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March 2010

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

FULL PUBLIC REPORT

**Butanedioic acid, 1-[(1R,2S,5R)-5-methyl-2-(1-methylethyl)cyclohexyl] ester
(INCI: Menthyl succinate)**

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, Water, Heritage and the Arts.

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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FULL PUBLIC REPORT

This assessment report is for an extension of original assessment certificate for Butanedioic acid, 1-[(1R,2S,5R)-5-methyl-2-(1-methylethyl)cyclohexyl] ester. Based on the submission of new information by the extension notifier, some sections of the original assessment report for Butanedioic acid, 1-[(1R,2S,5R)-5-methyl-2-(1-methylethyl)cyclohexyl] ester have been modified. These modifications have been made under the heading 'Extension Applicant' in the respective sections.

**Butanedioic acid, 1-[(1R,2S,5R)-5-methyl-2-(1-methylethyl)cyclohexyl] ester
(INCI: Menthyl succinate)****1. APPLICANT AND NOTIFICATION DETAILS****APPLICANT(S)**

Holder of the original assessment certificate (No.2960, LTD/1409)

Johnson & Johnson Pacific Pty Ltd (ABN 73 001 121 446)

45 Jones Street

ULTIMO NSW 2007

Applicant for an Extension of the Original Assessment Certificate:

International Flavours & Fragrances (Australia) Pty Ltd (ABN 77 004 269 658)

310 Frankston Dandenong Road

DANDENONG SOUTH VIC 3175

NOTIFICATION CATEGORY

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

No details are claimed exempt from publication.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

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

Boiling point, Density, Vapour pressure, Water solubility, Hydrolysis as a function of pH, Partition coefficient, Adsorption/Desorption, Dissociation constant, Particle size, Flash point, Flammability limits, Autoignition temperature.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

None

2. IDENTITY OF CHEMICAL**MARKETING NAME(S)**

Listerine Total Care Mouthwash (contains notified chemical at < 0.05%)

Menthyl succinate (INCI name)

Physcool

Extension Applicant:

Sweet Garden Mint (contains notified chemical at 5-15%)

Cooler 1

CAS NUMBER

77341-67-4

CHEMICAL NAME

Butanedioic acid, 1-[(1R,2S,5R)-5-methyl-2-(1-methylethyl)cyclohexyl] ester

OTHER NAME(S)

Butanedioic acid, mono[(1R,2S,5R)-5-methyl-2-(1-methylethyl)cyclohexyl] ester (9CI)

Butanedioic acid, mono[5-methyl-2-(1-methylethyl)cyclohexyl] ester, [1R-(1.alpha.,2.beta.,5.alpha.)]-

Mono-menthyl succinate

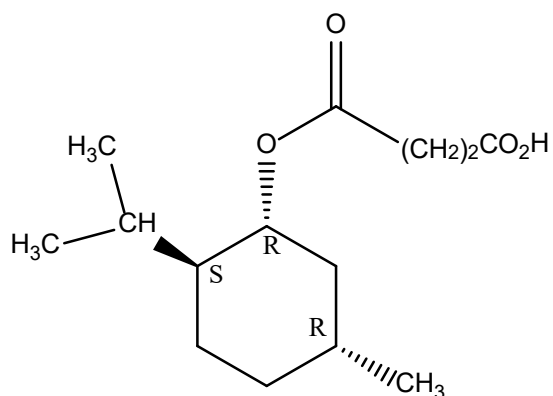
MOLECULAR FORMULA

 $C_{14}H_{24}O_4$

MOLECULAR WEIGHT

256.3 Da

STRUCTURAL FORMULA



ANALYTICAL DATA

Reference IR spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 99%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS None

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

ADDITIVES/ADJUVANTS None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: White powder

Property	Value	Data Source/Justification
Melting Point/Freezing Point	60°C	MSDS
Boiling Point	353°C at 101.3 kPa	Estimated (EPIWEB v 4.0)
Density	Not determined	Not isolated from aqueous solution
Vapour Pressure	2.3 x 10 ⁻⁵ kPa at 25°C	Estimated (EPIWEB v 4.0). Modified Antoine method using measured melting point of 60°C.
Water Solubility	44 mg/L at 20°C	Estimated
Hydrolysis as a Function of pH	Expected to be slow.	Estimated
Partition Coefficient (n-octanol/water)	log P _{ow} = 4.1 at 20°C	Estimated
Adsorption/Desorption	log K _{oc} = 2.1-2.4 at 20°C	Estimated
Dissociation Constant	pKa = 4.2	Analogue data (succinic acid)
Particle Size	Not determined	Not isolated from aqueous solution
Flash Point	Not determined	Not isolated from aqueous solution
Flammability	Not determined	Not isolated from aqueous solution
Autoignition Temperature	Not determined	Not expected to autoignite under normal conditions of use.
Explosive Properties	Not expected to be explosive	The structural formula contains no explosives.

DISCUSSION OF PROPERTIES

The notified chemical is predicted to be lipophilic and to have a low vapour pressure and low water solubility based on modelling (EPIWEB, 2009). While abiotic hydrolysis is expected to be slow, the notified chemical is likely to be rapidly hydrolysed by esterases under environmental conditions.

Reactivity

The notified chemical is expected to be stable under normal storage and handling conditions.

5. INTRODUCTION AND USE INFORMATION

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

The notified chemical will be imported as a component of finished personal care products at a concentration of < 0.05%.

Extension Applicant:

The notified chemical will be imported as a component of Sweet Garden Mint flavour at a concentration of 5-15%.

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

Year	1	2	3	4	5
LTD/1409 Tonnes	0.4	0.5	0.6	0.7	0.8
Extension Tonnes*	1.0	1.0	1.0	1.0	1.0

*Combined introduced volume for original notifier and extension applicant.

Note: The original notifier and extension applicant understand that as the original assessment was conducted under a Limited Notification the combined introduced volume of the notified chemical can not exceed 1 tonne per annum.

PORT OF ENTRY

Melbourne

TRANSPORTATION AND PACKAGING

The notified chemical will be imported as a component of a finished cosmetic mouthwash in bottles up to 1 L for retail sale and transported by road to the notifiers warehouse and then onto the retail store's central distribution centres.

Extension Applicant:

The notified chemical will be imported as a component of Sweet Garden Mint flavour in 55 gallon (~200 L) plastic drums. After reformulation, the finished cosmetic mouthwash (containing the notified chemical at < 0.05%) will be packaged in bottles up to 1 L for retail sale.

USE

The notified chemical is a component of a flavour mixture used in a cosmetic mouthwash.

OPERATION DESCRIPTION

There will be no manufacture or reformulation of the notified chemical within Australia.

Extension Applicant:

The Sweet Garden Mint flavour (containing the notified chemical at up to 15%) will be dispensed and weighed manually, and added to the mixer. After blending, the finished cosmetic mouthwash product (containing the notified chemical at < 0.05%) will be packaged in bottles up to 1 L by an automated process. Blending and packaging will be conducted in enclosed systems. Samples for quality control testing will be taken from the mixer.

6. HUMAN HEALTH IMPLICATIONS**6.1 Exposure assessment****6.1.1 Occupational exposure****EXPOSURE DETAILS**

Transport, storage and retail workers are not expected to be exposed to the notified chemical except in the unlikely event of an accident or spill.

*Extension Applicant:***NUMBER AND CATEGORY OF WORKERS**

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Transport and warehouse	1-5	0.5	100-150
Quality control	3-6	0.5	100-150
Formulators	2	6	100-150
Packaging	3-6	6	100-150

EXPOSURE DETAILS

Transport, storage and retail workers are not expected to be exposed to the notified chemical (at up to 15%) except in the unlikely event of an accident or spill.

Dermal and ocular exposure to the notified chemical at up to 15% may occur during weighing and addition to the mixer. Dermal and ocular exposure to the notified chemical at up to 0.05% may occur during cleaning of the blending vessels and taking samples for quality control testing. Given blending and packaging will be conducted in enclosed systems, exposure to the notified chemical is not expected during these processes. The proposed use of impervious gloves, coveralls and safety glasses by all workers should limit exposure.

Given the low vapour pressure of the notified chemical inhalation exposure is not expected.

6.1.2. Public exposure

The public will be exposed to the notified chemical at a concentration of up to 0.05% when using mouthwash products. Dermal and oral will therefore be the primary routes of exposure. Given the low vapour pressure of the notified chemical inhalation exposure is not expected. Accidental ocular exposure may occur, but is not expected to be significant.

Based on data reported by the Soap and Detergent Association (SDA) for European use, 8.5% of mouthwash is estimated to be ingested, equivalent to 70.8 mg/kg bw/day for a 60 kg adult using 10 g of the mouthwash product per use 5 times a day (SDA, 2005). Therefore exposure to the notified chemical at 0.05% is estimated as 0.04 mg/kg bw/day.

6.2. Human health effects assessment

No toxicity data were submitted.

The notified chemical is generally recognized as safe (GRAS) as a flavor ingredient by the expert panel of the Flavor and Extract Manufacturers Association (FEMA) (Smith et al, 1996).

The Joint FAO/WHO Expert Committee on Food Additives JECFA concluded that the substance does not present a safety concern at current levels of intake when used as a flavouring agent (1999a).

Toxicokinetics

The notified chemical has a low molecular weight and is highly lipophilic; therefore penetration into the strata corneum would be expected. However, given its low water solubility (44 mg/L) the rate of transfer into the epidermis is expected to be low.

The notified chemical would be expected to hydrolyse in the body to (-)-menthol (CAS No. 2216-51-5) and butanedioic acid (CAS No. 110-15-6); the latter being endogenous to humans. Menthol is known to be readily absorbed by the oral route and largely eliminated as glucuronides. It has been reported that 70-80% is eliminated in urine and faeces within 48 hrs (JECFA, 1999a, 1999b).

Acute toxicity

The notified chemical is expected to have a low acute oral toxicity based on a reported LD50 of > 5000 mg/kg on a study conducted on rats (JECFA, 1999a).

Repeated dose toxicity

No repeat dose toxicity data was available for the notified chemical, however in a two year study conducted on groups of 50 rats of each sex fed the equivalent of 190 and 380 mg/kg bw/day of racemic menthol¹ in their diet, the NOEL was determined to be 380 mg/kg bw/day based on the absence of any treatment related effects (JECFA, 1999b).

Irritation and Sensitisation

No irritation/sensitisation data was available for the notified chemical. The notified chemical may possess irritant properties as it contains a carboxylic acid group, a structural alert for skin irritants (Hulzebos, 2005) and eye irritants (Tsakovsha, 2007). Indeed, the notified chemical is listed on Safe Work Australia's hazardous substance information system (HSIS) as a severe eye irritant.

The notified chemical does not contain structural alerts for sensitisation and therefore is not expected to present as a sensitiser.

Genotoxicity

No genotoxicity data was available for the notified chemical, however neither menthol¹ nor its metabolites were found to be genotoxic in a number of in vitro studies, including reverse mutation and chromosomal aberration tests, and in vivo tests (JECFA, 1999b).

Developmental toxicity

No developmental toxicity data was available for the notified chemical, however in a study conducted on the expected metabolite of the notified chemical, (-)-menthol, no teratogenic effects were observed when tested at maximum doses of 190-430 mg/kg bw/day in mice, rats, hamsters and rabbits (JECFA, 1999b).

Carcinogenicity

No carcinogenicity data was available for the notified chemical; however racemic menthol¹ was concluded to be not carcinogenic in studies conducted on rats and mice (JECFA, 1999b).

¹Based on limited data, there is no indication of a difference in the metabolism and toxicity of (-)-menthol, the expected metabolite, and racemic menthol (JECFA, 1999b).

Health hazard classification

The notified chemical is listed on Safe Work Australia's hazardous substance information system (HSIS) as an eye irritant with the following risk phrase:

R41: Risk of serious damage to eyes

Cutoffs:

Conc \geq 10%: Xi; R41

\geq 5%Conc < 10%: Xi; R36

Based on the available data the notified chemical is not classified as hazardous for other endpoints under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

Given workers will only be exposed to low levels of the notified chemical in the event of an accident or spill, the risk to workers to the notified chemical is considered to be negligible.

Extension applicant:

The notified chemical is a severe eye irritant. Workers most at risk of eye irritation will be reformulators handling the notified chemical at concentrations (at up to 15%) above the cut-off level for eye irritancy (\geq 5%). The proposed use of safety glasses by workers should minimise this risk. The risk to other workers is considered negligible as they will be exposed to low concentrations of the notified chemical (i.e. < 0.05%).

Overall, given the proposed use of PPE including safety glasses, the risk to workers to the notified chemical is not considered unacceptable.

6.3.2. Public health

The greatest risk of exposure to the notified chemical to the public will be by the oral route when using mouthwash products containing the notified chemical. The estimated exposure to the notified chemical in the mouthwash at up to 0.05% is 0.04 mg/kg bw/day. Given the NOEL (380 mg/kg bw/day) of the expected metabolite menthol is three orders of magnitude greater than the estimated exposure, the risk to the public is considered acceptable.

The risk of irritation effects are considered to be low/negligible based on the low concentration.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical will not be manufactured or reformulated in Australia. It is imported as a component of a finished cosmetic mouthwash in consumer containers.

There is unlikely to be any significant release to the environment, given the proposed relatively low level use for the product containing the notified chemical, the formulation and sealed packaging containers.

Extension Applicant:

The notified chemical will be imported into Australia in ~200 L drums. Environmental release is unlikely during importation, storage and transportation, and spillage during a transport accident will be the most likely reason for environmental release.

Releases from the formulation facilities are anticipated to be limited given the use of enclosed and automated systems. Wash water, estimated to contain approximately 0.2% of the imported notified chemical, from spill clean-up and equipment cleaning will be discharged into a site wastewater treatment plant. After on-site treatment, water will be discharged to the sewer as industrial wastewater.

RELEASE OF CHEMICAL FROM USE

It is expected that the majority of the imported quantity of the notified chemical (estimated to be 99%) will be washed to the sewer as the chemical is intended for use in personal care products. This release will occur in a diffuse and widespread manner.

Extension Applicant:

It is expected that the majority of the imported quantity of the notified chemical (estimated to be 98%) will be washed to the sewer as the chemical is intended for use in personal care products. This release will occur in a diffuse and widespread manner.

RELEASE OF CHEMICAL FROM DISPOSAL

It is estimated that 1% of the finished product goes into the garbage collection system as residues in empty containers. These residues may be sent to landfill with the containers, or washed to sewer when consumers rinse the containers before recycling.

Extension Applicant:

Approximately 1% of the notified chemical is expected to remain in the imported drums. The empty drums will be sent to a licensed waste disposal company or recycled, where the notified chemical will be thermally decomposed into water and oxides of carbon and nitrogen.

7.1.2 Environmental fate

No environmental fate data were submitted. The notified chemical is expected to be easily hydrolysed in sewage treatment plants and the environment to menthol and succinic acid. These natural products can be expected to biodegrade easily. The notified chemical is not expected to bioaccumulate in fish because of the ease of enzymatic (esterase) hydrolysis in living organisms.

7.1.3 Predicted Environmental Concentration (PEC)

A PEC for the aquatic environment can be determined as tabulated below, assuming all the product containing the notified chemical is rinsed to sewer after use.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	800	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	800	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	2.19	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	21.374	million
Removal within STP	0%	
Daily effluent production:	4,275	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.51	µg/L
PEC - Ocean:	0.051	µg/L

7.2. Environmental effects assessment

No ecotoxicity data were submitted. The notifier has provided model estimates (EPIWEB, 2009) for the acute aquatic toxicity, as tabulated below.

Organism	Duration	Predicted LC50/EC50
Fish	96 hour	21.06 mg/L
Fish (saltwater)	96 hour	25.43 mg/L
Daphnid	48 hour	32.88 mg/L
Green algae	96 hour	11.14 mg/L
Mysid shrimp	96 hour	9.89 mg/l

7.2.1 Predicted No-Effect Concentration

The PNEC can be determined as tabulated below by application of a thousand-fold assessment factor to the estimated acute toxicity to mysid shrimp.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
Mysid 96 hour LC50	9.9	mg/L
Assessment Factor	1000	
PNEC:	9.9	µg/L

7.3. Environmental risk assessment

The risk quotients ($Q = \text{PEC}/\text{PNEC}$) are tabulated below.

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	0.51	9.9	0.052
Q - Ocean	0.051	9.9	0.0052

The notified chemical is not considered to pose a risk to the environment as the risk quotients are less than one.

Extension applicant:

The circumstances in the extension application are not expected to impact on the original environment risk assessment. Although there will be an increase in volume to 1 tonne per annum, the risk quotients will still be less than one. Therefore there are no changes required in the risk assessment.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

The notified chemical is listed on Safe Work Australia's hazardous substance information system (HSIS) as an eye irritant with the following risk phrase:

R41: Risk of serious damage to eyes

Cutoffs:

Conc \geq 10%: Xi; R41

\geq 5%Conc < 10%: Xi; R36

Based on the available data the notified chemical is not classified as hazardous for other endpoints under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

and

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

<i>Estimated mysid toxicity</i>	<i>Hazard category</i>	<i>Hazard statement</i>
96 hour LC50 = 9.9 mg/L	Acute 2	Toxic to aquatic life

As eye irritation data has not been cited, GHS classification for this endpoint has not been undertaken.

Human health risk assessment

Under the conditions of the occupational settings described, the notified chemical is not considered to pose an unacceptable risk to the health of workers.

When used in the proposed manner, the notified chemical is not considered to pose an unacceptable risk to public health.

Environmental risk assessment

On the basis of the PEC/PNEC ratio and the reported use pattern, the notified chemical is not considered to pose a risk to the environment.

Risk assessment (extension applicant)

In contrast to the original notifier, the extension applicant will import the notified chemical at a higher concentration that will undergo reformulation to give the same finished cosmetic mouthwash product. Given the higher concentration of the notified chemical as introduced and classification as an eye irritant, additional recommendations have been added to the original assessment (see below).

The circumstances in the extension application are not expected to impact on the environmental risk assessment, therefore no changes are required.

Recommendations**CONTROL MEASURES****Occupational Health and Safety**

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

Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- A copy of the MSDS should be easily accessible to employees.
- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Extension applicant:

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced in a flavour mix:
 - Avoid contact with eyes;
 - An eye wash station should be available;
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced in a flavour mix:
 - Eye protection.

Disposal

- The notified chemical should be disposed of to landfill.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by containment, collection and subsequent safe disposal.

Regulatory Obligations

Secondary Notification

This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under Section 64(1) of the Act; if
 - the importation volume exceeds one tonne per annum notified chemical;or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the chemical has changed from as a component of a finished cosmetic mouthwash at a concentration of < 0.05%, or is likely to change significantly;
 - the amount of chemical being introduced has increased from 1 tonne per annum, or is likely to increase, significantly;
 - the chemical has begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

Material Safety Data Sheet

The MSDS of the notified chemical and products containing the notified chemical provided by the notifier were reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

Extension applicant:

The MSDS of the introduced product containing the notified chemical provided by the extension applicant was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

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