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

FULL PUBLIC REPORT

Arachidyl Glucoside

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**Director
Chemicals Notification and Assessment**

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FULL PUBLIC REPORT

Arachidyl Glucoside

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Orica Limited (ABN 24 004 145 868)
1 Nicholson Street
Melbourne VIC 3000

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)

Data items and details claimed exempt from publication:

Detailed Composition

Detailed Non-Hazardous Impurities

Exact percentage of notified chemical in Montanov 202 and in finished products

Names of finished products

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

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

Vapour pressure

Water solubility

Hydrolysis as a function of pH

Dissociation constant

Particle size

Flammability

Autoignition

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

Commercial Evaluation Permit No. 581 (CEC/488) 2002 issued to Fernz Speciality Chemicals, now Orica Limited.

NOTIFICATION IN OTHER COUNTRIES

Montanov 202, the commercial mixture to be imported, containing <20% notified chemical, is authorised as a quasi drug for use in Japan by Ministry of Health and Welfare n8 20900CZY00013000. EINECS number for the notified chemical: 309-369-5.

2. IDENTITY OF CHEMICAL

CHEMICAL NAME

D-glucoside, eicosyl

OTHER NAME(S)

Arachidyl glucoside

D-Glucopyranoside, C20 straight chain monoalkyl-

MARKETING NAME(S)

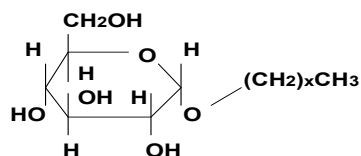
Arachidyl glucoside

Montanov 202 (commercial mixture containing <20% notified chemical and >80% eicosanol and docosanol)

CAS NUMBER
100231-68-3

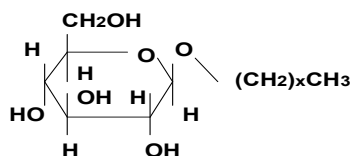
MOLECULAR FORMULA
 $C_{26}H_{52}O_6$

STRUCTURAL FORMULA



Where $x = 19$

1-Eicosyl alpha-D-Glucopyranoside



Where $x = 19$

1-Eicosyl beta-D-Glucopyranoside

MOLECULAR WEIGHT
460

SPECTRAL DATA

METHOD	Infra-red (IR) spectroscopy
Remarks	The IR Spectrum provided was for Montanov 202 with major peaks at 661, 720, 759, 1059, 1378, 1466, 2849, 2916 and 2966 cm^{-1} . A film of the test substance was placed between NaCl plates for the determination.
TEST FACILITY	SEPPIC S.A.

METHODS OF DETECTION AND DETERMINATION

METHOD	IR spectroscopy
TEST FACILITY	SEPPIC S.A.

3. COMPOSITION

DEGREE OF PURITY

The notified chemical is produced as part of the commercial mixture Montanov 202, which contains up to 20% notified chemical and >80% eicosanol and docosanol. The notified chemical is not manufactured in isolation or subsequently separated.

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None.

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

Chemical Name	1-Eicosanol		
CAS No.	629-96-9	Weight %	50-60% of Montanov 202

Chemical Name 1-Docosanol
CAS No. 661-19-8 *Weight %* 25-35% of Montanov 202

Chemical Name 1-Octadecanol
CAS No. 112-92-5 *Weight %* 1-2% of Montanov 202

ADDITIVES/ADJUVANTS
None.

4. INTRODUCTION AND USE INFORMATION

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

The notified chemical will be imported at up to 1.5% in finished cosmetic products, and at up to 20% in the commercial mixture Montanov 202.

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>	0.975	0.975	0.975	0.975	0.975

USE

Used at levels of less than 1.5% as an emulsifier and to contribute to qualities of smoothness, thickness and creamy consistency in cosmetic cream and lotion products.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY

Sydney and Melbourne.

IDENTITY OF MANUFACTURER/RECIPIENTS

The recipient for Montanov 202 will be:

Orica Limited Warehouse and Distribution Centre
215 Dohertys Road
LAVERTON, VIC 3026

The identity of local manufacturers for reformulation of Montanov 202 into finished cosmetic products is not yet known.

Johnson & Johnson Pacific Pty Ltd will import the notified chemical in finished cosmetic products to their warehouse at:

Exel Logistics
Cnr Walter's Road and Great Western Highway
ARNDELLE PARK, NSW 2148

TRANSPORTATION AND PACKAGING

Montanov 202 will be imported in 20 kg drums on pallets inside containers, and will travel from the wharf by road to the Orica Limited Warehouse and Distribution Centre. It will be transported from there to local reformulation sites (as yet unspecified) by road.

Finished products containing the notified chemical will be imported in small jars and bottles up to 400 mL, suitable for retail sale. These containers will be packed in cardboard cartons, with cartons packed 12 per cardboard shipper. The shippers will be transported in a container from the wharf to the Johnson & Johnson warehouse. Cartons will then be transported from the warehouse to retail

customers' central distribution centres by road.

5.2. Operation description

The majority of the notified chemical is expected to be imported in finished products. In this case, the products will be in small containers suitable for retail sale. The products will be transported to warehouse facilities, and thence to retail outlets for sale to the public.

However, there may be significant use in locally formulated products at a later date. In this case, imported Montanov 202 will be transported from the notifier's warehouse to local manufacturers for reformulation. Reformulation operations will likely involve weighing an appropriate amount of Montanov 202 into a separate container, then adding it directly to a mixing tank. In the mixing vessel heat will be required to melt Montanov 202. QA chemists will sample from the mixing vessel using a dip tube (large pipette). Filling and packing of retail containers will most likely be automated, with packers monitoring the line filler and the capper. Store persons will remove pallets of finished product from the end of the packing line to the finished store.

5.3. Occupational exposure

Number and Category of Workers

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration (hours per day)</i>	<i>Exposure Frequency (days per year)</i>
Transport & Storage	12	4	12
Professional Compounder	1	8	12
Chemist	1	3	12
Packers (Dispensing and Capping)	2	8	12
Store persons	3	4	12

Exposure Details

Transport & Storage of Imported Finished Products

Approximately ten dockside and warehouse workers per shipment will be involved in transporting imported finished products from the wharf to the notifiers' sites and placing pallets of product into their warehouses. Dockside and warehouse workers may handle monthly shipments for 4 hours per day. A further two warehouse workers will be involved in transferring pallets of imported finished products from the notifier's warehouse to retailers' central distribution depots.

Dockside and warehouse workers routinely wear uniforms and safety shoes. They are not expected to have any contact with the notified chemical except in the case of spills.

Reformulation

If local manufacture of finished products using reformulated Montanov 202 becomes viable, the following exposure will apply. Reformulation processes are expected to occur monthly at most.

Store persons will receive Montanov 202 when delivered from the wharfs and store it in the raw material store.

Quantities of Montanov 202 would be released to the compounder for production. The compounder will weigh an appropriate amount into a separate container, then add it directly to the mixing tank. Mixing and dispensing will be carried out in a closed system, or in a system designed to prevent the creation of aerosols or dust hazards. In the mixing vessel heat will be used to melt Montanov 202. During this process, there is potential for accidental drips and spills, or accidental release of vapours, resulting in dermal, ocular or inhalation exposure. The compounder is to wear safety goggles, gloves and protective clothing. Personal respiratory protection is generally not used, as inhalation exposure is limited by local exhaust ventilation. Respirators will be required if local ventilation is inadequate.

A chemist will sample Montanov 202 using a dip tube (large pipette), for QA testing. This process carries a risk of dermal or ocular exposure due to accidental spills or splashes. The chemist will wear PPE appropriate for the protection of eyes and skin.

Packers will monitor the line filler and capper where the finished product (containing up to 1.5% notified chemical) is filled into retail containers. Packers will wear safety glasses, gloves and

protective clothing to limit accidental exposure.

Store persons will remove pallets of finished product from the end of the packing line to storage.

In general, occupational exposure will be limited by provision of appropriate PPE including safety glasses with side shields or goggles, aprons or coveralls, gloves, full face shields if exposure to aerosols or splashes is likely, heat resistant gloves for handling of heated product, and respirators if ventilation is inadequate.

Spills should be contained with absorbent material and placed in an appropriate sealed container for disposal.

5.4. Release

RELEASE OF CHEMICAL AT SITE

The notified chemical will not be manufactured in Australia. It will be reformulated into personal skin care products or imported in ready to use products. In the latter case the release during transport and storage is minimal due to the size and type of packaging.

Release of the notified chemical will be generated during reformulation via:

- Spills	less than 1%	maximum 9.75 kg,
- Import container residues	less than 1%	maximum 9.75 kg,
- Process Equipment cleaning	up to 3%	maximum 29.25 kg.

These losses would be expected if local manufacture of cosmetics from directly imported Montanov 202 takes place.

RELEASE OF CHEMICAL FROM USE

Less than 1% notified chemical will remain in end-use containers when disposed of to landfill, generally in domestic rubbish. This equates to less than 9.75 kg annually. Since it is a component in skin care products the majority of the notified chemical will ultimately be washed into the sewer.

5.5. Disposal

Reformulation solid wastes, including spills and import containers and any residues present, will be disposed of to landfill. This represents less than 19.5 kg per year of the notified chemical. A further 9.75 kg will be disposed of to landfill in end-use containers.

The process equipment cleaning effluent, containing up to 3% (29.25 kg/year) of notified chemical, will be disposed of to the on-site wastewater collection system and then to a biological treatment plant. Approximately 94% of the notified chemical will end up in the sewer from end use of cosmetic products, making it a total of 975 kg annually.

5.6. Public exposure

The commercial product Montanov 202 will not be sold to the general public. The public will only be exposed to Montanov 202 in the event of accidental spill and breach of import containers. The material safety data sheets (MSDS) supplied for Montanov 202 have instructions for clean-up and disposal of any accidental spills and public exposure as a result of a transport accident is likely to be negligible.

If the notified chemical is blended in Australia to produce finished cosmetic creams or lotions, engineering controls and standard operating procedures largely prevent any significant release of the notified chemical from the site of blending. Thus direct public exposure to the notified chemical as a result of blending is considered to be negligible.

The notified chemical will be sold in finished products to the general public for cosmetic use. Therefore widespread public exposure is expected. Members of the public are likely to make dermal and possibly ocular contact with the notified chemical as a result of use of the product at a concentration of up to 1.5%

The notified chemical may be released into the environment as a result of disposal of waste from

blending, accidental spills during transport or disposal of diluted products and containers after use. The environmental releases are expected to be relatively small and most of the notified chemical released into the environment is expected to enter sewers where large dilutions are expected. Therefore, environmental concentrations are expected to be very low, and public exposure through the environment is considered negligible.

6. PHYSICAL AND CHEMICAL PROPERTIES

Most physico-chemical information below relates to Montanov 202, the product to be imported (see section 3 for composition).

Appearance at 20°C and 101.3 kPa White flakes

Melting Point/Freezing Point 74-78°C

METHOD SEPPIC Method S52009B
Remarks This result is for Montanov 202.
No test report provided.

Density 859 kg/m³ at 20°C

METHOD OECD TG 109 Density of Liquids and Solids.
Remarks Pycnometer method. This result is for Montanov 202.
TEST FACILITY SEPPIC S.A. (2004)

Vapour Pressure Not determined

METHOD
Remarks The notified chemical is imported as a solid in a solid mixture. Vapour pressure is expected to be low, for the notified chemical and for Montanov 202. The lowest molecular weight component in Montanov 202 is 1-octadecanol, which has a vapour pressure of <10⁻⁵ kPa.

Water Solubility >100 g/L at 20°C

Remarks Estimation of the water solubility is difficult due to the surface activity of the notified chemical. This result is for Montanov 202, which forms an emulsion in water up to at least 10%. Water solubility would be lower based on log K_{ow} and log K_{oc} estimates.

Hydrolysis as a Function of pH Not determined.

Remarks This test has not been carried out as Montanov 202 is supplied and recommended (and has been sold overseas for at least 2 years) for use in the pH range of 3-9. The notified chemical is expected to be stable over a wide pH range due to its ether linkage and its non ionic nature. Under extreme pH and temperature, the notified chemical hydrolyses to C20 fatty alcohol and glucose. Hydrolysis products are claimed to be easily biodegraded.

Partition Coefficient (n-octanol/water) log K_{ow} = 7.18 (calculated estimate)

METHOD KowWin log Kow calculation (QSAR).
Remarks The notified chemical is an emulsifier and therefore it was not possible accurately to measure the n-octanol-water partition coefficient. An estimated value has been determined from the contributions to log Kow from the individual components using a fragmentation procedure.
TEST FACILITY SEPPIC (2004)

Adsorption/Desorption log K_{oc} = 5.285 (calculated estimate)

METHOD	log Koc calculation (QSAR).
Remarks	The notified chemical is an emulsifier and therefore it was not possible accurately to measure adsorption/desorption. An estimated value has been determined from the log Koc Lyman equation of $\log Koc = 0.544 * \log Kow + 1.377$.
TEST FACILITY	SEPPIC (2004)

Dissociation Constant Not determined.

Remarks	Not conducted because the notified chemical contains no groups likely to dissociate. pH of a 5% emulsion is 5.5 to 7.5 at 20 °C.
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Particle Size Not determined.

Flash Point >100°C at 101.3 kPa

METHOD	AFNOR Method No NFT60103 (AFNOR, 1968)
Remarks	No test report provided.

Flammability Limits Not determined.

Autoignition Temperature Not determined.

Explosive Properties Not determined.

Reactivity

Remarks	The notified chemical as contained in Montanov 202 is stable under normal environmental conditions. Montanov 202 is compatible with other cosmetic substances under normal usage conditions and is stable between pH 3 and pH 9. In extreme conditions (extreme pH and temperature), the notified chemical in Montanov 202 hydrolyses to a C20 fatty alcohol and glucose.
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7. TOXICOLOGICAL INVESTIGATIONS

Toxicological studies below were conducted using either Montanov 202 or Montanov 68, which contains 10-40% of a mixture of cetyl glucoside, stearyl glucoside, cetyl alcohol and stearyl glucoside. Montanov 68 components are shorter alkyl chain analogues of Montanov 202 components.

<i>Endpoint and Result</i>	<i>Test Material</i>	<i>Assessment Conclusion</i>
Eye irritation – Hen's egg test on chorio-allantoic membrane	1% Montanov 202	Non irritant
Eye irritation – Red blood cell test	1% Montanov 202	Non irritant
Human patch test – irritation	5% Montanov 202	Non irritating
Guinea pig, skin sensitisation – adjuvant test/non-adjuvant test.	Montanov 202	Slight evidence of sensitisation
Guinea pig, skin sensitisation – adjuvant test/non-adjuvant test.	Montanov 68	No evidence of sensitisation
Human repeat insult patch test – sensitisation	5% Montanov 202	Non irritating Slight evidence of sensitisation
Genotoxicity – bacterial reverse mutation	Montanov 202	Non mutagenic

7.1. Eye irritation

7.1.1. Hen's egg test

TEST SUBSTANCE	Montanov 202 was dissolved as a 1% solution in demineralised water.												
METHOD	Hen's egg test – chorio-allantoic membrane of a hen's egg												
Remarks - Method	<p>The test compound is applied to the chorio-allantoic membrane of embryonated hen's eggs. In this test the highly vascularised chorio-allantoic membrane mimics the cornea. Irritant compounds induce hyperaemia, haemorrhage and protein coagulation on the membrane surface.</p> <p>Fresh, intact White Leghorn hen fertilised eggs of about 60 g are incubated at 37.5°C for 10 days, with the large end up. Eggs were automatically rotated every hour and 0.3 mL of the prepared sample was spread over the chorio-allantoic membrane using a 1 mL pipette. Rinsing with 5mL of demineralised water was carried out 20 seconds later.</p> <p>Hyperaemia, haemorrhage and coagulation were scored against a scale of irritant effects 0.5, 2 and 5 minutes after treatment to maxima of 5, 7 and 9 respectively. The numerical scores were summed to give a single numerical value for 4 or 6 eggs treated with each compound or concentration. The mean score value allows the irritant potential to be assigned to one of 5 classes (non irritant, slightly irritant, moderately irritant, irritant and severely irritant).</p> <p>The classification was determined using the following chart:</p> <table><tr><th>CLASS</th><th>SCORE</th></tr><tr><td>Non Irritant</td><td>Score < 1</td></tr><tr><td>Slightly Irritant</td><td>1 <= Score < 5</td></tr><tr><td>Moderately Irritant</td><td>5 <= Score < 9</td></tr><tr><td>Irritant</td><td>9 <= Score < 12</td></tr><tr><td>Severely Irritant</td><td>Score >= 12</td></tr></table>	CLASS	SCORE	Non Irritant	Score < 1	Slightly Irritant	1 <= Score < 5	Moderately Irritant	5 <= Score < 9	Irritant	9 <= Score < 12	Severely Irritant	Score >= 12
CLASS	SCORE												
Non Irritant	Score < 1												
Slightly Irritant	1 <= Score < 5												
Moderately Irritant	5 <= Score < 9												
Irritant	9 <= Score < 12												
Severely Irritant	Score >= 12												

RESULTS

Hyperaemia

No signs of hyperaemia observed.

Haemorrhage
Coagulation
Remarks - Results

No signs of haemorrhage observed.
No signs of coagulation observed.
No positive or negative controls were included in the test.

CONCLUSION

1% Montanov 202 was non-irritating under the conditions of the test.

TEST FACILITY

SEPPIC (2000a)

7.1.2. Red blood cell test

TEST SUBSTANCE

Montanov 202 was dissolved in phosphate buffered isotonic saline (PBS) to produce a 1% solution. This was then diluted 100 times for the Haemolysis solution and 10 times for the Denaturation solution.

METHOD

The RBCA (red blood cell) test uses red blood cells to quantify adverse effects of surfactants on cytoplasmic membranes (haemolysis) and cellular proteins (denaturation). Various concentrations of test sample were incubated with a red blood cell suspension for 10 minutes. At the end of the incubation period, the resulting supernatant was monitored to evaluate haemolysis and protein denaturation. The Lysis/ Denaturation ratio was then calculated. The L/D ratio may be compared with acute eye irritation data.

Haemolysis

Eight aliquots (from 10 to 80 µL) of 1% Montanov 202 were made up to 975 µL with PBS, after which 25 µL samples of red blood cells were added and incubated at room temperature for 10 minutes, then centrifuged for 1 minute. The supernatant absorbance was measured at 530 nm. At each concentration the relative percentage of haemoglobin released was calculated. The concentration of test substance causing 50% RBC lysis, L, was calculated.

Denaturation

A 1% solution of Montanov 202 was prepared in PBS. To 100 µL of this preparation was added 25 µL of red blood cells that had undergone lysis (releasing oxyhaemoglobin) in 875 µL of PBS. This was incubated at room temperature for 10 minutes and then centrifuged for 1 minute. The supernatant was decanted and the absorbance measured at 540 nm (E540) and 575 nm (E575). The ratio of E575/E540, D, is a measure of the denaturation of oxyhaemoglobin.

Calculation

The relationship between haemolysis (L) and denaturation (D), defined as the lysis/denaturation ratio L/D, was calculated for each sample.

Remarks – Method

Irritant classification was based on the following:

IN VIVO EYE IRRITATION	IN VITRO L/D
Non Irritant	>100
Slightly Irritant	>10
Moderately Irritant	>1
Irritant	>0.1
Very Irritant	<0.1

RESULTS

The Lysis value was >1000 µL. L>=1000 is classified as non haemolysing.

The Denaturation value was 1.4%. D<=10% is classified as non denaturing.

The eye irritation index for 1% Montanov 202, calculated as the Lysis/ Denaturation ratio, was determined to be >100.

No positive or negative controls were included in the test.

CONCLUSION 1% Montanov 202 was non irritating under the conditions of the test.

TEST FACILITY SEPPIC (2000b)

7.2. Skin irritation – human patch test

TEST SUBSTANCE 5% Montanov 202

METHOD Single Patch Test

Study Design Induction Procedure: Single application to the skin of the back under occlusive patch for 48 hours.

Study Group 10 adult Caucasian volunteers (7 women and 3 men)

Vehicle Paraffin oil

Remarks - Method Macroscopic examinations of the skin were performed 30 minutes after patch removal. Test sites were compared with patch-only controls, and only differences between test and control sites were scored. The following reactions (with scales) were recorded: erythema (0-4), oedema (0-3), presence of papulae/vesicles/bullae/pustules (0-4), dryness/desquamation (0-4), detergent effect (0-4) and reflectivity (0-4).

The index of Primary Cutaneous Irritation (maximum 23) was calculated by summing the scores for each reaction for the entire cohort, then dividing by the number of subjects. Irritant classification was based on the following:

PCI index	Classification
0	Very well tolerated
0<PCI<0.5	Well tolerated
>=0.5	Slight intolerance to Very badly tolerated

Individual scores were also taken into account when interpreting results.

RESULTS

Remarks - Results No signs of irritation were observed in any of the test subjects.

CONCLUSION Montanov 202 (5%) was non-irritating under the conditions of the test.

TEST FACILITY IEC (1996)

7.3. Skin sensitisation

7.3.1. Guinea pig – Magnusson and Kligman test

TEST SUBSTANCE Montanov 202

METHOD OECD TG 406 Skin Sensitisation – Magnusson and Kligman method.

Species/Strain Guinea pig/Hartley (Charles River, France)

PRELIMINARY STUDY Maximum Non-irritating Concentration:
topical: 50%

MAIN STUDY

Number of Animals Test Group: 10 female Control Group: 5 female

INDUCTION PHASE Induction Concentration:
intradermal: 5% (maximum administrable)
topical: 50%

Signs of Irritation None reported.

CHALLENGE PHASE

1st challenge topical: 50% and 20%

2nd challenge
Remarks - Method

Not conducted.
None.

RESULTS

<i>Animal</i>	<i>Challenge Concentration</i>	<i>Number of Animals Showing Skin Reactions after:</i>			
		<i>1st challenge</i>		<i>2nd challenge</i>	
		<i>24 h</i>	<i>48 h</i>	<i>24 h</i>	<i>48 h</i>
<i>Test Group</i>	50%	1/10	0/10		
	20%	0/10	0/10		
<i>Control Group</i>	50%	0/5	0/5		
	20%	0/5	0/5		

Remarks - Results

No positive control was included in the test.

CONCLUSION

There was slight evidence of reactions indicative of skin sensitisation to Montanov 202 under the conditions of the test.

TEST FACILITY

Evic-Ceba (1997)

7.3.2. Guinea pig - Magnusson and Kligman test

TEST SUBSTANCE

Montanov 68

METHOD

OECD TG 406 Skin Sensitisation – Magnusson and Kligman method
EC Directive 96/54/EC B.6 Skin Sensitisation - Magnusson and Kligman method

Species/Strain

Guinea pig/Dunkin-Hartley (Centre de Production Animale, France)

PRELIMINARY STUDY

Maximum Non-irritating Concentration:
intradermal: 10% (maximum concentration tested)
topical: 10% (maximum concentration tested)

MAIN STUDY

Number of Animals

Test Group: 6 female + 5 male Control Group: 2 female + 3 male

INDUCTION PHASE

Induction Concentration:
intradermal: 10%
topical: 10%

Signs of Irritation

None reported.

CHALLENGE PHASE

1st challenge

topical: 10% and 5%

2nd challenge

Not conducted.

Remarks - Method

None.

RESULTS

<i>Animal</i>	<i>Challenge Concentration</i>	<i>Number of Animals Showing Skin Reactions after:</i>			
		<i>1st challenge</i>		<i>2nd challenge</i>	
		<i>24 h</i>	<i>48 h</i>	<i>24 h</i>	<i>48 h</i>
<i>Test Group</i>	10%	2/11	0/11		
	5%	2/11	0/11		
<i>Control Group</i>	10%	2/5	0/5		
	5%	1/5	0/5		

Remarks - Results

None.

CONCLUSION

There was no evidence of reactions indicative of skin sensitisation to Montanov 68 under the conditions of the test.

TEST FACILITY

Phycer (2004)

7.3.3. Human repeat patch test

TEST SUBSTANCE	5% Montanov 202
METHOD	Marzulli & Maibach's method
Preliminary Study	Repeated epicutaneous 48-hour applications under occlusive patch. Four successive occlusive epicutaneous applications to the arm of 10 volunteers (9 women and 1 man), for 48 or 72 hours. 3 concentrations were tested on each subject: 1%, 2.5% and 5% (w/w).
Main Study Design	Induction Procedure: 9 consecutive applications of 5% (w/w) Montanov 202, to the arm, for 24-72 hours. Rest Period: 15 days Challenge Procedure: Single application of 5% (w/w) Montanov 202, to the back, for 48 hours.
Main Study Group	50 adult Caucasian volunteers (45 women and 5 men) started the study 49 were evaluated for irritation (44 women and 5 men) and 48 were evaluated for sensitisation (43 women and 5 men)
Vehicle	Distilled water
Remarks - Method	Macroscopic examinations of test sites for signs of irritation and/or sensitisation were performed 24 and 48 hours after the 8 th induction application, and after the challenge application, by comparison with a negative vehicle-only control patch. Both irritation and sensitisation were scored on a scale of 0 (no reaction) to 4 (severe erythema and/or oedema). A mean irritation index was calculated for the entire cohort.

Classification of irritancy potential was according to the following:

Mean Irritation Index	Classification
<0.25	Non-irritant
0.25<=MII<1	Slightly irritant
1<=MII<2	Irritant
2<=MII<3	Very irritant
3-4	Severely irritant

An individual sensitisation score of 3 or more was considered positive evidence for sensitising potential of the test substance.

RESULTS	
Preliminary Study	No irritation was observed at any of the concentrations tested.
Main Study-Induction	A single instance of slight irritation (irritation score of 1) was observed in 10/49 of subjects. Several instances of slight irritation were observed in 4/49 of subjects. The mean irritation index for all subjects during the induction phase was 0.06.
Main Study-Challenge	A single instance of slight reaction (sensitisation score of 1) was observed in 2/48 subjects. Slight to mild reaction (sensitisation scores of 1-2) was observed at both 24 and 48 hour time points in 1 subject. No subject showed a response that was considered positive for sensitisation.
CONCLUSION	Montanov 202 was non-irritating and showed limited evidence of sensitisation under the conditions of the test.

TEST FACILITY IEC (1997a)

7.4. Genotoxicity – bacteria

TEST SUBSTANCE	Montanov 202
METHOD	OECD TG 471 Bacterial Reverse Mutation Test.

Species/Strain	Plate incorporation procedure Method also conforms to guidelines published by the major Japanese Regulatory Authorities. <i>S. typhimurium</i> : TA1535, TA1537, TA98, TA100 <i>E. coli</i> : WP2uvrA ⁻
Metabolic Activation System	Aroclor 1254-induced rat liver S9 fraction.
Concentration Range in Main Test	a) With metabolic activation: 0-5000 µg/plate b) Without metabolic activation: 0-5000 µg/plate
Vehicle	Dimethylformamide
Remarks - Method	None.

RESULTS

<i>Metabolic Activation</i>	<i>Test Substance Concentration (µg/plate) Resulting in:</i>			
	<i>Cytotoxicity in Preliminary Test</i>	<i>Cytotoxicity in Main Test</i>	<i>Precipitation</i>	<i>Genotoxic Effect</i>
<i>Absent</i>				
Test 1	None observed	None observed	1500	None observed
Test 2	None observed	None observed	1500	None observed
<i>Present</i>				
Test 1	None observed	None observed	1500	None observed
Test 2	None observed	None observed	1500	None observed

Remarks - Results	Negative controls were within the historical range and positive controls demonstrated the sensitivity of the test.
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CONCLUSION	Montanov 202 was not mutagenic to bacteria under the conditions of the test.
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TEST FACILITY	SafePharm (1998)
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7.5. Comedogenicity – human repeated use study

TEST SUBSTANCE	5% Montanov 202
METHOD	“Normal conditions of use”
Study Design	Test article applied twice a day, to the skin of the face and neck, for 4 weeks. Applications were performed by volunteers at home, under normal conditions of use as a skin and face care lotion.
Study Group	Of 21 adult Caucasian female volunteers whose facial skin showed acneic tendency, 9 had oily skin and 12 had “mixed with oily tendency” skin. 8 subjects had “sensitive” facial skin. Age range: 20 to 44 years.
Vehicle	Not specified: “white thick emulsion”.
Remarks - Method	Local tolerance was evaluated at the end of the 4-week application period, from cutaneous clinical examinations. Comedogenicity was evaluated by a statistical comparison of the number of “retentional and inflammatory elements” at the start and at the end of the study.

RESULTS

Remarks - Results	20/21 subjects reported “rather good to very good” acceptability of the test material (the remaining subject reported moderate acceptability). 19/21 reported no adverse cutaneous symptoms. The remaining 2 subjects, both of whom had “sensitive” facial skin (including 1 subject with prior experience of adverse reactions to cosmetics), reported weak to moderate skin dryness for 5-15 minutes after each application. No evidence of intolerance was observed at the end of the study.
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None of the subjects reported ocular symptoms.

No significant comedogenic effect was observed when comparing skin scores from the beginning and the end of the study.

CONCLUSION

Montanov 202 (5%) was well tolerated and non comedogenic under the conditions of the test.

TEST FACILITY

IEC (1997b)

8. ENVIRONMENT

Ecotoxicological studies below were conducted using either Montanov 202 or Montanov 68, which contains 10-40% of a mixture of cetyl glucoside, stearyl glucoside, cetyl alcohol and stearyl glucoside. Montanov 68 components are shorter alkyl chain analogues of Montanov 202 components.

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	Montanov 68.
METHOD	EC Directive 84/449 - Annex V Method C5 (1984) Adapted Modified Sturm Test
Inoculum	Activated sludge from a municipal sewage treatment plant receiving little or no industrial effluent (from Pierre-Benite- 69310 Lyon)
Exposure Period	28 days
Auxiliary Solvent	None.
Analytical Monitoring	Determination of CO ₂ production by back titration with barium hydroxide
Remarks - Method	Concentration of test substance (Montanov 68) and reference substance (sodium acetate) was 20 mg/L.

RESULTS

<i>Test substance</i>		<i>Sodium acetate</i>	
<i>Day</i>	<i>% Degradation</i>	<i>Day</i>	<i>% Degradation</i>
2	5	2	3
10	78	10	14
15	97	15	20
20	97	20	68
25	97	25	85
28	97	28	84

Remarks - Results

The test substance showed biodegradability of 97% in 28 days under the conditions of a Modified Sturm test, which was reached by day 15. The 10-day window criterion was also clearly met (78% degraded by day 10). The test was validated, as the reference substance (sodium acetate) showed a biodegradability of >84% for the 28 day study period.

This is in line with literature results (Madsen et al, 2000) for similar alkyl glycosides, with alkyl polyglycosides of C8-16 having biodegradabilities of 100% (Modified OECD screening test, 28 d) and 80% (Closed bottle test, 30 d), and alkyl polyglycosides of C12-16 having biodegradabilities of 100% (Modified OECD screening test, 28 d) and 78% (Closed bottle test, 30 d).

CONCLUSION

The test substance can be classified as readily biodegradable.

TEST FACILITY

Societe d'Elevage Piscicole Controle (1991)

8.1.2. Bioaccumulation

REMARKS

Not determined. However, due to its ready biodegradability the notified chemical is unlikely to bioaccumulate.

8.2. Ecotoxicological investigations

No ecotoxicological data are available for the notified chemical, however literature data (Madsen et al, 2000) is available for toxicity of other alkyl glycosides to fish, *Daphnia* and algae:

For Zebra fish, the reported 96 h LC50 of alkyl glycosides with alkyl polyglycosides of C8-16 is 7.8 mg/L, while that for alkyl polyglycosides of C12-14 is 2.5-5.0 mg/L.

For *Daphnia magna*, the reported 48 h EC50 of alkyl glycosides with alkyl polyglycosides of C8-16 is 85 mg/L, while that for alkyl polyglycosides of C12-14 is 7-12 mg/L.

For algae, the reported 96 h EC50 of alkyl glycosides with alkyl polyglycosides of C8-16 are 14.8 mg/L and NOEC = 5.0 mg/L. Again the C12-14 analogue is more toxic with a 72 h EC50 of 6-11 mg/L.

As the notified chemical is a mix of C20 and C22 alcohol chains, the C12-14 alkyl polyglycoside data are considered more relevant, since toxicity appears to rise with longer chains (the C8-16 analogues may be expected to have contained a significant proportion of C8-10 chains).

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified chemical will be imported into Australia either in a ready to use product or as part of the commercial mixture Montanov 202 for subsequent formulation into products. The majority (97%) of the imported polymer will eventually be discharged into sewerage systems through washing. Approximately 3% will be disposed of to landfill in empty containers from reformulation or end-users, and from clean up of spills. Up to 29.25 kg per annum will be released due to equipment cleaning during the reformulation process, which will go to on-site treatment.

The notified chemical forms an emulsion up to at least 10% and therefore may be relatively mobile in both the aquatic and terrestrial compartments. However, the estimated K_{oc} and K_{ow} are high, indicating that it may be expected to be immobile in soil and sediments. All these results need to be treated with caution due to the surface activity of the notified chemical, which can be classed as readily biodegradable based on analogue data, and as such is likely to be biodegraded in the sewer. Residual chemical disposed of to landfill with empty containers can also be expected to be adsorbed to soil particles and will be degraded through biological and abiotic processes. The ready biodegradability of the notified polymer will limit bioaccumulation.

Given the use pattern of the notified chemical, the predicted environmental concentration (PEC) in the aquatic environment can be estimated using the following worst-case scenario, assuming the maximum importation volume of 975 kg, year-round use of the notified chemical, and no removal due to biodegradation or physical/chemical means:

Amount released	975 kg
Number of days used	365
Australian population	20.2 million
Water use per person	200 L
PEC _{sewer/freshwater}	$\frac{975\,000\,000\,000}{365 \times 20\,200\,000 \times 200}$
	= 0.661 µg/L
PEC _{ocean} (dilution factor of 10)	0.0661 µg/L

The actual PECs are likely to be much lower, since the notified chemical is readily biodegradable.

9.1.2. Environment – effects assessment

While no data were provided on environmental effects, the use of this chemical indicates high exposure to the aquatic environment. As such the absolute predicted no effect concentration (PNEC) cannot be derived, but based on literature data (Madsen et al, 2000) an estimate for the PNEC may be obtained.

Using the lowest relevant LC50 for zebra fish, 96 h LC50 = 2.5 mg/L, and assuming a safety factor of 1000 as only surrogate data are available, the PNEC is 2.5 µg/L.

9.1.3. Environment – risk characterisation

The risk associated with release of all of the imported notified chemical can be estimated by determining the aquatic risk quotient (RQ = PEC/PNEC).

Location	PEC	PNEC	Risk Quotient (RQ)
<u>Australia-wide STPs</u>			
Aquatic			
Ocean outfall	0.0661 µg/L	2.5 µg/L	0.026
Freshwater	0.661 µg/L	2.5 µg/L	0.264

Since the RQ values are less than 1, the proposed use of the notified chemical is unlikely to pose an unacceptable risk to aquatic life, as long as import volumes do not rise significantly above 1000 kg per annum.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Transport & Storage

Occupational exposure to the notified chemical during transport and storage of Montanov 202 (the imported mixture containing <20% notified chemical), or of finished products containing up to 1.5% notified chemical, is only likely in the event of accidental container spillage involving breach of import packaging. Exposure in these circumstances is expected to be infrequent and acute, and can be limited by use of gloves, goggles, masks and protective clothing during clean-up operations.

Reformulation

During local reformulation of Montanov 202 into cosmetic creams and lotions, dermal exposure is the most likely route. Ocular exposure may also occur as a result of accidental drips or spills. Exposure may occur when workers weigh out Montanov 202 and add it to the mixing vessel, and also during sampling for QA testing.

Exposure during mixing operations is expected to be minimal, as closed systems will be used.

Exposure during dispensing of finished product into retail containers is expected to be minimal, as automated systems will be used. Exposure is only likely in the event of accidental container spill or breakage; in this case exposure will be limited by the concentration of notified chemical in retail products (up to 1.5%).

9.2.2. Public health – exposure assessment

Public exposure to Montanov 202 is expected to be negligible. Montanov 202 will not be sold to the general public. Exposure to Montanov 202 during transport or industrial use will only occur in the event of serious accidental spill; exposure would be limited by clean-up and disposal operations in accordance with the MSDS.

Widespread public exposure is expected to the notified chemical at up to 1.5% in finished cosmetic creams and lotions. Frequent, prolonged dermal exposure is expected, with a concomitant chance of accidental ocular exposure.

9.2.3. Human health – effects assessment

Montanov 202 has been tested in a number of studies for irritancy and sensitisation potential. In two tests for surrogate markers of eye irritation (Hen's Egg Test on Chorio-Allantoic Membrane and Red Blood Cell test), 1% Montanov 202 was found to be non-irritant. However, 1% Montanov is <0.2% notified chemical, which is lower than the proposed concentrations of notified chemical in cosmetic products (up to 1.5%).

In an adjuvant test in guinea pigs, higher concentrations of Montanov 202 showed slight evidence of sensitisation, although this was well below the level required for classification as a potential sensitiser. In a similar test in guinea pigs, Montanov 68, a commercial mixture containing shorter chain analogues of the components of Montanov 202, showed no evidence of sensitisation.

Montano 202 was non genotoxic in a bacterial reverse mutation test.

In human studies, 5% Montanov 202 was found to be non irritating and non sensitising in single and repeat insult patch tests. 5% Montanov 202 was also found to be well tolerated and non comedogenic after 4 weeks of twice daily application to the face and neck of female volunteers prone to acne. 5% Montanov 202 corresponds most closely to the proposed levels of notified chemical in finished cosmetic products.

Based on the available data, the notified chemical is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2002).

9.2.4. Occupational health and safety – risk characterisation

The most likely route of occupational exposure is through dermal contact with Montanov 202 or with finished products containing up to 1.5% notified chemical.

Although systemic toxicity of the notified chemical or Montanov 202 has not been tested, there are no indications of likely hazards to human health in the structure of the notified chemical or the known properties of Montanov 202. However, exposure to the notified chemical should be limited as far as possible by the use of gloves, goggles and protective clothing during operations involving potential exposure to Montanov 202. Local exhaust ventilation, and the expected low vapour pressure of the notified chemical, will limit the risk of inhalation exposure.

Available toxicological data show that the notified chemical is not irritating or sensitising at the low concentrations proposed for finished cosmetic products. However, the risk of irritation or sensitisation following dermal exposure to Montanov 202 is not known. Therefore gloves, goggles and protective clothing should be worn during operations involving potential exposure to Montanov 202.

9.2.5. Public health – risk characterisation

It is expected that public exposure to Montanov 202 will be minimal except in the rare event of an accidental spill involving breach of import packaging. There will be widespread public exposure to the notified chemical from frequent, prolonged dermal exposure to cosmetic creams and lotions containing up to 1.5% notified chemical. Based on the low concentrations of notified chemical in finished products, and the available toxicological data, the public risk from exposure to the notified chemical through all phases of its life cycle is considered to be low.

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

10.1. Hazard classification

Based on the available data the notified chemical is not classified as a hazardous substance under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

10.2. Environmental risk assessment

On the basis of the estimated PEC/PNEC ratio, the notified 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 at up to 1.5% in cosmetic creams and lotions.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified chemical and products containing the notified chemical provided by the notifiers were in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 2003). They are 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 notified chemical and products containing the notified chemical provided by the notifier were 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

- 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

- The following control measures should be implemented by the reformulator to minimise environmental exposure during the formulation personal care products of the notified chemical:
 - All process and storage areas are bunded with any drains going to an onsite effluent treatment plant.

Disposal

- The notified chemical should be disposed of to landfill.

Emergency procedures

- Spills/release of the notified chemical should be handled by containment, collection by either manual means or adsorption, and then placed in a labelled sealable container.

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:

- (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.

No additional secondary notification conditions are stipulated.

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