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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Vivaldie

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Street Address:	334 - 336 Illawarra Road MARRICKVILLE NSW 2204, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 8577 8888.
Website:	www.nicnas.gov.au

Director

Chemicals Notification and Assessment

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
International Flavours and Fragrances Australia Ltd.
301 Frankston-Dandenong Road
Dandenong South
Victoria 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: flammability limits and autoignition temperature.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
US EPA: PMN P01-930 (International Flavors and Fragrances)
EC - Spain: VIIB 2002 (International Flavors and Fragrances)
Environment Canada: December 2002

2. IDENTITY OF CHEMICAL

CHEMICAL NAME
3-Hexene, 1-[(2-methyl-2-propenyl)oxy]-(3Z)

OTHER NAMES
(Z) -3–Hexenyl 2-methylallyl ether
1-(2-methyl-allyloxy)-hex-3-ene

MARKETING NAME(S)
Vivaldie

CAS NUMBER
292605-05-1

MOLECULAR FORMULA
$C_{10}H_{18}O$

STRUCTURAL FORMULA

MOLECULAR WEIGHT
154

SPECTRAL DATA

ANALYTICAL METHOD	NMR
Remarks	^{1}H, 5.30-5.50, 4.96, 4.87, 3.88, 3.36-3.43, 2.30-2.40, 2.01-2.12, 1.74, 0.94-0.97 ppm.
TEST FACILITY	IFF

ANALYTICAL METHOD	UV
Remarks	Solvent: 10%(v/v) 0.1 H_2O/Methanol (pH 7) λmax = 199 nm, ε = 2601.33 $Lmol^{-1}cm^{-1}$ Solvent: 10%(v/v) 0.1 N HCl/Methanol (pH 2-3 approximately) λmax = 199 nm, ε = 3990.85 $Lmol^{-1}cm^{-1}$ Solvent: 10%(v/v) 0.1 N NaOH/Methanol (pH 9-10 approximately) λmax = 205 nm, ε = 364.45 $Lmol^{-1}cm^{-1}$
TEST FACILITY	IFF

ANALYTICAL METHOD	IR
Remarks	3076-2857 (broad), 1478-1458, 1454, 1104 cm^{-1}.
TEST FACILITY	IFF

METHODS OF DETECTION AND DETERMINATION

ANALYTICAL METHOD	Gas chromatography
Remarks	IE value (CBW/OV1): 0.927(99%) OV1 column: 50m x 0.32 mm x 0.5 µm fused silica bonded methyl silicone CBW column: 50m x 0.32 mm x 0.3 µm fused silica nonbonded methyl silicone Temperature program: 75 to 225 degrees @ 2 degrees/minute.
TEST FACILITY	IFF

3. COMPOSITION

DEGREE OF PURITY
98.5% Typical, 98.0% - 99.0% Range

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None identified.

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

Chemical Name	2-methyl-2-propene-1-ol		
CAS No.	513-42-8	*Weight %*	1.5% Typical 1-2% Range

ADDITIVES/ADJUVANTS
None

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
Imported as part of a finished fragrance oil (2% maximum) or in end-use consumer products at concentrations ranging from 0.01 to 0.1%.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	1	1	1	1	1

USE
Vivaldie will be used as an odorant in alcoholic perfumery, cosmetics, toiletries, household products, soaps and detergents. The concentration of Vivaldie in a finished fragrance oil is a maximum of 2%. The resulting concentration of Vivaldie in end-user consumer products is 0.01-0.1%. Typical products at the high end of the concentration range (0.1%) are colognes and deodorant sprays. Typical products at the low end of the concentration range (0.01%) are body lotions, creams and shampoos.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
International Flavours and Fragrances (Australia), Pty Ltd. (IFF)

TRANSPORTATION AND PACKAGING
Vivaldie will be imported into Australia as a component of finished fragrance oils at up to 2% in sealed, polypropylene lined steel drums (208 litres) or as a component of a finished consumer products in standard consumer packagings. Vivaldie will be transported from the docks by road to the notifiers warehouse. The finished fragrance oil will then be transported to customers, typically by road, when needed. The finished consumer product containing the fragrance oil at up to 0.1% will be transported to retail stores for distribution.

5.2. Operation Description

The drummed fragrance oil will be sold by the importer to the cosmetic and household products industry. The production process, mainly involving a blending operation, will be highly automated and will often occur in a fully enclosed environment. Plant operators will only be involved in opening and closing drums, weighing and charging the mixing vessel, and cleaning and maintenance tasks. Waste will generally be disposed of by incineration or through a wastewater treatment plant prior to release to the environment.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Transport and Warehouse workers	5	None	Incidental Exposure only

<u>Plant operators</u>

Mixer	5	4 hr/day	2 days/year
Drum handling	5	4 hr/day	2 days/year
Drum cleaning/washing	10	4 hr/day	2 days/year
Maintenance	5	4 hr/day	2 days/year
Quality control worker	2	0.5 hr/day	2 days/year
Packager	10	4 hr/day	2 days/year

Exposure Details

At the IFF facility, transport and warehouse workers will be exposed to the 2% fragrance oil only in the event of a spill due to an accident or leaking drum. Workers will wear protective overalls, hard hats, chemical resistant gloves and safety glasses.

During formulation into consumer products, the number and category of workers will vary depending on the nature of the customer's business. However, it is anticipated that typical practices by cosmetic and consumer product manufacturers will include the use of local exhaust ventilation, enclosed mixing vessels and filling areas, and appropriate PPE. It is expected that some but not all formulation plant would have fully automated systems.

At customer facilities (cosmetic and consumer product manufacturers), exposure is possible during handling of the drums, weighing and transfer of the fragrance oil, quality control processes and cleaning and maintenance of the equipment. Skin, inhalation and eye contact (due to splashing) are likely to be the main routes of exposure. Good personal hygiene practices (eg. wash hands after any contact, before breaks and meals, etc) and industrial standard PPE will be used. The plant will have ventilation and self-contained breathing apparatus if required. The production process will be in compliance with good manufacturing practices, including the availability of eyewash fountains and/or safety showers in the vicinity of the blending areas.

Only workers qualified and trained in the safety of working with chemicals and chemical mixtures will be permitted to handle the Vivaldie mixtures. A copy of the MSDS will be easily accessible to employees. Employees will routinely undergo medical surveillance every two years.

Once perfume oils containing Vivaldie have been incorporated into consumer products, the maximum concentration of Vivaldie in the products will be 0.1%, and any further occupational exposure as a result of accidental contact with the products would be very low. Laboratory technicians and maintenance workers may be exposed to the products, and would normally employ personal protective equipment and good working practices, in order to minimise exposure to all ingredients of the products.

5.4. Release

RELEASE OF CHEMICAL AT SITE

At formulation sites, it is expected that less than 1% per annum of the notified chemical will remain in the empty import containers, which are likely to be rinsed, and the rinsate either added into the production of the next batch or released into the sewer. The cleaned import containers will either be recycled or disposed of to landfill. Release to the environment during reformulation and cleaning processes are expected to be small as closed, automated systems are used, and will total less than 1% per annum of the notified chemical. Wastes from these processes will be disposed generally to sewer but if in a solid state may go to landfill.

RELEASE OF CHEMICAL FROM USE

Since the notified chemical will be used in household, laundry and personal cleaning products, up to 97% per annum is expected to be released to sewer. The release from the chemical remaining in the consumer product containers is expected to be in low amounts (less than 1% annually). These containers, which will vary in size and construction material, will be disposed of into domestic rubbish and ultimately landfill. The material of construction of these containers may be glass, plastic, metal or paperboard.

5.5. Disposal

The notified chemical will ultimately be disposed of in either the sewer (major) or landfill. The

emptied imported drums may potentially be rinsed and re-used, sent to a recycler, or sent to landfill for disposal. Drum rinse waters may be reused, discharged to an on-site wastewater treatment plant and/or the sewer. Following use, emptied product containers are expected to be disposed of through domestic garbage disposal from where they will enter landfill or a recycling program.

5.6. Public exposure

The main source of public exposure would be through consumer use of household and cosmetic products containing the notified chemical at up to 0.1%. The range of consumer products in which Vivaldie may be used is varied, including cosmetics, perfumery and personal cleaning products, as well as household and laundry products. Exposure will be mainly by skin contact, with personal products either washed off after use, or left on the skin. Inhalation exposure may also occur, and is expected to be higher through use of spray products or those where the perfume volatilises quickly.
Inadvertent public exposure to perfume oils containing Vivaldie at up to 2% could occur in case of accidents in transport.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa Clear to yellow liquid

Melting Point/Freezing Point < -76°C

METHOD By gradual cooling to -76 °C
Remarks The test material was cooled for several hours and it was demonstrated that Vivaldie did not become a solid and remained fairly mobile at -76 °C for several hours.
TEST FACILITY IFF R&D Facility (2000)

Boiling Point 64.1 – 184.1°C at 101.3 kPa

METHOD OECD TG 103 Boiling Point.
EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks Sample tested had purity of 98.91%. Results corrected to compensate for small variation from standard in atmospheric pressure. Dry point reported as 56.8°C. It is noted that the boiling point range is wide, considering the relatively high purity of the sample. It is possible that decomposition occurred during testing and/or that there are small quantities of low-boiling impurities in the material. The identified impurity 2-methyl-2-propene-1-ol has a reported boiling point of 114°C (Chemfinder 2003) and therefore does not account for the low initial boiling point of 64.1°C.
TEST FACILITY Bioevaluation Consultants (2001a)

Boiling Point 126°C at 7.45 kPa

METHOD Internal IFF test. The distillation flask containing 500 g Vivaldie and 15 g Primol was slowly heated to 150°C under vacuum at 51 mm Hg to give 490 g of Vivaldie, b.p. 126°C/56mm..
Remarks Carried out under reduced pressure, and thus cannot be directly related to test above. The notifier calculates that this reduced pressure boiling point would be equivalent to a boiling point of 210°C at atmospheric pressure.
TEST FACILITY IFF R&D Facility (2003a) Boiling Point, A. Narula, Fragrance Synthesis.

Boiling Point Estimated 193.1±19.0°C at 101.3 kPa

Remarks Calculated using-Advanced Chemistry Development (ACD) Software Solaris V4.76. Accessed via Chemical Abstracts Service (2003):

Density 818 kg/m^3 at 25°C

METHOD EC Directive 92/69/EEC A.3 Relative Density.
Remarks Test documentation not supplied.
TEST FACILITY IFF R&D Facility (2003b)

Vapour Pressure 0.01 kPa at 25°C .

METHOD EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks Test documentation not supplied. This experimentally obtained value is lower than the modelled value below.

This result indicates that the chemical is volatile (Mensink et al, 1995).
TEST FACILITY IFF R&D Facility (2003b)

Vapour Pressure 0.088 kPa at 25°C .

Remarks Calculated using-Advanced Chemistry Development (ACD) Software Solaris V4.76. Accessed via Chemical Abstracts Service (2003):

This result indicates that the chemical is volatile (Mensink et al, 1995).

Water Solubility 0.078 g/L at 20°C

METHOD EC Directive 92/69/EEC A.6 Water Solubility.
Remarks Analytical Method: Shake flask and gas chromatography.

Three light protected bottle flasks were set up with a measured amount of test material (Vivaldie), approximately 0.5 g, and 100 mL of distilled water. They were placed in a water bath at 30°C and shaken. The first flask was shaken for 24 hours and then removed, the second for 48 hours and the third for 72 hours. When removed from the 30°C bath the flasks were put in a 20°C bath and stirred for a further 24 hours, after which an aliquot was taken from each flask and analysed by GC/FID.

This result indicates that the test material is moderately soluble in water (Mensink et al 1995).
TEST FACILITY Centre International de Toxicologie, (2001a).

Hydrolysis as a Function of pH Not conducted

Remarks Vivaldie is not expected to hydrolyse as there are no hydrolysable groups.

Partition Coefficient (n-octanol/water) log Pow at 20°C = 4.09

METHOD EC Directive 92/69/EEC A.8 Partition Coefficient.
OECD TG 117.
Remarks Analytical Method: HPLC

The test material and a selection of reference substances were dissolved in the mobile phase (methanol and Milli-Q water). All injections were done in duplicate, with the calibration substrances eluting before and after the test material.

This result indicates that the chemical is hydrophobic.
TEST FACILITY Centre International de Toxicologie, (2001b).

Adsorption/Desorption Estimated log K_{oc} = 2.16 at 20°C.

METHOD PCKOC, EPIWIN Estimation Package
Remarks A computer model (PCKOCWIN V1.66) was used to estimate K_{oc}. The estimation is based on the chemical structure and the molecular weight.

This result indicates that the notified chemical would have high to very high mobility in soil or sediments (McCall et al, 1981).

Dissociation Constant Not Conducted

Remarks Vivaldie is stable in water and is not subject to decomposition or dissociation.

Particle Size Not applicable as notified chemical is liquid.

Flash Point 59°C at 101.3 kPa

METHOD EC Directive 92/69/EEC A.9 Flash Point.
Remarks
TEST FACILITY Bioevaluation Consultants (2001b)

Flammability Limits Not determined.
Chemical will not be available in pure form, but will be introduced at up to 2% in perfume oils.

Autoignition Temperature Not determined.
Estimated by notifier to be above 210^0C.

Explosive Properties Not expected to be explosive.

METHOD Estimated by Calculation
Remarks Based on an assessment of the chemical structure and the oxygen balance using the following calculation, the explosivity of Vivaldie is predicted to be negative. Oxygen balance = [-1600(2X +Y/2-Z)]/MW = -290 where X = number of carbon atoms, Y = number of hydrogen atoms, Z = number of oxygen atoms and MW = the molecular weight. Lothrop and Handrich (1949)

Reactivity Expected to be stable.

Remarks No test results submitted. Notifier states that Vivaldie is expected to be stable in water and air under normal conditions of temperature and pressure. IFF R&D Facility (2003b)

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint	*Assessment Conclusion*
Rat, acute	Low: oral LD50 > 2000 mg/kg bw
Rat, acute dermal LD50	Not tested
Rat, acute inhalation LC50	Not tested
Rabbit, skin irritation	moderately irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation - adjuvant test.	limited evidence of sensitisation.
Human repeated insult patch test	no evidence of sensitisation
Repeat dose toxicity.	Not tested
Genotoxicity - bacterial reverse mutation	non mutagenic
Genotoxicity – in vivo	Not tested
Pharmacokinetic/Toxicokinetic studies	Not tested
Developmental and reproductive effects	Not tested
Carcinogenicity	Not tested

7.1. Acute toxicity – oral

TEST SUBSTANCE Notified chemical 98.1% purity

METHOD	OECD TG 401 Acute Oral Toxicity – Limit Test. EC Directive 92/69/EEC B.1 Acute Toxicity (Oral) – Limit Test.
Species/Strain	Rat/Sprague-Dawley ICO:OFA-SD (IOPS Caw)
Vehicle	None
Remarks - Method	None

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 Male	2000	0
2	5 Female	2000	0

LD50	> 2000 mg/kg bw
Signs of Toxicity	There were no deaths following the administration of a single oral dose of Vivaldie at 2000 mg/kg bodyweight. There were no signs of systemic toxicity. All animals showed expected gains in body weight over the study period. No abnormalities were noted at necroscopy. Sedation and piloerection was observed in 4/5 males and 5/5 females on day 1 only.
Effects in Organs	Terminal autopsy revealed no macroscopic lesions.
Remarks - Results	None
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	Centre International de Toxicologie (2001c)

7.4. Irritation – skin

TEST SUBSTANCE	Notified chemical 98.91% purity
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 male
Number of Animals	Three
Vehicle	None
Observation Period	15 days
Type of Dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations. The pH of the notified chemical was measured to be approximately 4. An additional test was carried out on one animal, with 3 minutes exposure to the notified chemical on one flank.

RESULTS: 4 H EXPOSURE

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	1.7	2.0	2.0	2.0	> 15 days	1
Oedema	0	0	0	0	-	0

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

RESULTS: 3 MINUTES EXPOSURE

Lesion	*Mean Score* Animal No.*	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1			
Erythema/Eschar	1.7	2	6 days	0
Oedema	0	0	0	0

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

Remarks - Results

After a 3-minute exposure on one animal, a very slight or well-defined erythema (grade 1 or 2) was observed from day 2 to day 6. A dryness of the skin was also noted from day 5 to day 13.

After a 4-h exposure on three animals, a very slight or well-defined erythema was noted in all animals from day 1, persisting to day 6, 10 or to the end of the observation period in the different animals. A dryness of the skin was noted in all animals from day 5, persisting to day 13 (one animal) or to the end of the observation period (2 animals).

CONCLUSION

The notified chemical is moderately irritating to skin.

TEST FACILITY

Centre International de Toxicologie (2001d)

7.5. Irritation - eye

TEST SUBSTANCE

Notified chemical, 98.91% purity

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 male
Number of Animals: Three
Observation Period: 5 days
Remarks - Method: No significant protocol deviations. The pH of the notified chemical was measured to be approximately 4.

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	1	0	1	4 days	0
Conjunctiva: chemosis	0	1	0	1	4 days	0
Conjunctiva: discharge	0	0	0	0	0	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

The 1 h observation was masked in all animals by residual test substance.

CONCLUSION

The notified chemical is slightly irritating to the eye.

TEST FACILITY

Centre International de Toxicologie (2001e)

7.6. Skin sensitisation

TEST SUBSTANCE

Notified chemical 98.91% purity

METHOD	OECD TG 406 Skin Sensitisation - GPMT EC Directive 96/54/EC B.6 Skin Sensitization - GPMT.
Species/Strain	Guinea pig/Hartley Crl: (HA) BR
PRELIMINARY STUDY	Maximum Non-irritating Concentration: intradermal: < 1% w/w topical: 50% w/w
MAIN STUDY	
Number of Animals	Test Group: 10 males, 10 females Control Group: 5 males, 5 females
INDUCTION PHASE	Induction Concentration: intradermal injection 10% in corn oil topical application 50% in 80/20 ethanol/water
Signs of Irritation	No information supplied
CHALLENGE PHASE	
1st challenge	topical application: 50% w/w in acetone
2nd challenge	topical application: not conducted
Remarks - Method	For topical induction, skin was pretreated on day 7 with 10% sodium lauryl sulfate in vaseline. No data was presented on the effects on skin on induction, to confirm the irritation potential identified in the pre-testing.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*				
		1st challenge			*2nd challenge*	
		24 h	*48 h*	*72 h*	*24 h*	*48 h*
Test Group	50% in acetone	0	2/20	2/20	-	-
					--	-
Control Group		0	0	1/10	-	-
					-	-

Remarks - Results	In the control group, a discrete erythema and dryness of the skin was noted in 1/10 animals. In the treated group a discrete erythema was noted in 2/20 animals at 48 h and 72 h. At 72 h dryness of the skin was noted in these 2 animals and in a further 6/20 animals. As the cutaneous reactions were present in treated and control groups at a similar low incidence, they may not be indicative of sensitisation.
CONCLUSION	There was limited evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	Centre International de Toxicologie (2001f)

7.8. Genotoxicity - bacteria

TEST SUBSTANCE	Notfied chemical of 98.91% purity
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 for Test 1 with and without S9, and for Test 2 without S9. Pre incubation procedure for Test 2 with S9 only.
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100, TA102. *E. coli*: WP2 uvrA.
Metabolic Activation System	S9 fraction from rats induced with Aroclor 1254.

Concentration Range in Main Test	a) With metabolic activation: 31-5000 µg/plate, depending on the strains used. b) Without metabolic activation: 31-2500 µg/plate, depending on the strains used..
Vehicle	DMSO
Remarks - Method	No significant protocol variations

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in PreliminaryTest	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	≥ 500 µg/plate	≥ 125 µg/plate	none	negative
Test 2	-	≥ 62 to 312 µg/plate, depending on strain	none	negative
Present				
Test 1	≥ 500 or 2500 or 5000 µg/plate, depending on strain	≥ 250 or 625 µg/plate, depending on strain.	5000 µg/plate	negative
Test 2 (preincubation)	-	≥ 125 to > 500 µg/plate, depending on strain.	> 500 µg/plate	negative

Remarks - Results	Toxicity was observed at lower doses in pre-incubation method (Test 2). The test substance did not cause a marked increase in the number of revertants per plate pf any of the tester strains either in the presence or absence of microsomal enzymes prepared from Aroclor 1254 induced rat liver (S9). Negative controls were within historical controls. 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	Centre International de Toxicologie (2001g)

ADDITIONAL INVESTIGATIONS

7.13T. Skin sensitisation – human volunteers

TEST SUBSTANCE	Notified chemical at 0.5%
METHOD	Human Repeated Insult Patch Test /Adaptation of Draize Patch Test.
Study Design	Approximately 0.2 mL of the test article was placed on an occlusive patch and applied to skin of each subject. A control substance of distilled water in the vehicle was also tested on each subject. After 9 applications and a rest period of 14 days, a challenge patch was applied to a new site. Scoring of the effects on skin were carried out immediately before each induction application, and at 24, 48 and 72 h after challenge.
Study Group	115 subjects, 17 males and 98 females ranging in age from 18 to 69 years at beginning of study. 109/115 subjects completed the test.
Vehicle	75:25 Alcohol SD39C:Diethyl phthalate
Induction Procedure	The test substance was applied to the back of each subject for 24 h. The test was repeated on each Monday, Wednesday and Friday until 9 applications had been made. Controls using vehicle only were also tested simultaneously on each subject.
Rest Period	14 days
Challenge Procedure	Application of sample to a previously unpatched site.
Remarks - Method	The test article was volatilised at least 30 minutes but less than 90 minutes on the patch prior to application to the skin.
RESULTS	
Remarks - Results	Neither the sample nor the control produced any reaction in the subjects.
CONCLUSION	A human repeat insult patch test was conducted using the notified chemical at diluted with 75:25 alcohol:diethyl phthalate to 0.5% under occlusive dressing. The notified chemical was non-irritating and non-sensitising under the conditions of the test.
TEST FACILITY	Essex (2001)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	Vivaldie
METHOD	OECD TG 301 F Ready Biodegradability: Manometric Respirometry Test.
Inoculum	Activated sludge from Eye Sewage Treatment Works, which predominantly treats domestic sewage.
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Manometric electrolytic cells. A potassium hydroxide trap was used to absorb any carbon dioxide produced during degradation.
Remarks - Method	The reference substance was sodium benzoate. The dilution water was purified, softened tap water with measured amounts of minerals and salts solutions. Treatments: - 1 and 2: dilution water and inoculum,

- 3: dilution water, inoculum plus reference substance,
- 4 and 5: dilution water, inoculum plus test substance,
- 6: dilution water, inoculum plus reference substance and test substance,
- 7: Ultrapure water and test substance,
- 8: Ultrapure water only

RESULTS

Test substance		*Reference Substance- Sodium benzoate*	
Day	*% degradation*	*Day*	*% degradation*
5	0	5	67.0
15	0	15	76.6
28	0	28	86.2

Remarks - Results: The validity of the study was confirmed since the inoculum control's oxygen consumption was below 60 mgO_2. The oxygen consumption of the inoculum control was 17.6 mgO_2, which is slightly less than the normal range of 20-30 mgO_2, but is acceptable.

CONCLUSION: The notified chemical is not readily biodegradable, since it did not reach 60% degradation or greater.

TEST FACILITY: Huntingdon Life Sciences Ltd (2001)

8.1.2. Bioaccumulation

The notified substance is not readily biodegradable and will be totally discharged to water. The estimated partition co-efficient is 4.09 (log K_{ow}), and the notifer has calculated a bioaccumulation factor (BCF) using the EPIWIN BCF Program (v2.14) is 281.4, which indicates the notified chemical has a moderate potential for bioaccumulation. However, using the US EPA's PBT Profiler model (www.pbtprofiler.net), which makes estimations based on the chemical's structure, it was indicated that it is not anticipated to bioaccumulate (BCF 140). It should be noted that this value was determined using an estimated water solubility of 50 mg/L and logK_{ow} of 3.7 at 25°C.

8.2. Ecotoxicological investigations

The following fish, Daphnia and algae ecotoxicity results were estimated using USEPA's ECOSAR program as a vinyl/allyl ether, while a complete study of the inhibition of microbial activity was undertaken.

8.2.1. Acute toxicity to fish

TEST SUBSTANCE: Vivaldie

METHOD: Estimated by calculation using USEPA's ECOSAR program
- Species
- Exposure Period: 14-day
- LC50: 3.132 mg/L at 14 days (estimated).

CONCLUSION: The notified chemical is estimated to be toxic to fish.

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE: Vivaldie

METHOD: Estimated by calculation using USEPA's ECOSAR program

Species	*Daphnid*
Exposure Period	48 hours
LC50	1.016 mg/L (estimated)
CONCLUSION	The notified chemical is estimated to be toxic to *Daphnia magna*.

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	Vivaldie
METHOD	Estimated by calculation using USEPA's ECOSAR program
Exposure Period	96- hours
Remarks – Results	The EC50 was 0.642 mg/L (estimated).
CONCLUSION	The notified chemical is estimated to be very toxic to green alga.

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Vivaldie,
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test. EC Directive 87/302/EEC C.4 Activated Sludge Respiration Inhibition Test.
Inoculum	A mixed population of activated sewage sludge micro-organisms
Exposure Period	3 hours
Concentration Range Nominal	1, 3.16, 10, 31.6 and 100 mg/L
Remarks – Method	Water hardness: 280±20 mg $CaCO_3$/L. Two controls: activated sludge and dechlorinated water solution. Reference substance: 3,5-Dichlorophenol at 4, 12 and 36 mg/L.
RESULTS	
IC50	> 100 mg/L
NOEC	100 mg/L
Remarks – Results	The EC_{50} of the reference substance was 12.6 mg/L. Since the reference substance EC_{50} is in the range 5-30 mg/L and the respiration rates on the two controls are within 15% of each other, the study was valid. 100 mg/L was the highest test concentration that could be prepared due to the water solubility of the test substance.
CONCLUSION	The IC50 indicates that the notified chemical does not inhibit respiration of microbial populations.
TEST FACILITY	Centre International de Toxicologie, 2001h.

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified chemical is moderately volatile, therefore it will dissipate into air from the surfaces to which the products containing the fragrance oil is applied (eg. skin, aquatic and terrestrial environments). The notified chemical is not expected to hydrolyse in the environmental pH range 4 to 9, and it is not readily biodegradable. Due to its moderate water solubility (0.078 g/L) and its adsorption coefficient (est. log K_{oc}=2.16) the notified chemical will be highly mobile in soil and sediments.

Relatively minor quantities may potentially be released during formulation, storage, handling and transportation, (eg. uncontained spills and leaks) resulting in discharges to land or aquatic environments. A small amount of wastes containing the notified chemical will be generated

during the production of end-user products. Generally, these wastes will go into on-site treatment plants where they are unlikely to adsorbed on to sludge but rather will be 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 fragrance oil, container residues may potentially constitute less than 10 kg of the notified chemical per annum. Over time, residues of the notified chemical in containers will enter the leachate from the landfill but at very low concentrations and in a diffuse manner.

All of the notified chemical in the cosmetic and cleaning 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 using a worst-case scenario, assuming that all 1000 kg of the notified chemical used is discharged into sewerage systems throughout Australia and none is attenuated within these systems.

Amount released	1000 kg
Australian population	19.5 million people
Average daily water consumption per person	200 L
Days in year	365
$PEC_{(STP)}$	1 000 000 000 / (19500 000 x 200 x 365) = 7.02×10^{-4} mg/L = 0.7 µg/L
Dilution factor inland	1
Worst case $PEC_{(inland)}$	0.7 µg/L
Dilution factor marine	10
Worst case $PEC_{(marine)}$	0.07 µg/L

The biodegradability test results indicated that the notified chemical was not readily biodegradable. The results obtained using the SIMPLETREAT model (European Commission 1996) for modelling partitioning and losses in sewage treatment plants (STP) using molecular weight (154 g/mole), vapour pressure (10 and 88 Pa) and water solubility (78 mg/L), indicated the following partitioning:

- to air 12%
- water 68%, and
- to sludge 20%.

It also indicated that there would be no degradation in the plant and 32% would be removed from influent/water.

This indicates that 68% of the notified chemical has the potential to remain in the STP effluent when released to the natural water body. Thus the above $PEC_{(inland)}$ and $PEC_{(marine)}$ can be refined to give potential $PEC_{(inland)}$ of 0.5 µg/L and $PEC_{(marine)}$ 0.05 µg/L.

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m^2/year (10 ML/ha/year). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 0.1 m of soil (density 1000 kg/m^3). Using these assumptions, irrigation with a concentration of 7×10^{-1} mg/L, under worst case scenario, may potentially result in a soil concentration of approximately 7×10^{-2} mg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 0.35 mg/kg and 0.7 mg/kg, respectively.

While a potential for bioaccumulation is indicated, this is not expected from the proposed low level of import and diffuse use pattern. Calculations based on its water solubility and partition co-efficient confirm this low potential.

9.1.2. Environment – effects assessment

The estimated aquatic toxicity data are as follows: toxic to fish and Daphnia, very toxic to algae.

Using the lowest end point (ie. EC_{50} value of 0.642 mg/L for green algae), a predicted no effect

concentration (PNEC - aquatic ecosystems) of 6.42 x 10^{-4} mg/L (0.6 μg/L) has been derived by dividing the EC_{50} value by a worst-case scenario uncertainty (safety) factor of 1000, since only estimated data are available for three trophic levels.

9.1.3. Environment – risk characterisation

Location	PEC	PNEC	Risk Quotient (RQ)
Australia-wide STPs			
Ocean outfall	0.07 μg/L	0.6 μg/L	0.12
Inland River	0.7 μg/L	0.6 μg/L	1.2

The risk quotient values estimated based on the worst-case scenario of discharging the entire amount of the notified chemical imported into sewage systems in Australia are less than 1, except for an inland river where it is slightly above 1. However, it is very unlikely that all of the notified chemical will be discharged into an inland river. The risk will be reduced by the likely removal during treatment in STPs (as shown above), indicating a RQ of 0.83. Therefore, the proposed use of the notified chemical is unlikely to pose an unacceptable risk to the aquatic life.

However, due to the toxic nature of the notified chemical, if import quantities increase above 1 tonne, then the risk characterisation should be re-examined with measured test results for toxicity.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

The notified chemical will be imported into Australia at up to 2% of finished fragrance oils in sealed 208 litre containers, which are transported to the notifier's warehouse by road, and later to the formulation plants. Waterside, transport and warehouse workers are unlikely to be exposed unless the containers are damaged.

Fragrance oil containing up to 2% of the notified chemical will be incorporated into the final consumer products (alcoholic perfumery, cosmetics, toiletries, household products, soaps, and detergents) at formulation plants. The final consumer products will contain approximately 0.01 to 0.1 % of the notified chemical. At each plant there is potential exposure of workers to the fragrance oil and/or the final product during formulation, which may occur for up to 4 h per day, on 2 days per year. Dermal, inhalation or ocular exposure may occur during weighing and transfer of the fragrance oil to the mixer, quality control sampling and packaging of the final consumer product. It is expected that coveralls, gloves and safety glasses will be worn by workers during formulation, the formulation area will be well ventilated, and some processes will be fully automated. Dermal and ocular exposure would be reduced by good hygiene and use of PPE.

The volatility of the notified chemical has not been clearly characterised, with inconsistencies between measured and calculated data for both vapour pressure and boiling point, and a measured boiling point temperature range wider than the purity of the chemical would suggest. It is possible that the material contains some low boiling point components. The estimated vapour pressure of 0.01 to 0.1 kPa indicates that inhalation exposure could occur, especially in any formulation process involving heating above ambient temperature. However inhalation exposure would be reduced by the low concentration in the imported fragrance oil (≤ 2%) and even lower concentration in the finished product (≤ 0.1%). The notifier has stated that the formulation plants will have adequate ventilation and self-contained breathing apparatus if required, which would further reduce the potential for inhalation exposure.

Overall the exposure to workers is expected to be low because of the low concentrations in the fragrance oil and finished products, the intermittent nature of potential exposure, and the controlled nature of the formulation process.

9.2.2. Public health – exposure assessment

The main source of exposure of the public to the notified chemical would be consumer use of one or more perfumed end-use household or personal products containing the chemical. There is potential for repeated low level exposure to the public, through use of products containing the notified chemical.

The greatest potential dermal exposure would occur from personal products deliberately applied to the skin, especially those which are not washed off after use, and those with relatively high levels of the chemical (0.1%). Colognes and spray deodorants would fall into this category. An example of an above-average use scenario for dermal exposure is as follows:

> If it is assumed that skin application of 1 g of a cologne or deodorant occurs 5 times a day and that there is 100% uptake, a 60 kg consumer would have dermal exposure to 0.083 mg/kg bw/day of the notified chemical.

Inhalation exposure can occur during use of both household and personal products, and might be expected to be higher when the product volatilises quickly eg use of dishwashing detergent or shampoo in hot water, or during use of a spray product. An example of inhalation exposure using a concentration of 0.05% is as follows:

> If it is assumed that 1 g of dishwash detergent containing 0.05% of the notified chemical is used 3 times per day, and there is 100% uptake, a 60 kg consumer would have inhalation exposure to 0.025 mg/kg bw/day of the notified chemical.

The above calculations give an indication of possible consumer exposure but would not be representative of the full range of exposure for individuals, which will vary with a number of factors, eg number and type of products used that contain the notified chemical, frequency of use, body weight.

Public exposure from transport, storage, reformulation or disposal is considered to be negligible.

9.2.3. Human health - effects assessment

The notified chemical is of low acute oral toxicity in rats, the only route in which acute toxicity was tested. It is a slight eye irritant in rabbits. Testing on rabbits indicates that it is moderately irritating to skin, and this finding is strengthened by the erythema and dryness observed in a human repeated insult patch test. Only limited evidence of sensitisation was found in a guinea pig maximisation test, and no sensitisation was found in a human repeat insult patch test. The notified chemical was non-mutagenic in a bacterial reverse mutation study, which was the only genotoxicity test performed. No repeated dose testing was carried out.

The notified chemical would be classified as a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999) and assigned the risk phrase R38: Irritating to skin.

The notified chemical is flammable, with a flash point of 59^{o}C at 101.3 kPa, and would be classified as a Dangerous Good under the Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG Code) (FORS, 1998).

9.2.4. Occupational health and safety – risk characterisation

On the basis of the data provided, the notified chemical is not acutely toxic, irritant to eyes, sensitising or genotoxic. The chemical is moderately irritating to skin, but will not be handled by workers except as part of a mixture (up to 2%) in imported perfume oils, or as part of the finished consumer products (up to 0.1%). At these concentrations the skin irritation effects of the chemical are expected to be low.

Dermal and inhalation exposure to workers may occur during the formulation process, whereby perfume oil is incorporated into consumer products. Use of safe work practices and engineering

controls would reduce potential exposure. Considering the low toxicity of the notified chemical, the low concentration in perfume oils and consumer products, intermittent nature of exposure and the standard engineering controls used in formulation, the risk of adverse effects to formulation workers is low. Use of PPE will further reduce the risk.

During transport and storage of the perfume oils or consumer products, the potential for exposure is very low, and the risk to workers considered similarly very low.

9.2.5. Public health – risk characterisation

The public will be exposed to the notified chemical through use of consumer household and personal care products containing it at levels of 0.01 to 0.1%. Depending on patterns of use, repeated low level dermal and inhalation exposure to consumers may occur. The potential for skin irritation identified through animal testing is expected to be low at the concentrations used. On the basis of the toxicological testing carried out, the notified chemical is of low hazard for other endpoints. Given that the concentration of the chemical in consumer products is low and the potential toxicity is low, the chemical poses a low risk to public health.

Exposure of the public to the notified chemical during transport, storage or formulation is unlikely and the risk to the public through this route is negligible.

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

10.1. Hazard classification

Based on the available data the notified chemical is classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*. The classification and labelling details are:
R10: Flammable
R38: Irritating to skin.
S24/25 Avoid contact with skin and eyes.
S37 Wear suitable gloves

The notified chemical is classified as a Dangerous Good under the Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG Code) (FORS, 1998):
Class 3 – Flammable liquid, Packing Group III.

According to the Globally Harmonised System for the Classification and Labelling of Chemicals (UN, 2003), the notified chemical is classified as:

	Hazard category	***Hazard statement***
Flammable liquids A2.6	3	Flammable liquid and vapour
Skin corrosion / irritation A2.18	3	Causes mild skin irritation

Based on the data currently available, it is not possible to categorise the notified chemical for the environment according to the Globally Harmonised System for the Classification and Labelling of Chemicals. However, ECOSAR estimates indicate that the notified chemical is toxic to fish and daphnia, and very toxic to algae.

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 and low level of import.

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 household and personal consumer products.

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, 1994a). 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, 1994b). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

REGULATORY CONTROLS

Hazard Classification and Labelling

- The NOHSC Chemicals Standards Sub-committee should consider the following hazard classification for the notified chemical:
  - R10: Flammable
  - R38: Irritating to skin.
  - S24/25 Avoid contact with skin and eyes.
  - S37 Wear suitable gloves

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - ≥ 20%: R38: Irritating to skin

- The notified chemical should be classified as follows under the ADG Code:
  - Class 3 (flammable liquid), Packing Group III.

- Suppliers should label the notified chemical as a Class 3 dangerous good with the class label [Flammable Liquid 3] and the risk and safety phrases listed above.

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical in perfume oil blends and consumer products:
  - Use of a closed or semi-closed system for weighing and formulation processes, where possible
  - Local exhaust ventilation or good general ventilation should be provided if the weighing and formulation process is an open one.

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical in perfume oil blends and consumer products:

- Prevent splashes and spills.
- Avoid direct handling of the perfume blends where possible.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical in perfume oil blends and consumer products:
  - Chemical resistant gloves, protective overalls and goggles/faceshield.
  - Respiratory protection should be used if the perfume blend is handled in a confined space.

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

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

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

Environment

- The following control measures should be implemented by reformulator to minimise environmental exposure during product formulation of the notified chemical:
  - Bunding and catch drains to prevent any material entering stormwater drains or adjacent natural waterways.

Disposal

- The notified chemical should be disposed of to on-site effluent treatments plants or to approved landfills.

Emergency procedures

- Spills/release of the notified chemical should be contained and adsorbed by using sand or inert powder and earth. The collected material should be placed in labelled, sealable drums and disposed of to landfill.

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 Sub-Section 64(1) of the Act; if
- the importation volume exceeds one tonne per annum notified chemical; or
- the notified chemical is imported as a pure chemical or at ≥ 20% in a mixture; or
- the concentration of the notified chemical in a product available to the public increases to ≥ 0.5%; or
- Further toxicological data on the notified chemical becomes available eg a 90-day repeated dose study.

or

(2) Under Sub-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.

If import increases above 1 tonne, ecotoxicity studies with fish, Daphnia and algae will have to be undertaken to confirm high toxicity and the full results and reports submitted for assessment.

Test reports for vapour pressures and adsorption/desorption will also have to be submitted.

If the notified chemical is imported as a pure chemical rather than as part of a mixture, a test report for auto-ignition temperature will have to be submitted.

13. BIBLIOGRAPHY

Bioevaluation Consultants (2001a) Boiling point of Vivaldie, Miserey, France. (Unpublished report provided by notifier).

Bioevaluation Consultants (2001b) Flash-point of Vivaldie, Miserey, France. . (Unpublished report provided by notifier).

Centre International de Toxicologie (2001a) Water Solubility of Vivaldie, BP 563 – 27005 Evreux, France. . (Unpublished report provided by notifier).

Centre International de Toxicologie (2001b) Estimation of the Partition Coefficient (Pow) of Vivaldie using High Performance Liquid Chromatography (HPLC) Method, BP 563 – 27005 Evreux, France. . (Unpublished report provided by notifier).

Centre International de Toxicologie (2001c) Acute Oral Toxicity in Rats to Vivaldie. Centre International de Toxicologie, BP 563 – 27005 Evreux, France. . (Unpublished report provided by notifier).

Centre International de Toxicologie (2001d) Acute Dermal Irritation in Rabbits to Vivaldie. Centre International de Toxicologie, BP 563 – 27005 Evreux, France. . (Unpublished report provided by notifier).

Centre International de Toxicologie (2001e) Acute Eye Irritation in Rabbits to Vivaldie, BP 563 – 27005 Evreux, France. . (Unpublished report provided by notifier).

Centre International de Toxicologie (2001f) Skin Sensitization Test in Guinea Pigs with Vivaldie, BP 563 – 27005 Evreux, France. . (Unpublished report provided by notifier).

Centre International de Toxicologie (2001g) Bacterial Reverse Mutation Test with Vivaldie, BP 563 – 27005 Evreux, France. . (Unpublished report provided by notifier).

Centre International de Toxicologie (2001h) Activated Sludge Respiration Inhibition Test with Vivaldie, BP 563 – 27005 Evreux, France. . (Unpublished report provided by notifier).

Chemical Abstracts Service (2003) Scifinder search CAS 292605.

ChemFinder (ChemFinder.Com) (2003) http://www.chemfinder.cambridgesoft.com/ Accessed 5/8/03.

Essex Testing Clinic, Inc. (2001) Clinical Safety Evaluation: Test article 01-206-01 (0.5% Vivaldie in alcohol:DEP 75:25). Verona, New Jersey. . (Unpublished report provided by notifier).

European Commission (1996). Technical Guidance Document in Support of Commission Directive 93/67/EEC on Risk Assessment for New Notified Substances and Commission Regulation (EC) No 1488/94 on Risk Assessment for Existing Substances – Part II. Office for Official Publications of the European Communities, Luxembourg.

FORS (Federal Office of Road Safety) (1998) Australian coded for the transport of dangerous goods by road and rail (ADG code), 6th Ed. Canberra, AGPS.

Huntingdon Life Science Ltd. (2001) Vivaldie: Assessment of Ready Biodegradability by Manometric Respirometry. Cambridgeshire, England. . (Unpublished report provided by notifier).

IFF R&D Facility (2000) Freezing Point, A. Narula, Fragrance Synthesis. . (Unpublished report provided by notifier).

IFF R&D Facility (2003a) Boiling Point, A. Narula, Fragrance Synthesis. . (Unpublished report provided by notifier).

IFF R&D Facility (2003b) Analytical Certificate, Vivaldie. . (Unpublished report provided by notifier). . (Unpublished report provided by notifier).

Lothrop, W.C. & Handrich, G.R. (1949) (cited in notifier submission). The relationship between Performance and Constitution of Pure Organic Explosive Compounds. Chemical Reviews 44, pp 419-445

McCall PJ, Laskowski DA, Swann RL and Dishburger HJ (1981) Measurement of sorption coefficients of organis chemicals and their use in environmental fate analysis. In *Test Protocols for Environmental Fate and Movement of Toxicants*. Association of Officiaal Analytical Chemists Symposium Proceedings, 94th Annual Meeting, October 21-22 1980, Arlington Virginia. P 89-109. AOAC, Washington DC.

Mensink BJWG. Montforts M, Wijkhuizen-Maslankiewicz L, Tibosch H. and Linders JBHJ (1995) Manual for summarising and evaluating the environmental aspects of pesticides. National Institute of Public Health and Environmental Protection, Bilthoven, The Netherlands. Report No. 679101022.

NOHSC (1994a) National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)]. Australian Government Publishing Service: Canberra.

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

NOHSC (National Occupational Health and Safety Commission) (1999) Approved criteria for classifying hazardous substances [NOHSC:1008(1999)]. Canberra, AGPS.
United Nations (2003) Globally Harmonized System of Classification and Labelling of Chemicals (GHS). United Nations: New York / Geneva.