File No: SN/17

May 2007

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Arachidyl Glucoside

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 Water Resources.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at 334-336 Illawarra Road, Marrickville NSW 2204.

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

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Director
NICNAS

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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

Assessment of the notified chemical was carried out under the *Industrial Chemicals (Notification and Assessment) Act 1989* (the IC(NA) Act), as LTD/1183, with the Summary Report of the assessment published in the *Chemical Gazette* of 1 March 2005.

In August 2006, the Director of NICNAS was informed of changes to the import volume by Johnson and Johnson only. Under the IC(NA) Act, the Director declared that a secondary notification was required for the chemical known as Arachidyl Glucoside.

In accordance with Section 65 of the IC(NA) Act, a notice requiring the secondary notification of Arachidyl Glucoside. was published in the *Chemical Gazette.* The notice of 6 March 2007 stipulated the following data were required to undertake further assessment of Arachidyl Glucoside.

Part C Toxicity

Human Health
- (a) the chemical's toxic effects after a single oral administration;
- (b) the chemical's toxic effects after a single dermal exposure;
- (d) the extent of dermal irritation caused by the chemical
- (e) the extent of eye irritation caused by the chemical;
- (g) the toxic effects of the chemical on administration for a period of 10 to 14 days;
- (k) any production by the chemical of chromosome damage in mammalian cells grown in vitro

Any additional data available on toxicological and/or ecotoxicological effects of the chemical.

This report, SN/17, represents the revised assessment for Arachidyl Glucoside. This report also contains information from the original assessment for the other joint notifier (Originally Orica now Bronson and Jacobs) who is not an applicant for this secondary notification. New information submitted by the applicant (Johnson and Johnson Pacific Pty Ltd) and considered in this secondary notification assessment are located in this report at Sections:

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This information completes the notification requirements for the standard category.

NOTIFICATION CATEGORY
Secondary Notification.
The information provided fulfils the data requirements for a standard notification. Certain data requirements may have been waived (see below).

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
Acute dermal toxicity
Acute inhalation
Repeat dose toxicity
In vitro genotoxicity
Ready biodegradability
Acute toxicity to fish
Acute/chronic toxicity to aquatic invertebrates
Algal growth inhibition test
Inhibition of microbial activity

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
Assessment of the notified chemical was carried out under the *Industrial Chemicals (Notification and Assessment) Act 1989* (the IC(NA) Act), as LTD/1183, with the Summary Report of the assessment published in the *Chemical Gazette* of 1 March 2005.

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)

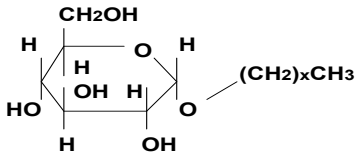
Arachidyl glucoside
D-Glucopyranoside, C20 straight chain monoalkyl-

MARKETING NAME(S)
Arachidyl glucoside
Montanov 202 (commercial mixture containing <20% notified chemical and >80% eicosanol and docosanol)

CAS NUMBER
100231-68-3

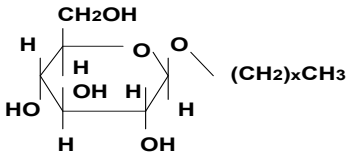
MOLECULAR FORMULA
$C_{26}H_{52}O_6$

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 2966cm^{-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 <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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	Tonnes	Tonnes	Tonnes	Tonnes	Tonnes
Original assessment	0.975	0.975	0.975	0.975	0.975
Secondary Notification	3.5	4.0	4.0	4.0	4.0
Maximum total amount imported	4.475	4.975	4.975	4.975	4.975

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:
Bronson & Jacobs Pty Ltd
70 Marple Ave
Villawood NSW 2163
In some cases the material may be despatched directly to customer sites.

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 Bronson and Jacobs or customer site. 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

Category of Worker	*Number*	*Exposure Duration (hours per day)*	*Exposure Frequency (days per year)*
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. Release during a transport accident is not likely to constitute a major hazard, as the material is likely to be containerised, or in packaging designed to withstand impact. Accidental spills during transportation should be relatively easily recovered and disposed of.

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

- Spills less than 1% less than 50 kg,
- Import container residues less than 1% less than 50 kg,
- Process Equipment cleaning up to 3% less than 150 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 50 kg annually. Since it is a component in skin care products the majority (up to 97%) 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 100 kg per year of the notified chemical. A further 50 kg will be disposed of to landfill in end-use containers.

The process equipment cleaning effluent, containing up to 3% (150 kg/year) of notified chemical, will be disposed of to the on-site wastewater collection system and then to a biological treatment plant. Approximately 97% (up to 4850 kg) of the notified chemical will end up in the sewer from end use of cosmetic products.

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 20ºC and 101.3 kPa White flakes

Melting Point/Freezing Point 74-78ºC

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

Density 859 kg/m^3 at 20ºC

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 pressue of <10^{-5} kPa.

Water Solubility >100 g/L at 20ºC

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 Kow and log Koc 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*logKow + 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.

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.

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 alcohol. Montanov 68 components are shorter alkyl chain analogues of Montanov 202 components. Acute dermal toxicity, repeat dose oral toxicity and in vitro genotoxicity studies performed on higher molecular weight analogues, alkyl polyglycosides, have also been reported.

Endpoint and Result	*Test Material*	*Assessment Conclusion*
Rat, acute oral	Montanov 202 (10-20% notified chemical)	LD50>2000 mg/kg bw, low toxicity
Rat, acute dermal	Alkyl (C8-C10) Polyglycosides	LD50>2000 mg/kg bw, low toxicity
Rat, acute dermal	Alkyl (C12-C14) Polyglycosides	LD50>2000 mg/kg bw, low toxicity
Rabbit, skin irritation	5% Montanov 202	Slightly irritating
Rabbit, skin irritation	5% Montanov 202	Slightly irritating
Rabbit, eye irritation	5% Montanov 202	Slightly irritating
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
Rat, repeat dose <oral> toxicity – 90 days.	Alkyl (C12-C14) Polyglycosides	NOAEL 250 mg/kg bw/day
Genotoxicity – bacterial reverse mutation	Montanov 202	Non mutagenic
Genotoxicity – in vitro mammalian cytogenetictest	Alkyl (C12-C14) Polyglycosides	Non genotoxic
Genotoxicity – in vitro cytogenetic test	Alkyl (chain length not specified) Polyglycoside	Non genotoxic
Comedogenicity	5% Montanov 202	Non comedogenic

7.1. Acute toxicity – oral

TEST SUBSTANCE	Montanov 202 (10-20% notified chemical)
METHOD	Similar to OECD TG 401 Acute Oral Toxicity – Limit Test.
Species/Strain	Rat/WISTAR
Vehicle	Liquid paraffin (1:4, Montanov 202:vehicle)
Remarks - Method	Statement of GLP. Significant protocol deviations include: 1. No pathology performed.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5 males	2000	0/5
II	5 females	2000	0/5

LD50	> 2000 mg/kg bw (10-20% notified chemical)
Signs of Toxicity	None.
Effects in Organs	Not applicable

Remarks - Results	There were no deaths or notified chemical related clinical signs or remarkable body weight changes during the study period.
CONCLUSION	The notified chemical at a concentration of 10-20% is of low toxicity via the oral route.
TEST FACILITY	COSMEPAR (1996a)

7.2.1. Acute toxicity – dermal

TEST SUBSTANCE	Alkyl (C12-C14) Polyglycosides
METHOD	Unspecified in summary report.
Species/Strain	Rabbit
RESULTS	
Remarks - Results	LD50>2000 mg/kg
CONCLUSION	The test substance is of low toxicity via the dermal route.
TEST FACILITY	USEPA (2005)

7.2.2. Acute toxicity – dermal

TEST SUBSTANCE	Alkyl (C8-C10) Polyglycosides
METHOD	Unspecified in summary report.
Species/Strain	Rabbit
RESULTS	
Remarks - Results	LD50>2000 mg/kg
CONCLUSION	The test substance is of low toxicity via the dermal route.
TEST FACILITY	USEPA (2005)

7.3. Acute toxicity – inhalation

REMARKS	Not determined

7.4.1 Irritation – skin

TEST SUBSTANCE	5% Montanov 202 (0.5-1% notified chemical)
METHOD	Similar to OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 males
Vehicle	None, liquid applied neat.
Observation Period	48 hours
Type of Dressing	Occlusive
Remarks - Method	Significant protocol deviations: 1. No clinical observations made at 24 and 72 hours 2. Occlusive dressing used 3. Exposure period 24 h 4. Tested with and without scarification of the skin 5. Test material not removed from skin after exposure period

The experimental conditioned used in this study were such that they were more likely to produce an adverse effect than the standard OECD protocol.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0	0	0	1	< 48 hours	0
Oedema	0	0	0	0	-	0

*Calculated on the basis of the scores at 48, for EACH animal.

Remarks - Results: Slight erythema was noted in only one animal on scarified skin after one hour after patch removal by 48 hours this reaction was not observed.

CONCLUSION: The test substance is slightly irritating to the skin.

TEST FACILITY: EViC-CEBA (1998)

7.4.2. Irritation – skin

TEST SUBSTANCE: 5% aqueous dispersion of Montanov 202 (0.5-1% notified chemical)

METHOD: Similar to OECD TG 404 Acute Dermal Irritation/Corrosion.

Species/Strain: Rabbit/New Zealand White

Number of Animals: 3 males

Vehicle: None, administered as supplied.

Observation Period: 48 hours

Type of Dressing: Occlusive

Remarks - Method: Statement of GLP.

Significant protocol deviations:

1. No clinical observations made at 24 and 72 hours
2. Occlusive dressing used
3. Exposure period 24 h
4. Tested with and without scarification of the skin

The experimental conditioned used in this study were such that they were more likely to produce an adverse effect than the standard OECD protocol.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0	0	0	1	< 48 hours	0
Oedema	0	0	0	0	-	0

*Calculated on the basis of the scores at 48, for EACH animal.

Remarks - Results: Slight erythema was noted in only one animal after one hour after patch removal. By 48 hours this reaction was not observed in either animal.

CONCLUSION: The test substance is slightly irritating to the skin.

TEST FACILITY: COSMEPAR (1996b)

7.4.3. Skin irritation – human patch test

TEST SUBSTANCE 5% Montanov 202 (0.5-1% notified chemical)

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)

7.5.1 Irritation – eye

TEST SUBSTANCE 5% Montanov 202 in solution (0. 5-1% notified chemical)

METHOD Similar to OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain Rabbit/New Zealand White
Number of Animals 3
Observation Period 7 days
Remarks - Method

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	0.7	0	0	1	>48 h <72 h	0
Conjunctiva: chemosis	0	0	0	0	0	0
Conjunctiva: discharge	0	0	0	2	< 24 h	0
Corneal opacity	0	0	0	0	0	0
Iridial inflammation	0	0	0	0	0	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

Remarks - Results After one hour discharge of the conjunctiva was noted in all three animals but was not present after 24 hours. Slight redness of the conjunctiva was observed in all three animals after one hour and in one animal up to 48

hours.

CONCLUSION The test substance is slightly irritating to the eye.

TEST FACILITY EViC-CEBA (1998)

7.5.2 Eye irritation - 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 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.

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.

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).

The classification was determined using the following chart:

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 No signs of haemorrhage observed.

Coagulation No signs of coagulation observed.

Remarks - Results 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)

7.5.3 Eye irritation - 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)

7.6.1 Skin sensitisation - Guinea pig – Magnusson and Kligman test

TEST SUBSTANCE

Montanov 202 (10-20% notified chemical)

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	Not conducted.	
Remarks - Method	None.	

RESULTS

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

7.6.2. Skin sensitisation - 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

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

7.6.3. Skin sensitisation - Human repeat patch test

TEST SUBSTANCE	5% Montanov 202
METHOD	Marzulli & Maibach's method Repeated epicutaneous 48-hour applications under occlusive patch.
Preliminary Study	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 8th 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)

7.7. Repeat dose toxicity

TEST SUBSTANCE Alkyl (C12-C14) Polyglycosides

METHOD
- Species/Strain: Not specified / Rat (strain unspecified)
- Route of Administration: Oral – gavage
- Exposure Information: Total exposure days: 90 days; Dose regimen: 5/7 days per week; Post-exposure observation period: 27
- Vehicle: Unknown
- Remarks - Method: Full study report not cited.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	males and females (no. unknown)	0	0
II (low dose)	males and females (no. unknown)	250	0
III (mid dose)	males and females (no. unknown)	500	0
IV (high dose)	males and females (no. unknown)	1000	0
VI (high dose recovery)	males and females (no. unknown)	1000	0

Mortality and Time to Death
No deaths were reported.

Clinical Observations
No adverse treatment-related effects reported.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
No adverse treatment-related effects reported.

Effects in Organs
Adverse treatment-related effects were limited to the forestomach in both males and females in the mid and high dose group although these effects were reversible after 27 days. No other adverse treatment-related effects were reported.

Remarks – Results
A LOAEL of 500 mg/kg bw/day was established based on acanthosis, subepithelial inflammatory oedema, and hyperkeratosis (females only) of the forestomach at this dose level.

CONCLUSION
The No Observed (Adverse) Effect Level (NO(A)EL) was established as 250 mg/kg bw/day in this study, based on treatment-related effects at higher dose levels.

TEST FACILITY USEPA (2005)

7.8. Genotoxicity – bacteria

TEST SUBSTANCE	Montanov 202 (10-20% notified chemical)
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. Plate incorporation procedure Method also conforms to guidelines published by the major Japanese Regulatory Authorities.
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: 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

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	None observed	None observed	1500	None observed
Test 2	None observed	None observed	1500	None observed
Present				
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.
CONCLUSION	Montanov 202 was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	SafePharm (1998)

7.9.1. Genotoxicity – in vitro

TEST SUBSTANCE	Alkyl (C12-C14) Polyglycosides
METHOD	In vitro Mammalian Cytogenetics Assay.
Remarks	No study details were provided in the summary.
CONCLUSION	The test substance was negative with and without activation, in vitro, under the conditions of the test.
TEST FACILITY	USEPA (2005)

7.10. Genotoxicity – in vitro

TEST SUBSTANCE	Alkyl polyglycoside (chain length not specified)
METHOD	In vitro cytogenetic test in Chinese hamster V79 lung fibroblasts
Remarks - Method	No study details were provided in the summary.
CONCLUSION	The test substance was considered to be non-mutagenic under the conditions of the test.
TEST FACILITY	USEPA (2005)

7.11. 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. 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

Test substance		*Sodium acetate*	
Day	*% Degradation*	*Day*	*% Degradation*
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 new ecotoxicological data has been provided.

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 150 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 Koc and Kow 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 a maximum importation volume of 5000 kg, year-round use of the notified chemical, and no removal due to biodegradation or physical/chemical means:

Amount released to sewer	5000 kg
Number of days used	365
Australian population	20.5 million
Water use per person	200 L
$PEC_{sewer/freshwater}$	5000 000 000 000 365X20 500 000X200 = 3.34 µg/L
PEC_{ocean} (dilution factor of 10)	0.334 µg/L

The actual PECs are likely to be much lower, since the notified chemical is readily biodegradable. Therefore, the DEW STP model (Environment Australia, 2003) has been used to estimate how the notified chemical will behave in a sewage treatment plant. The modelled results, assuming a yearly release to sewer of 5000 kg, are as follows:

Daily chemical release:	13.70	kg
Daily effluent production (100% population)	4,099	ML
Amount remaining in effluent	7%	
Amount removed due to degradation	21%	
Chemical load partitioning to sludge/biosolids:	72%	

As can be seen from the results it is likely that approximately 7% of the notified chemical loading will remain in the effluent leaving the STP and be released to either a freshwater/marine water body. In which case the $PEC_{freshwater}$ and the PEC_{ocean} become 0.23 and 0.02, respectively.

Partitioning to biosolids in STPs Australia-wide may result in an average biosolids concentration of 24.06 mg/kg (dry wt). Biosolids will either be disposed of to landfill or they maybe applied to agricultural soils at an assumed average rate of 10 t/ha/year. Assuming a soil bulk density of 1000 kg/m^3 and a soil mixing zone of 0.1 m, the concentration of the notified chemical may approximate 0.241 mg/kg in applied soil. STP effluent re-use for agricultural irrigation occurs throughout Australia The following calculation is undertaken assuming an application rate of 1000 L/m^2/year (10 ML/ha/year) and that any notified chemical in the water is assumed to infiltrate and accumulate in the top 0.1 m of soil (density 1000 kg/m^3).

PECsoil (mg/kg) (assumes no degradation)

		Recycled water	Application of biosolids
Soil concentration	1 year	0.002	0.241
	5 years	0.01	1.205
	10 years	0.02	2.41

However, the PEC_{soils} is expected to be lower due to the degradation of the notified chemical which will continue in the soil.

Bioaccumulation is not expected due to the diffuse use pattern, and the notified chemical's ready biodegradability, which would limit its bioaccumulation potential.

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 aquatic 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 aquatic PNEC is 2.5 µg/L.

However, as no ecotoxicity data is available for soil organisms, a soil PNEC cannot be estimated.

9.1.3. Environment – risk characterisation

The risk associated with the use of the notified chemical in personal care products can be estimated by determining the aquatic risk quotient (RQ = PEC/PNEC).

The risk associated with the worst case scenario, where all of the imported notified chemical is released and there is no removal in the STP, is estimated below and indicates a marginal risk in freshwater.

Location	PEC	PNEC	Risk Quotient (RQ)
Freshwater	3.34 µg/L	2.5 µg/L	1.34
Ocean outfall	0.33 µg/L	2.5 µg/L	0.13

However, this risk will be mitigated by the behaviour of the notified chemical in the STP (as discussed in the previous section) and is recalculated below taking into account the likely removal in the STP.

Location	PEC	PNEC	Risk Quotient (RQ)
Freshwater	0.23 µg/L	2.5 µg/L	0.092
Ocean outfall	0.02µg/L	2.5 µg/L	0.009

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.

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

Toxicokinetics
No information was submitted on the notified chemical. USEPA (2005) reports that similar chemicals are hydrolysed to form sugar and long chain alcohols, which are then processed as carbohydrates and lipids, with most metabolites excreted via urine.

Acute toxicity
Montanov 202, containing 10-20% of the notified chemical was of low oral toxicity to rats (LD50>2000 mg/kg). Alkyl polyglycoside analogues were also of low acute oral toxicity (USEPA, 2005). The analogue alkyl polyglycosides were also of low toxicity via the dermal route, however it should be notified that the notified chemical may have a higher potential for dermal absorption because of its lower molecular weight.

Irritation
Montanov 202 has been tested in a number of studies for irritancy. 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%). A 5% solution of Montanov 202 (0.5-1% notified chemical) was slightly irritating to rabbit eyes and skin. Because of the low concentration used in the studies the irritation potential of the notified chemical cannot be fully characterised.

Skin sensitisation
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.

Repeated dose toxicity
A higher molecular weight analogue polyglycoside was found to have a NOAEL of 250 mg/kg bw/day in a 90 oral study in rats. Adverse treatment related effects were limited to the site of

contact (forestomach) in animals treated at higher doses.

It is expected that the analogue and notified chemical would have similar routes of metabolism. Whilst the chain length of the formed alcohol differ, alcohols with a chain length C18-C22 are of low acute toxicity and did not cause adverse effects when dosed at 1000 mg/kg bw/day in a 28 day study (ECB (2000a), ECB (2000b), ECB (2000c))

Genotoxicity
Montanov 202 was non genotoxic in a bacterial reverse mutation test and the analogue polyglycoside was not genotoxic in two in vitro mammalian cytogenic studies.

Human studies
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.

It should be noted that all available toxicological data relates either to low concentrations of the notified chemical or to analogue data.

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 with the highest level of exposure expected during manual weighing and transfer of Montanov 202.

Available toxicological data show that the notified chemical is not sensitising or significantly irritating 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.

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. In addition, a higher molecular weight analogue polyglycoside showed adverse effects only at the site of contact (forestomach) which were possibly related to irritation and therefore only applicable to the oral route of exposure. Exposure and hence the risk of adverse systemic effects would be limited 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.

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 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 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

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical in the product Montanov 202:
  - Gloves
  - Safety eyewear
  - Protective clothing
- 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 of 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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