File No: STD/1180

February 2006

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polymeflor

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Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Takasago International (Singapore) Pte Ltd (ABN 29 099 666 832) of Level 5, 815 Pacific Highway, Chatswood, NSW, 2067.

NOTIFICATION CATEGORY
Standard: Chemical other than polymer (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical Identity
Spectral Data
Purity and identity of impurities
Introduction volume

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Dissociation constant
Flammability limits
Acute toxicity – inhalation

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
EU (2004)
USA (2003)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Polymeflor

METHODS OF DETECTION AND DETERMINATION

Remarks The purity and identity of impurities were determined by Gas Chromatography-Mass Spectroscopy (GC-MS). Reference spectra were provided.

The notified chemical was characterised by infrared spectroscopy, ^{1}H nuclear magnetic resonance spectroscopy (NMR), ^{13}C NMR and UV/Visible spectroscopy. Spectra provided were consistent with the proposed structure.

3. COMPOSITION

DEGREE OF PURITY
> 90%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
All hazardous impurities are present at below the relevant cut offs for classification of the notified chemical as a hazardous substance

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical is imported as a component (maximum 1%) in fragrance mixtures.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	0.1 - 1	0.1 - 1	0.1 - 1	0.1 - 1	< 5

USE
The fragrance mixtures containing the notified chemical will be used in consumer products such as cosmetics, perfumery, personal cleaning products and household and laundry products. The concentration of the notified chemical in the end use products will be < 0.01%.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
The notified chemical may be introduced into a number of ports throughout Australia.

IDENTITY OF MANUFACTURER/RECIPIENTS
Formulation sites for the consumer products have not yet been identified.

TRANSPORTATION AND PACKAGING
The fragrance mixture containing the notified chemical will be imported in 200 kg drums. The formulated consumer products will be packed in a variety of containers ranging from 0.1 kg to 5 kg in size. Transport is expected to be by road.

5.2. Operation description

Formulation
At present, sites of formulation for the other end use products have not been identified and therefore specific operation descriptions cannot be provided. Formulation of these products will involve transfer of the fragrance mixture (containing ≤ 1 % notified chemical), blending with other ingredients and filling the formulated product (containing < 0.01%) into end packaging.

Transfer: Depending on the site of formulation, the notified polymer may be transferred manually, semi-automatically, e.g. by dip pipe, or automatically by dedicated pipework. Smaller quantities may be pre-weighed into smaller drums or buckets before addition to the blending vessel.

Blending: Depending on the site of formulation, blending vessels may be open or closed

Filling: Typically, the end packaging filling process will be automated, however, some manual input may be involved such as capping.

End use
There is potential for the formulated cleaning products (containing 0.01%) to be used occupationally, for example by professional cleaners using cleaning products or beauticians using cosmetic products.

Cleaning products are generally applied with a cloth or sponge, by mop or brush or by spray followed by wiping. In some cases, the cleaning product will be diluted with water prior to application. The dilution factor, which is often on the label, depends on the type of surface to be cleaned, the soil loading, and the type and method of application.

Depending on the nature of the cosmetic product these could be applied a number of ways such as by hand, using an applicator or sprayed.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and storage	10-20	1-2	50
Mixers	10-20	Up to 8	240
QC samplers	1-2	0.5	240
Cleaners/maintenance	5-10	Up to 8	240
End users (professionals)	> 1000	1-8	200

Exposure Details

Formulation

Workers involved with the transfer, blending and filling operations have the potential for exposure to the notified chemical, although the potential for exposure is usually greatest during the initial transfer. The main route of exposure is expected to be dermal although ocular exposure is possible. Workers could be exposed to notified chemical at a concentration of < 1% and < 0.01% prior to and post formulation respectively. The level of exposure would vary from site to site depending on the level of automation of the formulation process. Industrial standard personal protective equipment (PPE) is expected to be used at the formulation site.

Other workers that may be exposed to the notified polymer include quality control workers and workers involved in cleaning process equipment and waste disposal.

End use

Exposure to no more than 0.01% notified chemical could occur during final application of the cleaning/cosmetic products or during their addition to water if dilution is required. The main route of exposure is expected to be dermal, although ocular exposure to splashes is possible and inhalation of aerosols could occur where application is by spray. The level of exposure will vary depending on the method of application and work practices employed to minimise splashes and spills.

5.4. Release

RELEASE OF CHEMICAL AT SITE

The notified chemical will not be manufactured in Australia, thus there will be not be any environmental release during this phase. The notified chemical will be imported as a minor fragrance mixture component in 200 kg drums. It will be transported by road to the reformulation site directly or indirectly via warehouses. Environmental release is expected to arise only due to accidental spills during transportation or handling.

During reformulation, the notified chemical is mixed with other ingredients prior to being repackaged in 0.1-5.0 kg consumer packages. Environmental release during reformulation is expected to be less than 1% of the total annually imported volume, arising from accidental spills and from routine equipment cleaning.

RELEASE OF CHEMICAL FROM USE

The majority of the total annually imported volume of notified chemical is expected to be released to sewer after use.

5.5. Disposal

Residual notified chemical remaining in import containers is expected to be removed during drum recycling and either destroyed by thermal decomposition, or disposed of to landfill. This is expected to account for a further maximum of 1% of the total annually imported volume. Residual notified chemical remaining in the consumer packaging is expected to account for approximately 2% of the total annually imported volume. This quantity is expected to be disposed of to domestic landfill.

5.6. Public exposure

Since the notified chemical will be in products sold to the general public, widespread public exposure to the notified chemical at a concentration of 0.01% is expected. The frequency of and route of exposure (dermal, ocular and inhalation) will vary depending on the end use product and the method of application.

Since products containing the notified chemical are stored and used in a domestic environment, there is the possibility of accidental ingestion by a child.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa Clear Colourless liquid

Freezing Point < -20ºC

METHOD EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks The test material became increasingly viscous during cooling. Test performed in compliance with GLP standards.
TEST FACILITY Safepharm (2003a)

Boiling Point 230±2ºC at 101.85 to 101.95 kPa

METHOD EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks Determined using the method according to Siwoloboff. Test performed in compliance with GLP standards.
TEST FACILITY Safepharm (2003a)

Density 890 kg/m^3 at 20ºC

METHOD EC Directive 92/69/EEC A.3 Relative Density.
Remarks Determined using a pycnometer. Test performed incompliance with GLP standards.
TEST FACILITY Safepharm (2004a)

Vapour Pressure 0.0022 kPa at 25ºC

METHOD EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks Determined using an isoteniscope system, which has a recommended range of 0.01 to 100 kPa. Measurements were made at several temperatures (218-237°C) and linear regression was used to calculated the vapour pressure at 25°C. Test performed in compliance with GLP standards. With respect to the environment, the notified chemical is classified as volatile (Mensink *et al* 1995). For inhalation exposure considerations, the notified chemical is considered to be of low volatility (European Commission 2003).
TEST FACILITY Safepharm (2004b)

Water Solubility 0.364 g/L at 20ºC

METHOD EC Directive 92/69/EEC A.6 Water Solubility.
Remarks Determined using the flask method with the concentrations determined using high performance liquid chromatography. Test performed in compliance with GLP standards.
TEST FACILITY Safepharm (2003a)

Surface Tension 50.9 mN/m at 21.2 ±0.5ºC

METHOD EC Directive 92/69/EEC A.5 Surface Tension.
Remarks The surface tension result was not corrected using the Harkins-Jordan correction table, as the correction is not applicable to the apparatus used. Once calibrated, the balance and ring assembly used in this test give a direct reading for surface tension that is within the required accuracy (± 0.5 mN/m); this is as a result of the reduced ring dimensions. This deviation has been considered not to have affected the integrity of the study. Test performed in compliance with GLP standards.

The surface tension of a 0.296 g/L solution of test material has been determined to be 50.9 mN/m at 21.2 ± 0.5°C. The test material is considered to be a surface-active material.

TEST FACILITY Safepharm (2004a)

Hydrolysis as a Function of pH

METHOD EC Directive 92/69/EEC C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH.

pH	*T (°C)*	*t½*
4	25	>1 year
7	25	>1 year
9	25	>1 year

Remarks There was < 10% degradation by HPLC analysis in all buffers after 120 hours at 50°C. The linearity of the detector response in respect to concentration was assessed over the nominal concentration range of 0 to 500 mg/L. This was satisfactory with a correlation coefficient of 1.000 being obtained. Test performed in compliance with GLP standards.

TEST FACILITY Safepharm (2004a)

Partition Coefficient (n-octanol/water) log Pow = 4.01 at 30ºC

METHOD EC Directive 92/69/EEC A.8 Partition Coefficient.

Remarks HPLC Method. 0.0554 g of test material was diluted to 100 mL with acetonitrile. The test material eluted between the reference substances Naphthalene and Phenanthrene. Test performed in compliance with GLP standards.

TEST FACILITY Safepharm (2003a)

Adsorption/Desorption log K_{oc} = 2.82 at 30°C

METHOD EC Directive 2001/59/EC C.19 Estimation of the Adsorption Coefficient (Koc) on Soil and on Sewage Sludge Using High Performance Liquid Chromatography (HPLC).

Remarks 0.1025 g test material was diluted to 100 mL with methanol. The test material eluted between the reference substances Naphthalene and Endosufan-diol. Test performed in compliance with GLP standards.

TEST FACILITY Safepharm (2004a)

Dissociation Constant Not determined

Remarks There are no modes of chemical dissociation over the environmentally relevant pH range (4-9).

Particle Size Not applicable

Remarks Notified chemical is a liquid

Flash Point 96±2ºC at 103.01 kPa

METHOD EC Directive 92/69/EEC A.9 Flash Point.

Remarks Determined using a closed cup equilibrium method. The notified chemical is classified as a C1 combustible liquid according to NOHSC *National Code of Practice for the Storage and Handling of Workplace Dangerous Goods* (NOHSC 2001). Test performed in compliance with GLP standards.

TEST FACILITY Safepharm (2003b)

Flammability Limits Not determined

Remarks	Based on the flash point the notified chemical is not classified as flammable according to the Australian Dangerous Goods classification (FORS, 1998).

Autoignition Temperature 234±5ºC

METHOD	92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases).
Remarks	Test performed in compliance with GLP standards
TEST FACILITY	Safepharm (2004b)

Explosive Properties Not predicted to be explosive

METHOD	EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks	There are no chemical groups that would imply explosive properties, therefore the result has been predicted negative.
TEST FACILITY	Safepharm (2004b)

Oxidising Properties Not predicted to have oxidising properties

METHOD	EC Directive 92/69/EEC A.21 Oxidizing Properties (Liquids).
Remarks	There are no chemical groups that would imply oxidising properties, therefore the result has been predicted negative.
TEST FACILITY	Safepharm (2004b)

Reactivity

Remarks	Expected to be stable under normal conditions of use. Excessive heating should be avoided.

7. TOXICOLOGICAL INVESTIGATIONS

The following toxicological studies were conducted on the notified chemical with a ≥ 90% purity.

Endpoint	*Assessment Conclusion*
Rat, acute oral	low toxicity, LD50 > 2000 mg/kg bw
Rat, acute dermal	low toxicity, LD50 > 2000 mg/kg bw
Rat, acute inhalation	not determined
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating
Skin sensitisation – LLNA	no evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days.	NOAEL 500 mg/kg bw/day
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosome aberration test	clastogenic
Genotoxicity – in vivo mouse micronucleus test	non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE Notified chemical

METHOD OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
- Species/Strain: Rat/Sprague-Dawley
- Vehicle: Test substance administered as supplied
- Remarks - Method: No significant protocol deviations. Test performed in compliance with GLP standards.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	3 female	2000	0
II	3 female	2000	0

- LD50: > 2000 mg/kg bw
- Signs of Toxicity: There were no deaths or test substance-related clinical signs or remarkable body weight changes during the study period.
- Effects in Organs: No abnormalities were noted at necropsy.
- Remarks - Results: The LD50 cut-off estimated using the flow chart in Annex 2d of the OECD TG423 would be 5000 mg/kg bw.

CONCLUSION The notified chemical is of low toxicity via the oral route.

TEST FACILITY Safepharm (2003c)

7.2. Acute toxicity – dermal

TEST SUBSTANCE Notified Chemical

METHOD OECD TG 402 Acute Dermal Toxicity – Limit Test.
- Species/Strain: Rat/Sprague-Dawley
- Vehicle: Test substance administered as supplied.
- Type of dressing: Semi-occlusive.
- Remarks - Method: No significant protocol deviations. Test performed in compliance with GLP standards.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5 per sex	2000	0

LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	There were no signs of dermal irritation
Signs of Toxicity - Systemic	There were no deaths or test substance-related clinical signs or remarkable body weight changes during the study period.
Effects in Organs	No abnormalities were noted at necropsy.

CONCLUSION The notified chemical is of low toxicity via the dermal route.

TEST FACILITY Safepharm (2004c)

7.3. Acute toxicity – inhalation

Not determined. The notified chemical is of low volatility and it is used at 0.01% in final end-use products. Hence acute inhalation toxicity is not expected to be of significance.

7.4. Irritation – skin

TEST SUBSTANCE Notified chemical

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.
EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).

Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	Test substance administered as supplied.
Observation Period	72 hours
Type of Dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations. Test performed in compliance with GLP standards.

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	0	n/a	0
Oedema	0	0	0	0	n/a	0

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

CONCLUSION The notified chemical is non-irritating to the skin.

TEST FACILITY Safepharm (2003d)

7.5. Irritation – eye

TEST SUBSTANCE Notified chemical

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).

Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Observation Period	72 hours

Remarks - Method No significant protocol deviations. Test performed in compliance with GLP standards.

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	0.33	0.33	0.33	2	24 hours	0
Conjunctiva: chemosis	0.33	0.33	0.33	2	24 hours	0
Conjunctiva: discharge	0.33	0.33	0.33	3	24 hours	0
Corneal opacity	0	0	0	0	n/a	0
Iridial inflammation	0	0	0	0	n/a	0

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

CONCLUSION The notified chemical is slightly irritating to the eye.

TEST FACILITY Safepharm (2003e)

7.6. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE Notified chemical

METHOD OECD TG 429 Skin Sensitisation: Local Lymph Node Assay
Species/Strain Mouse/CBA:Ca
Vehicle Acetone/olive oil 4:1
Remarks - Method No significant protocol deviations. Test performed in compliance with GLP standards.

Positive control data taken from an earlier study.

RESULTS

Concentration (% w/w)	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance		
0 (vehicle control)	1123.8	n/a
25	1841.0	1.6
50	2930.8	2.6
100	3000.0	2.7
Positive Control (α-hexylcinnamaldehyde)		
5	not provided	2.8
10	not provided	2.3
25	not provided	5.5

Remarks - Results A simulation index of less than three was recorded for all three concentrations tested. There were no deaths or test substance-related clinical signs or remarkable body weight changes during the study period.

CONCLUSION There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical.

TEST FACILITY Safepharm (2003f)

7.7. Repeat dose toxicity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents. EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral).
Species/Strain	Rat/Sprague-Dawley
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 7 days per week Post-exposure observation period: 14 days
Vehicle	Arachis oil BP
Remarks - Method	No significant protocol deviations. Test performed in compliance with GLP standards. Doses selected based on 14 day repeat dose oral range-finding study where animals treated with 750 mg/kg bw/day either died during the study (1/3 males) or sacrificed early (2/3 males, 3/3 females). In the dose-range finding study, males treated with 750 mg/kg bw/day showed patchy pallor of the liver whilst females treated at this dose showed thickening of the non-glandular gastric epithelium.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5 per sex	0	0
II (low dose)	5 per sex	15	0
III (mid dose)	5 per sex	150	0
IV (high dose)	5 per sex	500	0
V (control recovery)	5 per sex	0	0
VI (high dose recovery)	5 per sex	500	0

Mortality and Time to Death

No mortality was observed during the treatment or recovery phases.

Clinical Observations

Increased salivation was detected up to ten minutes after dosing in all group IV animals from day three onwards, regressing completely following cessation of treatment, except in one group IV male on day 28 where increased salivation was observed one hour after dosing. One group IV female also showed increased salivation prior to dosing on day 19. The remaining clinical observations detected were isolated and transient and considered to be of no toxicological importance.

There were no treatment related changes in the behavioural and functional performance parameters measured or sensory reactivity. There was no significant difference in body weight gain and food and water consumption in treated animals when compared to controls.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Clinical Chemistry

A statistically significant increase in total protein was noted in group IV (8%, $P<0.05$) and group VI (6%, $P<0.01$) males compared to their respective controls. No similar effect was observed in females. A statistically significant decrease (20%, $P<0.01$) in aspartate aminotransferase levels was noted in group IV and group VI males compared to their respective controls. No similar effect was observed in females. All other statistically significant differences noted were either due to non-typical control values, only observed in recovery animals or the values were within the historical range, and as such were considered not to be related to the test substance.

Haematology

There were no significant findings in any of the parameters in any of the treated animals.

Urinalysis
There were no significant findings in any of the parameters in any of the treated animals.

Effects in Organs
Organ weight
A statistically significant decrease (20%, P<0.05) in absolute adrenal weight was noted in group IV males compared to controls. No similar effect was noted in relative adrenal weight and as such is considered to have arisen fortuitously. A statistically significant increase in relative kidney weight (21%, P<0.01) was noted in group III and group IV males. No similar effect was noted in the recovery males (group VI) or females. A statistically significant increase in relative liver weight (23%, P<0.001) was noted in group IV males. A similar increase (15%, but not significant) was noted in group IV females. The relative liver weights in the treated recovery group (group VI) were similar to their respective controls. A significant increase in relative testes weight was noted in all treated males (group II (19%, P<0.01), group III (18%, P<0.01), group IV (15%, P<0.05) compare to controls. The relative testes weights in the treated recovery group (group VI) were similar to the respective controls.

Macroscopic Findings
There were no remarkable necropsy findings. The observation of a red lung in one group II male was considered to be incidental.

Histopathology
There were no remarkable histopathological findings. All morphological changes are those commonly observed in rats, and there were no significant differences in the incidence or severity between control and treatment groups.

Remarks – Results
Clinical Observations
The increased salivation observed is often recorded following oral administration of an unpleasant tasting or slightly irritant test material and in isolation, is not considered to be indicative of systemic toxicity.

Clinical Chemistry
The increase in total protein was not biologically significant (<10%), no dose response relationship was present and in the absence of any evidence to suggest dehydration was considered to be of no toxicological importance. Elevated aspartate aminotransferase levels may indicate liver damage. The decrease in aspartate aminotransferase levels is not regarded as toxicologically significant.

Organ Weight
As the increase in relative liver and kidney weight were not accompanied by any histopathological change and appeared to reverse during the recovery phase, this effect may be interpreted as adaptive in nature. The increase in testes weight was not dose related and in the absence of histopathological changes, this increase was considered not to be toxicologically significant.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as 500 mg/kg bw/day in this study, based on the absence of treatment related effects.

TEST FACILITY Safepharm (2005a)

7.8. Genotoxicity – bacteria

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria. Plate incorporation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA$^-$

Metabolic Activation System	S9-Mix from phenobarbitone/β-napthoflavone induced rat liver.
Concentration Range in Main Test	a) With metabolic activation: 15 - 5000 µg/plate b) Without metabolic activation: 15 - 5000 µg/plate
Vehicle	Dimethylsulphoxide
Remarks - Method	No significant protocol deviations. Test performed in compliance with GLP standards. 4-Nitroquinoline-1-oxide was used as the positive control for strain TA98 and N-ethyl-N'—nitro-N-nitroguanidine was used as the positive control for strains TA100 and TS1535.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent	5000 (TA100)			
Test 1		5000 (TA1537, TA98, TA100, WP2uvrA$^-$) 1500 (TA1535)	> 5000	negative
Test 2		5000 (TA1535, TA1537, TA98, TA100) >5000 (WP2uvrA$^-$)	> 5000	negative
Present	5000 (WP2uvrA$^-$)			
Test 1		5000 (TA1535, TA1537, TA98, TA100) >5000 (WP2uvrA$^-$)	> 5000	negative
Test 2		5000 (TA1535, TA1537, TA98, TA100) >5000 (WP2uvrA$^-$)	> 5000	negative

Remarks - Results	The test substance did not cause a marked increase in the number of revertants per plate of any of the tester strains either in the presence or absence of activation. Negative controls were within historical limits. Positive controls confirmed the sensitivity of the test system

CONCLUSION The notified chemical was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY Safepharm (2003g)

7.9. Genotoxicity – in vitro

TEST SUBSTANCE Notified chemical

METHOD *In vitro* Mammalian Chromosome Aberration Test according to the requirements of the Japanese New Chemicals Substance Law.

Species/Cell Line	Chinese Hamster Lung Cells
Metabolic Activation System	S9-Mix from phenobarbitone/β-napthoflavone induced rat liver.
Vehicle	Dimethylsulphoxide
Remarks - Method	No significant protocol deviations from OECD TG 473 *In vitro* Mammalian Chromosome Aberration Test. Test performed in compliance with GLP standards.

The dose range used in the preliminary test was 7.81 to 2000 µg/mL for the six hour exposure group and 7.81 to 187.5 µg/mL for the 24 hour exposure group.

Test 2 (24 hour exposure) was not conducted based on the clear positive result observed Test 1.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period (hours)*	*Harvest Time (hours)*
Absent			
Test 1	0*, 15, 31.25, 62.5*, 93.75*, 125*, 187.5	6	24
Test 2	-	-	-
Present			
Test 1	0*, 7.81, 15.63, 31.25*, 62.5*, 93.75*, 125	6	24
Test 2	-	-	-

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	250	187.5	> 187.5	negative
Test 2	-	-	-	-
Present				
Test 1	62.5	93.75	> 125	positive
Test 2	-	-	-	-

Remarks - Results

In the absence of activation an ideal 50% toxicity was not achieved, the cytotoxicity values provided are the minimum concentration at which there were no metaphases.

The test substance induced a large and statistically significant increase in the frequency of cells with aberrations, in the presence of activation and at the maximum dose level (93.75 µg/mL) selected for metaphase analysis. This DNA damage occurred concurrently with a 26% reduction in cell viability. However, no statistically significant increase in frequency of cells with aberrations, in the presence or absence of activation, was observed at 62 µg/mL (with a 5% reduction in cell viability).

No statistically significant increase in the number of polyploid cells at any dose level was seen either in the absence or presence of activation.

Negative controls were within historical limits. Positive controls confirmed the sensitivity of the test system

CONCLUSION

The notified chemical was clastogenic to chinese hamster lung cells treated in vitro under the conditions of the test.

TEST FACILITY

Safepharm (2005b)

7.10. Genotoxicity – in vivo

TEST SUBSTANCE

Notified chemical

METHOD

OECD TG 474 Mammalian Erythrocyte Micronucleus Test.

	EC Directive 2000/32/EC B.12 Mutagenicity - Mammalian Erythrocyte Micronucleus Test.
Species/Strain	Mouse/Crl:CD-1(ICR)BR
Route of Administration	Intraperitoneal injection
Vehicle	Arachis oil
Remarks - Method	No significant protocol deviations. Test performed in compliance with GLP standards. Test substance administered only once. Doses were selected on the basis of a range-finding toxicity test.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
I (vehicle control 1)	7 male	0	24
II (vehicle control 2)	7 male	0	48
III (low dose)	7 male	150	24
IV (mid dose)	7 male	300	24
V (high dose 1)	7 male	600	24
VI (high dose 2)	7 male	600	48
VII (positive control, CP)	5 male	50	24

CP=cyclophosphamide.

RESULTS

Doses Producing Toxicity	Hunched posture, ptosis, ataxia and lethargy was observed in animals treated with 600 mg/kg bw.
Genotoxic Effects	The test substance did not induce a statistically significant increase in the frequency of micronucleated polychromatic erythrocytes PCE over the levels observed in the vehicle control. There was no statistically significant decrease in the PCE/NCE (normochromatic erythrocytes) ratio, demonstrating that the test substance was not cytotoxic to the bone marrow. Negative controls were within historical limits. Positive controls confirmed the sensitivity of the test system
Remarks - Results	Although no decrease in the PCE/NCE ratio was observed, the observation of clinical signs was taken to indicate that systemic absorption had occurred.

CONCLUSION	The notified chemical was non genotoxic under the conditions of this *in vivo* mouse micronucleus test.
TEST FACILITY	Safepharm (2005c)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE: Notified chemical.

METHOD: OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test.
EC Directive 92/69/EEC C.4-C Biodegradation: Determination of the " Ready" Biodegradability: Carbon Dioxide Evolution Test

Inoculum	activated sewage sludge
Exposure Period	28 days
Auxiliary Solvent	Nil
Analytical Monitoring	pH, temperature, CO_2.
Remarks – Method	The test material, at a concentration of 10 mg C/L, was exposed to activated sewage sludge micro-organisms with culture medium in sealed culture vessels in the dark at 21°C for 28 days. The degradation of the test material was assessed by the determination of carbon dioxide produced. Control solutions with inoculum and the standard material, sodium benzoate, together with a toxicity control were used for validation purposes.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% degradation*	*Day*	*% degradation*
0	0	0	0
10	0	10	69
20	4	20	76
28	15	28	84

Remarks – Results: The total CO_2 evolution in the control vessels on Day 28 was 37.33 mg/L and therefore satisfied the validation criterion in the OECD Test Guidelines.

The inorganic carbon / total carbon ratio of the test material suspension in the mineral medium at the start of the test was below 5% and hence satisfied the validation criterion given in the OECD Test Guidelines.

The difference between the values for CO_2 production at the end of the test for the replicate vessels was <20% and hence satisfied the validation criterion given in the OECD Test Guidelines.

The toxicity control attained 48% degradation after 28 days thereby confirming that the test material was not toxic to the sewage treatment micro-organisms used in the study. Sodium benzoate attained 84% degradation after 28 days thereby confirming the suitability of the inoculum and test conditions. However, the test material only attained 15% degradation.

CONCLUSION: The notified chemical cannot be classed as ready biodegradable.

TEST FACILITY: Safepharm (2003h)

8.1.2. Bioaccumulation

TEST SUBSTANCE: Notified chemical.

CONCLUSION

The n-octanol/water partition coefficient indicates that the notified chemical may bioaccumulate. Sorption to organic matter will not increase the bioaccumulation and biomagnification potential given the low measured K_{OC}.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE

METHOD

OECD TG 203 Fish, Acute Toxicity Test – Semi-static.
EC Directive 92/69/EEC C.1 Acute Toxicity for Fish – Semi-static.

Species	Rainbow Trout (*Oncorhynchus mykiss*)
Exposure Period	96 hours
Auxiliary Solvent	Nil
Water Hardness	100 mg $CaCO_3$/L
Analytical Monitoring	Temperature, pH, dissolved oxygen.
Remarks – Method	Following preliminary range-finding tests, fish were exposed to an aqueous solution of the test material over a range of concentrations for a period of 96 hours at 14°C. There were no reported deviations from the test guidelines.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*3 h*	*6 h*	*48 h*	*72 h*	*96 h*
Control		10	0	0	0	0	0
3.2		10	0	0	0	0	0
5.6		10	0	0	0	0	0
10		10	0	0	0	0	0
18		10	0	0	0	0	0
32		10	10	10	10	10	10

LC50	22 mg/L at 96 hours (95% CI: 16-29 mg/L). (Time Weighted Mean)
NOEC	4.6 mg/L at 96 hours. (Time Weighted Mean)
Remarks – Results	Analysis of freshly prepared test media at 0, 24, 48, and 72 hours, showed measured test concentrations to range from 81-98% of nominal indicating the correct dosing of the test vessels. However, the 24-hour old test media at 24, 48, 72 and 96 hours showed a decline in measured test concentrations with values observed to range from 70-88% of nominal. This decline was considered to be due to possible accumulation in the test organism. Individual data were not provided. The log P_{OW} value was estimated using a computer prediction model (EPIWIN) and gave a value of 3.17 thereby indicating the potential to accumulate on fish tissue. Also the pre-study media preparation trial performed showed no decline in measured concentrations in the absence of fish. The stability analysis performed and the pre-definitive test media preparation trial performed showed the test material to be stable in water over a 24-hour period. Therefore the test was not performed using dynamic, continuous flow test conditions. Given this decline in measure test concentrations over each 24 hour renewal period, it was considered justifiable to base the results on the time-weighted mean measured test concentrations of the test media to

give a "worst case" analysis of the data. The 96-hour LC50 based on the time weighted mean measured test concentrations of the test media was 22 mg/L with 95% confidence limits of 16-29 mg/L. The No Observed Effect Concentration was 4.6 mg/L.

Sub-lethal effects were observed at test concentrations of 10 mg/L and above. These responses were increased pigmentation, swimming at the bottom with increased pigmentation and the presence of moribund fish.

CONCLUSION The notified chemical is harmful to Rainbow Trout (United Nations, 2003)

TEST FACILITY Safepharm (2005d)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test - Static.
EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia - Static.

Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	Nil
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	Temperature, pH, dissolved oxygen.
Remarks - Method	Following a preliminary range-finding test, twenty daphnids (2 replicates of 10 animals) were exposed to an aqueous solution of the test material at concentrations of 1.0, 1.8, 3.2, 5.6, 10, 18, 32, 56 and 100 mg/L for 48 hours at a temperature of approximately 21°C under static test conditions. The test material was dissolved directly in reconstituted water, with the aid of ultrasonification for approximately 60 minutes, prior to dilution. The test material preparations were observed to be clear, colourless solutions throughout the duration of the test.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
Control		20	0	0
1.0		20	0	0
1.8		20	0	0
3.2		20	0	0
5.6		20	0	0
10		20	0	0
18		20	0	15
32		20	12	20
56		20	14	20
100		20	20	20

LC50	16 mg/L at 48 hours (95% CI: 14-17 mg/L)
NOEC	10 mg/L at 48 hours
Remarks - Results	Analysis of the test solutions at 0 hours showed the measured test concentrations to range from 84% to 110% of nominal values. Analysis of the test solutions at 48 hours showed the measured test concentrations to range from 82% to 89% of nominal values with the exception of the 1.0 and 1.8 mg/L test concentrations, which showed measured test concentrations of 67% and 73% of nominal values respectively. Analysis

of frozen duplicate samples of the 48-hour 1.0 and 1.8 mg/L test concentrations were considered to be unnecessary as these concentrations were below the No Observed Effect Concentration. Therefore the results are based on nominal test concentrations only.

CONCLUSION The notified chemical is harmful to Daphnids (United Nations, 2003).

TEST FACILITY Safepharm (2005e)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE

METHOD OECD TG 201 Alga, Growth Inhibition Test.
EC Directive 92/69/EEC C.3 Algal Inhibition Test.

Species	*Scenedesmus subspicatus*
Exposure Period	72 hours
Concentration Range	Nominal: 10, 20, 40, 80, 160 mg/L
Auxiliary Solvent	Nil
Analytical Monitoring	pH, Temperature.

Remarks - Method Following a preliminary range-finding test, algae was exposed to an aqueous solution of the test material at various concentrations, with three replicate flasks per concentration, for 72 hours, under constant illumination and shaking at a temperature of 24± 1°C.

Samples of the algal populations were removed daily and cell concentrations determined for each control and treatment group, using a Coulter® Multisizer Particle Counter.

The test material was suspected to be volatile and hence testing was conducted in completely filled, stoppered test vessels in order to minimise possible losses due to volatilisation. Following the recommendations of published data in order to prevent inhibition of growth due to the restriction of gaseous exchange, additional sodium bicarbonate was added to the culture medium to provide a source of carbon dioxide for algal growth.

RESULTS

Biomass		*Growth*	
EbC50	*NOEC*	*ErC50*	*NOEC*
33 mg/L at 72 h 95% CI: 30-35 mg/L	20 mg/L	63 mg/L at 72 h 95% CI: 53-76 mg/L	20 mg/L

Remarks - Results Analysis of the test preparations at 0 and 72 hours showed measured test concentrations to range from 92% to 112% of nominal. Analysis of a fourth test replicate at 72 hours that had remained unopened throughout the test duration showed measured test concentrations to range from 110% to 121% of nominal indicating that no losses due to volatility occurred. Actual concentrations declined over the time of the test, but individual data are not available.

The pH values of the control cultures were observed to increase from pH 8.3 at 0 hours to pH 9.8 at 72 hours. The pH deviation in the control cultures was equal to 1.5 pH units after 72 hours and therefore was within the limits given in the Test Guidelines. The cell concentration of the control cultures increased by a factor of 63 after 72 hours, which was in line with the OECD Test Guidelines.

CONCLUSION	The notified chemical is harmful to Algae (United Nations, 2003).
TEST FACILITY	Safepharm (2005f)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Notified chemical.
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test. EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test
Inoculum	Activated sewage sludge
Exposure Period	3 hours
Concentration Range	Nominal: 100, 18, 320, 560 and 1000 mg/L (dispersion) Nominal: 38, 68.4, 121.6, 212.8 and 342 mg/L (saturated solution)
Remarks – Method	Following a preliminary range-finding test conducted on the dispersed test material at various concentrations for a period of 3 hours at a temperature of 21°C with the addition of a synthetic sewage as a respiratory substrate. The results from this initial test are of significance in assessing toxicity of the dispersed test material to activated sewage sludge in a treatment facility where the location makes it unlikely that there would be sufficient time for saturation of the test material to occur prior to the test material entering the facility. The activated sewage sludge was also exposed to a saturated solution of the test material at various concentrations for a period of 3 hours at 21°C with the addition of a synthetic sewage as a respiratory substrate. Due to limitations imposed by the requirement to add both inoculum and synthetic sewage to the prepared stock solution, the test concentration of 342 mg/L was the maximum attainable test concentration that could be attained from the stock concentration of 380 mg/L. These results are of significance in assessing the toxicity of the test material to activated sewage sludge in a sewage treatment facility where saturation of the test material in aqueous media is likely to have occurred prior to the test material entering the facility. In each test, the rate of respiration was determined after 20 minutes and 3 hours contact time and compared to data for the control and a reference material, 3,5-dichlorophenol.
RESULTS	
IC50 (dispersion)	470 mg/L
IC50 (saturated solution)	370 mg/L
NOEC (dispersion)	180 mg/L
NOEC (saturated solution)	212.8 mg/L
Remarks – Results	The reference material has a 3-hour EC50 value of 10 mg/L. The validation criteria for the control respiration rates and reference material EC50 values were satisfied. In some instances, the initial and final dissolved oxygen concentrations were below those recommended in the test guidelines. This was considered to have had no adverse effect on the results of the study given that in all cases, the oxygen consumption rate was determined over the linear portion of the oxygen consumption trace. Although the NOEC values were similar in each test, the 30 minutes and 3-hour EC50 values for the test material when dispersed in the test system were higher than when the test material was in solution. This is considered to be due to the test material in the test where the test material was dispersed in the test system not all being in solution so not giving a true EC50 value.

CONCLUSION	The notified chemical is slightly inhibitory to microbial respiration..
TEST FACILITY	Safepharm (2004d)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

With respect to the environment the notified chemical is classified as volatile and some may evaporate from the skin, etc. In moving water, it is estimated to have a half-life of 2.95 days, where as in still water the half-life is estimated to be 37.13 days (EPI Suite, 2000). An atmospheric half-life of 22.9 h has been determined for the reaction with hydroxyl radicals (EPI Suite, 2000). The notified chemical is not expected to hydrolyse in the environmental pH range of 4-9, and it is not readily biodegradable. Due to its high water solubility (364 mg/L) and its adsorption coefficient (log K_{OC}=2.82), the notified chemical is not expected to be highly mobile in soil and sediments.

Relatively minor quantities may potentially be released during formulation, storage, handling and transportation, resulting in discharges to land or aquatic environments. A small amount of wastes containing the notified chemical will go into on-site treatment plants where they are likely to be partially adsorbed on to sludge with some released into sewer after treatment. In landfills, the notified chemical may occur in residues in disposed emptied containers from product use, product formulation and drum recycling facilities. Given the low import volume and the low concentration of the notified chemical in the products, container residues will potentially constitute less than 100 kg of the notified chemical per annum, based on the estimated annual import volume of 5000 kg. Over time, residues of the notified chemical in containers will adsorb to soil or enter the leachate from the landfill but at very low concentrations and in a diffuse manner.

As a worst case, all of the notified chemical in the consumer products will eventually be released into the aquatic environment via the sewerage systems through washing off the skin, hair etc or cleaning activities. The predicted environmental concentration (PEC) in the aquatic environment is estimated, assuming that maximum import volume of 5000 kg of the notified chemical used is discharged into sewerage systems throughout Australia and none is attenuated within these systems. The PEC for river and ocean has been calculated as follows using the Environment Australia (2003) Model:

Amount released per year:	5000.000 kg
No. days of release per year:	365.000
Average daily release:	13.699 kg
Australian Population:	20,100,000.000
Daily water use per person:	200.000 L
Daily effluent Production:	4.020 GL
PEC_{STP}	3.408 µg/L
PEC_{River} (1:1 dilution):	3.408 µg/L
PEC_{Ocean} (1:10 dilution):	0.341 µg/L

While a potential for bioaccumulation is indicated, this is not expected from the proposed low level of import and diffuse use pattern.

9.1.2. Environment – effects assessment

Ecotoxicity data are available for four taxonomic levels, including fish, invertebrate, algae and sewage sludge micro-organisms. The notified chemical is harmful to aquatic organisms, with *Daphnia* being the most sensitive (48 h EC50 = 16 mg/L). A predicted no effect concentration of 0.16 mg/L has been derived using an assessment factor of 100 to account for interspecies sensitivity and other adverse factors that may potentially arise in the environment if organisms are exposed to the notified chemical.

9.1.3. Environment – risk characterisation

	PEC	*PNEC*	*RQ*
River	3.41 µg/L	160 µg/L	0.02
Ocean	0.34 µg/L	160 µg/L	< 0.01

The risk quotient values estimated based on the worst-case scenario of discharging the entire import volume of 1 tonne of the notified chemical into sewage system in Australia are significantly less than 1. Therefore, the proposed use of the notified chemical is unlikely to pose an unacceptable risk to the aquatic environment.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Formulation

Dermal and possibly ocular exposure to the notified chemical could occur during the transfer of the fragrance mixture to the blending vessel. The level of exposure would vary from site to site depending on the level of automation of the formulation process. The estimated dermal exposure is 4.2 mg/day, based on EASE model (EASE) using reasonable worst case defaults for the exposure scenario 'manual addition of liquids' (European Commission, 2003) and assuming the notified polymer is present at concentration of 1%. Therefore, for a 70 kg worker and a 100% dermal absorption factor, systemic exposure is estimated to be 0.06 mg/kg bw/day.

Exposure would be further limited by the use of PPE.

Following formulation of the end use products, exposure to the notified chemical is expected to be very low due to the low concentration of the notified polymer (< 0.01%) and the expected use of PPE.

End use

Workers may be exposed to the notified polymer during final application of the formulated cleaning/cosmetic products or during their addition to water if dilution is required. Although the level and route of exposure will vary depending on the method of application and work practices employed, exposure is considered to be low due to the low concentration of the notified chemical (0.01%).

9.2.2. Public health – exposure assessment

Since the notified chemical will be in products sold to the general public, widespread public exposure to the notified chemical at a concentration of 0.01% is expected. Based on exposure to a range of household, personal care and cosmetic products in Europe (SDA, 2005), public exposure (dermal and inhalation) to the notified chemical through use of a wide range of products containing the notified chemical, is estimated to be 6.1 mg/kg bw/day, assuming a bodyweight of 60kg, a 100% dermal absorption factor, a concentration of 0.01% and that product usage (amount used per use and frequency of use) is similar in Australia to Europe. This estimate is considered to be an overestimate as it assumes all products (household, personal care and cosmetic) used by one person contain the notified chemical and uses the maximum 'product amount used' from the range in the dataset.

Based on exposure to a range of household, personal care and cosmetic products in Europe (SDA, 2005), maximum single product use exposure is expected for the products; fine fragrances, spray antiperspirants, body lotions and hand moisturiser. Exposure to the notified chemical is these products assuming a bodyweight of 60kg, a 100% dermal absorption factor, a concentration of 0.01% and that product usage (amount used per use and frequency of use) is similar in Australia to Europe, is as follows:

Fine fragrances: 1 mg/kg bw/day
Spray antiperspirant: 1.7 mg/kg bw/day
Body lotion: 0.9 mg/kg bw/day
Hand moisturiser: 0.9 mg/kg bw/day

If the notified chemical is used in baby care products, a child's exposure is estimated to be 3.3 mg/kg bw/day assuming a bodyweight of 15kg, a 100% dermal absorption factor, a concentration of 0.01% and that product usage (amount used per use and frequency of use) is similar in Australia to Europe. Since products containing the notified chemical are stored and used in a domestic environment, there is the possibility of accidental ingestion by a child.

9.2.3. Human health – effects assessment

Acute toxicity.
The notified chemical is of low acute toxicity via the oral and dermal routes.

Irritation and Sensitisation.
Based on the studies provided the notified chemical is considered to be non-irritating to the skin, slightly irritating to the eye and considered not to be a potential skin sensitiser.

Repeated Dose Toxicity.
In a 28-day oral repeat dose study in rats, a No Observed Adverse Effect Level (NOAEL) was established as 500 mg/kg bw/day, based on the absence of treatment related effects. A number of clinical signs of toxicity and mortality was observed in rats treated with 750 mg/kg bw/day in a 14-day preliminary study.

Mutagenicity.
The notified chemical was negative in an Ames bacterial reverse mutation test. In an *in vitro* chromosome aberration test in Chinese Hamster Lung Cells the notified chemical induced a large and statistically significant increase in the frequency of cells with aberrations in the presence of activation and at the maximum dose level (93.75 µg/mL). No evidence of genotoxicity was observed following an *in vivo* bone marrow micronucleus test in mice. Based on the weight of evidence and the fact that a clastogenic effect was only observed at cytotoxic concentrations, the notified chemical is not classified as genotoxic.

Hazard classification for health effects.
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 2004).

9.2.4. Occupational health and safety – risk characterisation

Reasonable worst-case exposure to the notified chemical during formulation was estimated to be 0.06 mg/kg bw/day. Based on a NOAEL of 500 mg/kg bw/day, derived from a 28-day rat oral study the margin of exposure (MOE) is calculated as 8300. MOE greater than or equal to 100 are considered acceptable to account for intra- and inter-species differences. Therefore, the risk of systemic effects using modelled worker data is acceptable for formulation workers. Although the notified chemical is a slight eye irritant, at a concentration of < 1%, the risk of an irritation effect is considered to be low.

Following formulation of the end use products, exposure is expected to be very low and as such the risk to workers is also considered to be low.

9.2.5. Public health – risk characterisation

Although the notified chemical is a slight eye irritant at the low concentration present in the consumer products, the risk of an irritant effect from contact with the notified chemical is considered to be low.

Based on a NOAEL of 500 mg/kg bw/day, derived from a 28-day rat oral study the margin of exposure (MOE) from a number of exposure scenarios is calculated as follows:

Product(s) used	*Adult/Child*	*Estimated Exposure <mg/kg bw/day>*	*MOE*

Wide range of household, personal care and cosmetic products.	Adult	6.1	82
Fine Fragrance	Adult	1	500
Spray antiperspirant	Adult	1.7	294
Body lotion	Adult	0.9	555
Hand moisturiser	Adult	0.9	555
Baby care products	Child	3.3	152

MOE greater than or equal to 100 are considered acceptable to account for intra- and inter-species differences. As the exposure from use of a wide range of household, personal care and cosmetic products is expected to be an overestimate of exposure (see section 9.2.2)and all other calculated MOE are > 100, the risk to public health is considered to be low.

Since products formulated with the notified polymer will be stored and used in a domestic environment, there is also the possibility for children to be exposed to the notified polymer by accidental ingestion. However, as the notified polymer is considered to be of low acute toxicity and given the low concentration of the notified chemical in the formulated products, the risk of lethal effects as a result of accidental ingestion 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 hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

and

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

	Hazard category	***Hazard statement***
Chronic hazards to the aquatic environment	3	Harmful to aquatic environment with long lasting effects

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio the chemical is not considered to pose a risk to the environment based on its reported use pattern.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

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

10.3.2. Public health

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

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

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

11.2. Label

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

12. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

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

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

- A copy of the MSDS should be easily accessible to employees.

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

Disposal

- The notified chemical should be disposed of by incineration or to landfill

Emergency procedures

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

12.1. Secondary notification

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

(1) Under Section 64(1) of the Act; if
  - the concentration of the chemical as introduced or in the final consumer products has increased, or is likely to increase significantly;

or

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

The Director will then decide whether secondary notification is required.

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