumers will apply the product on the face twice daily. The average quantity of the product used per application is 0.8 grams (0.016 grams notified chemical/application or 0.032 grams notified chemical/day).

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa White crystalline powder

Melting Point/Freezing Point 105°C

METHOD OECD TG 102 Melting Point/Melting Range.
EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks The melting point was determined in duplicate using Differential Scanning Calorimetry.
TEST FACILITY University Analytical Laboratory, UNSW (2003)

Boiling Point Not determined

Remarks The material decomposes at temperatures between 206 to 208°C

Density 501 kg/m^3

METHOD OECD TG 109 Density of Liquids and Solids.
Remarks The density of the powder was determined using the Air Comparison Pycnometer method.
TEST FACILITY University Analytical Laboratory, UNSW (2003)

Vapour Pressure Not determined

Remarks The notified chemical is not expected to have a significant degree of volatility. QSAR calculations using the EPA MPBPWIN v1.40 program gave values between 1.1×10^{-7} kPa and 4.1×10^{-7} kPa indicating slight volatility.

Water Solubility 2.8 g/L at 20°C

METHOD OECD TG 105 Water Solubility.
Remarks The water solubility was determined using the flask method at 20^0C. The test compound was dissolved in a known amount of water over a three-day period, centrifuged, and an aliquot of the supernatant evaporated and dried until a constant weight was achieved. Values for days 1, 2 and 3 were 2.77, 2.81 and 2.90 g/L respectively. The chemical can be considered readily soluble.
TEST FACILITY University Analytical Laboratory, UNSW (2003)

Hydrolysis as a Function of pH

METHOD OECD TG 111 Hydrolysis as a Function of pH.

pH	*T (°C)*	*Mean loss (%)*
4	50/20	11.1/8.5
7	50/20	1.4/10.7
9	50/20	1.5/4.1(gain)

Remarks The test was conducted over 5 days at 20 and 50°C. Concentrations were analysed by HPLC. The results for 20°C were not used because crystals were observed in the buffering solution and it is possible that the buffering salts may have salted out the test material at this temperature. At 50°C, losses after five days suggest that hydrolysis will not be a major removal process, with a half-life in the order of months under ambient conditions.
TEST FACILITY University Analytical Laboratory, UNSW (2003)

Partition Coefficient (n-octanol/water) log Pow at 20°C = 1.24

METHOD OECD TG 107 Partition Coefficient (n-octanol/water), Shake Flask Method.
Remarks Analytical Method: The concentration of the notified chemical in the aqueous

layer and the octanol layer was determined by HPLC. The mean Pow was based on 6 samples with a range of Pow = 17.00-17.48 (LogPow range of 1.23-1.24)

TEST FACILITY University Analytical Laboratory, UNSW (2003)

Adsorption/Desorption Not determined

Remarks The low Log Kow indicates partitioning to organic carbon will also be low. A Log Koc value of 1.48 has been derived through modelling (PCKOCWIN v1.66).

Dissociation Constant Not determined.

Remarks The notified chemical has a free carboxylic acid group; the pK_a is expected to be around 2.34 (based on glycine) [Merck Index, 2001]. This indicates the chemical may be ionised throughout the environmentally relevant pH range of 4-9.

Particle Size 42.0 microns

METHOD Coulter® LS Particle Size Analyzer.

Range (µm)	*Mass (% cumulative)*
<10.4	10
<21.8	25
<39.2	50
<58.2	75
<76.6	90

Remarks The particle size distribution was determined after dispersing the sample in cyclohexane. The particle size ranged from 1.7 µm to 170 µm with a mean particle size of 42 µm.

TEST FACILITY University Analytical Laboratory, UNSW (2003)

Flash Point Not determined

Remarks Expected to be greater than 200°C.

Flammability Limits Not determined

Remarks The product in which the notified chemical is to be introduced is non-combustible.

Autoignition Temperature Not determined

Remarks The product in which the notified chemical is to be introduced is non-combustible.

Explosive Properties Not determined

Remarks The notified chemical is not expected to present an explosive hazard.

Reactivity

Remarks The notified chemical is expected to be stable under normal conditions of use.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, sub acute oral LD50 >10000 mg/kg bw	low toxicity
Skin Irritation - Chorio-allantoic Membrane (1% notified chemical)	non-irritating
Skin Irritation – Red Blood Cells (10% notified chemical)	non-irritating
Human, skin irritation (1.6 notified chemical)	slightly irritating
Human, skin irritation (2% notified chemical)	slightly irritating
Human, skin irritation and sensitisation (5% notified chemical)	slightly irritating and no evidence of sensitisation
Human, skin sensitisation (1.6 notified chemical)	inadequate evidence of sensitisation

7.1. Subacute toxicity – oral

TEST SUBSTANCE	Notified chemical
METHOD	The method used is an in-house test method consisting of 10-day repeat dose study with limited observations similar to OECD TG 401 Acute Oral Toxicity.
Species/Strain	Rat/Sprague Dawley
Vehicle	Gum Arabic
Remarks - Method	The notified chemical was administered orally for 10 consecutive days as a 5% suspension in gum Arabic. Animal observation was conducted for 15 days after the last treatment. On day 15, autopsies were performed on the decedents and microscopic examinations on the organs of the abdomen and thorax were conducted on the survivors.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I (Low dose)	10/sex	2500	3
II (Mid dose)	10/sex	5000	2
III (High dose)	10/sex	10000	2

LD50	>10000 mg/kg bw
Signs of Toxicity	Three animals died between 6 to 15 days after administration of low dose and two animals died between 6 to 14 days after administration of mid and high dose. Weight reduction was observed in all dose groups. The weight reduction was not significant compared with control group and the animals seemed to recover towards the end of the observation period, except for males in mid dose group. Males in the mid dose group had lower weights compared with the control group and the weight reduction was observed throughout the treatment period. Decrease in food consumption in all groups at the end of treatment period was also observed.
Effects in Organs	The autopsy revealed thinning of the stomach wall in one animal at low dose and a dilated abdomen full of pus in another animal at mid dose group. No evidence of lesions was observed in high dose group. No microscopic observations were reported at necropsy.
Remarks - Results	The decrease in food consumption observed in all dose groups is reported to be due to overload of product in the intestines, which could also be the cause of observed weight loss.
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	Department Recherche et Essais Biolloigiques Stallergenes (1979)

7.2. Skin Irritation - Chorio-allantoic Membrane In vitro Screening

TEST SUBSTANCE	Notified chemical
METHOD	HET-CAM Test on the Chorio-allantoic Membrane of Fertilised Leghorn Hens' Eggs
Remarks - Method	The test was stated to be carried out based on the official method published on 26 December 1996, Appendix IV – Internal Procedure 57CO009
RESULTS	
Remarks - Results	There was no vasodilation observed from the new capillaries or dilation of capillaries, which were already visible. The score obtained was zero, which indicates that the notified chemical was a non-irritant. A summary only was provided. Scores for haemorrhage and coagulation were also zero.
CONCLUSION	The notified chemical was considered non-irritant at 1% concentration under the conditions of the test.
TEST FACILITY	Roso and Amalric (1999)

7.3. Skin Irritation – Red Blood Cell In vitro Screening

TEST SUBSTANCE	Notified chemical
METHOD	RBCA Test on Red Blood Cells
Remarks - Method	The test was stated to be carried out according to a method adapted from INVITTOX Protocol No: 37. A summary only was provided.
RESULTS	
Remarks - Results	The notified chemical did not show a hemolysing and denaturing properties when tested with red blood cells.
CONCLUSION	The notified chemical was considered non-irritant at 10% concentration under the conditions of the test.
TEST FACILITY	Roso and Guichard (2001)

7.4. Skin irritation – human volunteers

7.4.1. Single patch test – 5% notified chemical

TEST SUBSTANCE	Test substance containing 5% of the notified chemical.
METHOD	
Study Design	Single Patch Test
Study Group	10 female; age range 19 - 57
Vehicle	Distilled water
Procedure	The test substance was applied on the back of the subjects under an occlusive patch for 48 hours. A negative control containing water was performed under the same conditions. Cutaneous macroscopic examinations were performed about 30 minutes after removal of the patches and the reactions were scored.
Remarks - Method	All subjects completed the study.
RESULTS	
Remarks - Results	Neither significant cutaneous intolerance nor a reaction of pathological

	irritation was observed. Three subjects had very slight erythema (hardly visible).
CONCLUSION	The test substance containing 5% of the notified chemical is slightly irritating.
TEST FACILITY	Institut d'Expertise Clinique (1996)

7.4.2. 6 application repeat patch test – 1.6% notified chemical

TEST SUBSTANCE	Gel containing 1.6% of the notified chemical.
METHOD	The test was in accordance with Johnson and Johnson Consumer Products Worldwide Protocol Nos: 28252.05, 28269.05, 28271.15, 28150.05, 28151.15 and 28151.05C and the Informed Consent conforms with 21 CFR 50.25: Protection of Human Subjects.
Study Design	Cumulative Irritation Test
Study Group	32 subjects (10 male, 22 female, age range 20 – 68); 29 completed the study.
Procedure	The exposure treatment consisted of a total of 6 applications of the test substance on the back of each subject under semi-occlusive conditions for 48 hours (72 hours on the weekend) over a 14-day period. At the removal of each patch, the test site was evaluated and an identical patch applied to the same site.
Challenge Procedure	The gel containing 1.6% of the notified chemical exhibited slight irritation potential in the 29 subjects tested (total score of 48 out of a potential maximum score of 724).
Remarks - Method	Three subjects did not complete the study. None of these subjects discontinued due to test material reaction.
RESULTS	
Remarks - Results	Dryness and low-level, transient reactions were observed during the study. Distinct erythema (graded as 1) was observed at some stage in six out of twenty nine subjects.
CONCLUSION	The gel containing 1.6% of the notified chemical is not expected to cause irritation under conditions of normal use.
TEST FACILITY	Harrison Research Laboratories (2003a)

7.4.3. 21 day product trial – 2% notified chemical

TEST SUBSTANCE	Lotion containing 2% of the notified chemical.
METHOD	The test was in accordance with "Bonnes Pratiques Cliniques" by the Ministry of Employment and Population Affairs and the Ministry of Public Health and Family Affairs in France.
Study Design	The cutaneous tolerance of the product was assessed after clinical examination and questioning of the volunteers. The cosmetic qualities and acceptability were appreciated by means of a questionnaire at the end of the study. The sample given to volunteers was weighed before and after the study to calculate the average consumption of the product per volunteer for the test period. No application of any similar product to the tested one was allowed during the test period.
Study Group	20 female subjects, age range 20 – 65; 19 completed the study.

Procedure	After removal of make up with the usual cleansing milk, the volunteers were asked to apply the product to face by means of cotton wool at least twice a day for 21 (±1) days. The examinations were conducted before the first application of the product (Day 0) and at the end of the study (Day 22). After each examination, the volunteers were questioned about cutaneous reactions and any sensations of discomfort felt during the study. For the assessment of the cosmetic qualities and acceptability, the volunteers were asked to include any observations felt in the product evaluation sheet. At the end of the study, the volunteers were asked to complete a questionnaire.
Remarks - Method	Two subjects broke the container of the product and 1 subject did not bring back the flask at the end of the study.
RESULTS	
Remarks - Results	On Day 0, cutaneous disorders in four volunteers compatible with the inclusion criteria were observed. There was no sign of cutaneous intolerance observed at the end of the study. Six volunteers reported sensations of discomfort, such as drying up, pulling, stinging or casual redness (in 2 cases). Although these effects were treatment related, it was also reported that such effects could have been due to an insufficient moisturising power.
CONCLUSION	The lotion containing 2% of the notified chemical is well tolerated by the skin and the cosmetic qualities and acceptability were well appreciated by the volunteers.
TEST FACILITY	EVIC CEBA (1996)

7.5. Skin irritation and sensitisation– human volunteers

7.5.1. 9 application repeat insult patch test – 5% notified chemical

TEST SUBSTANCE	Test substance containing 5% of the notified chemical.
METHOD	Method of Marzulli and Maibach (Marzulli and Maibach, 1976)
Study Design	A preliminary study was conducted to determine the highest concentration not causing primary and cumulative irritation reactions. Based on the results from the preliminary study, the main study was conducted to investigate the irritation and sensitising potential of the notified chemical.
Study Group	Preliminary Study: 10 volunteers (9 females and 1 male; age range 21 – 63); Main Study: 50 volunteers (45 females and 5 males; age range 19 – 59)
Vehicle	Distilled water
Preliminary Study	Four successive applications (48 or 72 hrs) of three concentrations (1, 2.5 and 5%) were made under occlusive conditions.
Induction Procedure	The induction phase consisted of 9 consecutive patch applications of the test substance in occlusive conditions for 48 or 24 (4th application), or 72 hours for the first 2-week ends, to the skin of the arm. Skin reactions were observed (macroscopically) after removal of each patch.
Rest Period	15 days
Challenge Procedure	A single patch was applied to a site previously unexposed to the test subject (to the skin of the back). The patch was removed after 48 hours and the site graded. The sites were graded (macroscopically) at 24 and 48 hours after removal of the patch.
Remarks - Method	One subject discontinued during the induction period and another subject

during the rest period. No subjects discontinued due to test material reaction.

RESULTS

Remarks - Results: The maximum non-irritant concentration in the preliminary test was found to be 5%, the highest concentration used. In the main study, the majority of the subjects had minor transient irritation reaction. A single subject had a cumulative score (sum of irritation scores on a 0-4 scale over eight observations) of greater than 2. Neither pathological irritation, nor sensitisation reaction significant of a cutaneous intolerance was noted.

CONCLUSION: The test substance containing 5% of the notified chemical is slightly irritating and there was no evidence of sensitisation reaction under the experimental conditions used.

TEST FACILITY: Institut d'Expertise Clinique (1997)

7.5.2 9 application repeat insult patch test – 1.6% notified chemical

TEST SUBSTANCE: Gel containing 1.6% of the notified chemical.

METHOD: The test was conducted according to HRL Standard Protocol No. 100 and the Informed Consent were approved by the New England Institutional Review Board (NEIRB)

Study Design	Human Repeated Insult Patch Test
Study Group	238 subjects (81 male, 157 female, age range 18 – 69); 210 completed the study.
Vehicle	Not provided
Induction Procedure	The induction phase consisted of 9 consecutive applications of the test substance under 24 hour occlusive conditions for approximately 3 weeks. At 48 hour intervals the patch sites were evaluated and an identical patch applied to the same site.
Rest Period	Approximately 2 weeks
Challenge Procedure	Identical patches were applied to sites previously unexposed to the test subject. The patches were removed after 24 hours and the sites graded. The sites were graded again at 48, 73 and 96 hours.
Remarks - Method	One subject did not have a 24 hour reading, three subjects did not have 48 hour reading, another three subjects did not have 72 hour reading and nine subjects did not have 96 hour reading. A verbal report from the subjects who missed the 96 hour reading indicated that there were no reaction present. No subject discontinued due to test material reaction.

RESULTS

Remarks - Results: During the induction phase, two subjects exhibited erythema plus oedema reactions; their test sites were changed. The new test site exhibited no reaction. Other subjects exhibited low-level, transient reactions.

At challenge phase, low-level, transient reactions were observed. The cause of the oedematous reaction in two subjects during induction phase was not further investigated.

CONCLUSION: The gel containing 1.6% of the notified chemical showed no evidence of sensitisation under the conditions of the test.

TEST FACILITY: Harrison Research Laboratories (2003b)

8. ENVIRONMENT

8.1. Environmental fate

No test data for environmental fate endpoints were submitted. Modelled results are discussed in Section 9.1.1 below.

8.2. Ecotoxicological investigations

No ecotoxicity test data were submitted. Modelled and analogue data are discussed in Section 9.1.2 below.

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Based on physico chemical properties provided in Section 6 the notified chemical is readily soluble and only slightly volatile.

The notifier did provide modelling results for biodegradation, and these results have been confirmed. The modelling software used is the US EPA EPIWIN software (US EPA, 2000). The models referred to in this and the next section are components of EPIWIN.

QSAR modelling (EPA BIOWIN v 4.0) predicts that the notified chemical is expected to exhibit a primary biodegradation time frame in the order of days. Both MITI linear and non-linear models predict that the chemical will be readily biodegradable.

The bioconcentration factor (BCF) has been modelled to be 2.26 (EC, 2003) and 3.16 (BCFWIN v2.14). Therefore, the notified chemical is not expected to bioconcentrate.
The Henry's Law Constant is predicted to be 2.92×10^{-10} based on the vapour pressure/water solubility ratio, so removal from water bodies through volatilisation is only expected to be very slight.

Release through sewer can potentially occur in all regions of Australia for this consumer chemical. Consequently, predicted environmental concentrations (PEC) have been derived for both coastal and inland areas with sewage treatment plant (STP) releases to either ocean or river (DEH, 2003). Worst case assumptions used in estimating these concentrations include:

- All imported product is ultimately released to sewer (ie, no absorption by skin; no exporting of product)
- Release occurs over 365 days of the year
- There is no removal in the STP through biodegradation, adsorption or volatilisation.

The following PECs are determined:

PECocean	0.02 µg/L
PECriver	0.18 µg/L

Assuming inherent biodegradability, SIMPLETREAT (EC, 2003) predicts that 41% of this chemical will be removed through biodegradation in the STP prior to release, so actual expected concentrations could be significantly less than those above.

9.1.2. Environment – effects assessment

While no measured data are available for the notified chemical, one test result of a suitably close analogue (N-Methyl-N-(1-oxododecyl)glycine, Sodium salt) obtained from the US EPA Aquire Database shows a 48 h LD50 of 28.97 mg/L for brine shrimp (*Artemia* sp.).

Results of ECOSAR modelling for neutral organic acids suggest the chemical is not toxic to aquatic species with the following results obtained:

ECOSAR Class	*Organism*	*Duration*	*End Pt*	*Predicted mg/L (ppm)*
Neutral Organic SAR (Baseline Toxicity)	Fish	14-day	LC50	1240.893
--> Acid moeity found: Predicted values multiplied by 10				
Neutral Organics-acid	Fish	96-hr	LC50	7729.912
Neutral Organics-acid	Daphnid	48-hr	LC50	7859.130
Neutral Organics-acid	Green Algae	96-hr	EC50	4702.995
Neutral Organics-acid	Fish	30-day	ChV	880.997
Neutral Organics-acid	Daphnid	16-day	EC50	289.051
Neutral Organics-acid	Green Algae	96-hr	ChV	303.120

Based on analogue data, it appears ECOSAR may underestimate toxicity. Given the uncertainty, a predicted no effect concentration (PNEC) for the aquatic compartment may be obtained using the analogue result and applying an assessment factor of 1000.

The resulting PNECaquatic is determined to be 28.97 µg/L.

No sediment or terrestrial PNEC has been calculated as there is not expected to be any significant exposure to these compartments.

9.1.3. Environment – risk characterisation

Aquatic: PEC/PNEC ratios for ocean and river exposure are determined to be 0.00069 (0.02/28.97) and 0.007249 (0.21/28.97) respectively. These are worst case, as they assumed no removal in the STP even though degradation would be expected to occur. The PEC/PNEC calculations are both well below 1 indicating the potential for adverse impacts on aquatic biota is small at the proposed import levels.

Sediment: The chemical is not expected to sorb strongly to sediment, so exposure to sediment organisms is unlikely to result in concentrations where adverse effects are found. Consequently, the risk to sediment organisms is expected to be small.

Terrestrial: Exposure to the soil through use is not expected. SIMPLETREAT predicts little to no binding to sludge in the STP, therefore, exposure through application of sewage sludge to agricultural land is not expected. Exposure to soil organisms is unlikely to result in concentrations where adverse effects are found. Consequently, the risk to these organisms is expected to be small.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Four warehouse workers will handle the finished products containing the notified chemical while contained in their outer carton. Retail workers will handle the products in their retail packaging. These workers are unlikely to be exposed to the notified chemical except when plastic containers are damaged or punctured. Similarly, exposure to the notified chemical during transport of the product except in the event of transport accident.

The use of personal protective equipment (PPE) is not mandatory. However, PPE will be used and selected commensurate to work responsibilities.

9.2.2. Public health – exposure assessment

The public exposure to the personal care products containing the notified chemical will be widespread and repeated. During use, 0.8 g/day of the product containing the notified chemical is expected to be applied twice daily by dermal route. Assuming 20% of the product (containing 2% notified chemical) is absorbed by the skin, the consumer would be exposed to 6.4 mg/day notified chemical, which is equivalent to a systemic exposure of 0.107 mg/kg bw for a 60 kg female.

Overall, the public exposure to the notified chemical is low due to the low frequency (maximum

twice/day) of use, the low concentration (up to 2%) of the notified chemical present in the products, and the expected low systemic exposure of the notified chemical when used as facial gel.

9.2.3. Human health - effects assessment

The notified chemical has low oral toxicity in rats when dosed for 10 consecutive days. The study design did not allow for the determination of a No Observed Effect Level (NOEL); however, mortalities were observed at all doses. The toxicity is assumed to be of physical effects on the gastro intestinal tract due to large accumulation of test materials in animals, and no immediate toxicity was seen at high dose.

A number of studies to investigate the irritation potential of the notified chemical at concentrations between 1 to 10 have been carried out using leghorn eggs, red blood cell and human volunteers. The tests on eggs and red blood cells showed no evidence of irritation potential. In human volunteers, slight irritating effects were observed which were characterised by low level transient irritation effects, such as dryness and slight oedema. There was no evidence to show that the notified chemical at 1.6 and 5% is capable of eliciting sensitisation reaction based on the results obtained from two independent human volunteer studies.

On the basis of the data supplied, there is insufficient information to classify the notified chemical as a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2002).

9.2.4. Occupational health and safety – risk characterisation

The notified chemical will be imported as a component of finished personal care product. There is no manufacture, reformulation and packaging of the products containing the notified chemical in Australia. Worker exposure to the notified chemical is expected to be low since warehouse, retail and transport workers will handle the finished products containing the notified chemical while contained in their outer packaging.

Due to the low hazard of the notified chemical and the low potential for exposure, the risk posed by the notified chemical to occupational health and safety is low.

9.2.5. Public health – risk characterisation

Members of the public will make dermal contact with the personal care products containing the notified chemical. Assuming 20% dermal absorption, systemic exposure would be 0.107 mg/kg bw for a 60 kg female, which is much lower compared with the subacute oral LD50 in rats (>10000 mg/kg bw), and would provide an adequate margin of safety. Although mortalities were observed at all doses in the subacute oral study, the toxicity is assumed to be due to physical effects related to large accumulation of test material in the gastro intestinal tract of treated animals.

Based on the expected low toxicological hazard, low exposure during use, and the low concentration of the notified chemical in facial gels, the risk to public health is considered 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 classify the notified chemical as a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

As a comparison only, the classification of notified chemical using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations, 2003) is presented below. This system is not mandated in Australia and carries no legal status but is

presented for information purposes.

There are insufficient measured data to classify the notified chemical in accordance with GHS classification. However, based on the evidence available for environmental assessment, the notified chemical could tentatively be classified as Acute III with the corresponding Hazard Statement "Toxic to aquatic life." No chronic classification is necessary due to the predicted biodegradation and low LogKow.

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio:

The chemical is not considered to pose a risk to the environment based on its reported use pattern.

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 as a component of facial gels.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the products containing the 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 products containing the 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

- No specific engineering controls, work practices or personal protective equipment are required for the safe use of the notified chemical itself, however, these should be selected on the basis of all ingredients in the formulation.

  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.

Environment

Disposal

- Packaging containing residues of the end use product should be disposed of to landfill with household waste.

Emergency procedures

- Spills/release of the notified chemical should be swept up and placed in suitable receptacles for recovery or disposal.

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(1) of the Act; if
  - the importation volume exceeds one tonne per annum notified chemical, a full suite of toxicity and ecotoxicity data including a biodegradation study should be provided.

or

(2) 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.

13. BIBLIOGRAPHY

Department of the Environment and Heritage, 2003. Model and Guidance for Estimating Predicted Environmental Concentrations to Surface Water and Soil From Chemicals Released to the Environment Through a Sewage Treatment Plant. Chemical Assessment Section, Environment Protection Branch.

Department Recherche et Essais Biolloigiques Stallergenes (1979). Product: Lipacide C8G – Oral Subacute Toxicity in the Rat. Department Recherche et Essaia Biolloigiques Stallergenes, France (Unpublished study submitted by Johnson and Johnson Pacific Pty Ltd).

European Communities (2003) Technical Guidance Document on Risk Assessment in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances; Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances; Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. Part III

EVIC-CEBA (1996) Clinical Assessment of the Cutaneous Tolerance and Appreciation of the Cosmetic Qualities and Acceptability of the Product, Lotion Tonique COS 96001, Applied Under Normal Conditions of Use. Study No: Ic 190. EVIC-CEBA, Bordeaux, France. (Unpublished study submitted by Johnson and Johnson Pacific Pty Ltd).

Harrison Research Laboratories, Inc (2003a). Final Report Cumulative Irritation Test (CIT). Harrison Research Laboratories, Inc, NJ, USA. . (Unpublished study submitted by Johnson and Johnson Pacific Pty Ltd).

Harrison Research Laboratories, Inc (2003b). Final Report Repeated Insult Patch Test (RIPT) – Test Material: Gel Formula #727-946. Harrison Research Laboratories, Inc, NJ, USA. . (Unpublished study submitted by Johnson and Johnson Pacific Pty Ltd).

Institut D'Expertise Clinique (1996). Verification of the Good Epicutaneous Local Tolerance of Several Test Articles, after a Single Application to the Skin of the Back and Under Occlusive Patch Test for 48 Hours, in 10 Healthy Adult Volunteers: "Single Patch Test". Report No: R60346D. Institut D'Expertise Clinique, Lyon, France (Unpublished study submitted by Johnson and Johnson Pacific Pty Ltd).

Institut D'Expertise Clinique (1997). Evaluation of the Irritating and Sensitising Potentials of an Ingredient Used in Cosmetics, by Repated Epicutaneous 48 Hours Applications Under Occlusive Patch in %0 (or 49, or 48) Healthy Adult Volunteers: (Marzulli and Maibach's Method) – Lipacide C8G, diluted at 5.0% solution at pH6. Report No: 20168RD2. Institut D'Expertise Clinique, Lyon, France (Unpublished study submitted by Johnson and Johnson Pacific Pty Ltd).

NOHSC (2003). National Code of Practice for the Preparation of Material Safety Data Sheets 2nd Edition [NOHSC:2011(2003)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (2002). Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(2002)].National Occupational Health and Safety Commission, Canberra, AusInfo.

NOHSC (1994). National Code of Practice for the Labelling of Workplace Substances [NOHSC:2012(1994)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

Marzulli FN and Maibach HI (1976). Contact allergy, predictive testing in man. Contact Dermatitis, 2:1-17.

Rosso A and Amalric C (1999) Tolerance According to the HET-CAM Test on Red Blood Cells – Lipacide C8G-Lot 97147001.Study No: 9912A (Unpublished study submitted by Johnson and Johnson Pacific Pty Ltd).

Rosso A and Guichard C (2001) Tolerance According to RBCA Test on the Chorio-Allantoic Membrane of a Hen's Egg – Lipacide C8G-94292001 (1%, pH5).Study No: 9603A (Unpublished study submitted by Johnson and Johnson Pacific Pty Ltd).

U.S. Environment Protection Agency, 2000. EPIv3.10 (April 2001). Developed by EPA's Office of Pollution Prevention Toxics and Syracuse Research Corporation (SRC). US EPA, Washington DC.

United Nations (2003) Globally Harmonised System of Classification and Labelling of Chemicals (GHS). United Nations Economic Commission for Europe (UN/ECE), New York and Geneva.

University Analytical Laboratory, UNSW, 2003. Testing of Capryloyl Glycine to OECD Guidelines. Project Number 03142. University of New South Wales, NSW, Australia.