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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Fadex He 1819 PK

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Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Clariant (Australia) Pty Ltd (ABN 30 069 435 552)
675 Warrigal Road
Chadstone VIC 3148

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:
Identity of chemical;
Composition;
Detailed use; and
Import volume

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None known

NOTIFICATION IN OTHER COUNTRIES
Canada
EC

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Fadex He 1819 PK
Fadex ECS Liquid

3. COMPOSITION

DEGREE OF PURITY
>95%

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will not be manufactured in Australia. It will be imported as a component of a commercial product Fadex ECS Liquid at a concentration of <30%.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	<10	<10	<10	<10	<10

USE
Ultraviolet (UV) absorber for automotive textiles.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Melbourne or Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
Clariant (Australia) Pty Ltd
675 Warrigal Road
Chadstone VIC 3148

TRANSPORTATION AND PACKAGING
The notified chemical will be imported in 110 kg polyethylene drums as a component of a commercial product Fadex ECS Liquid.

The imported product will be typically transported by road from the docks to the notifier's warehouse. When needed for use as a component of polyester fabric-treatment mixture for use in automotive upholstery, the liquid product will be typically transported by road from the warehouse to the fabric-treatment plants. The final finished fabric containing the notified chemical (less than 1% by weight fabric) will be typically transport by road to car plant customers. Transport of the products will be in accordance with the Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG Code) (FORS, 1998).

5.2. Operation description

The imported product containing the notified chemical will not be manufactured in Australia. The production process will be characteristically a highly automated dye-house process (as described below) and occurs after the fabric is dyed and woven.

Following importation, warehouse or stores personnel will receive and store the commercial product prior to consignment. The product will be handled in the warehouse by forklift handling of pallets or manual handling of individual packages.

At the dye houses, weighing personnel will weigh the batch quantity of the imported product and add it to open vessels for dissolving in water and blending with other materials if necessary. The liquid auxiliary, which is formed after blending all the additives including the product containing the notified chemical will be manually poured via a delivery chute into the enclosed and automated dyeing machine or poured into an enclosed holding tank for pumping into the machine.

Dye house operators are involved in controlling valves to pump dyes and auxiliaries into the machines to make a treatment bath, and to remove wastewater at the end of the process. Workers are not expected to have contact with the treatment bath during the process.

The thermosol (heated solution) process used results in binding of the notified chemical to the

polyester fibres either rapidly/instantaneously (by means of an exhaust process) or within less than a minute (by means of a continuous process) depending upon the temperature used.

For both before-mentioned processes, the treated fabric is rinsed using typical dye house heat rinsing processes. (No further extreme heat washing will take place when the fabric is formed into automotive items).

Following treatment, the fabric treated with the notified chemical enters a hydroextractor to remove the bulk of moisture before the final drying on open frames. At this stage, the notified chemical will be fixed into the fabric fibres (as a result of the heating and subsequent cooling process used in the process). Any residue components of the product will be removed from the fabric during rinse phases. The notified chemical will be thermally bound to fabric (<1% by weight fabric). Negligible residue of the notified polymer is expected in the fabric as a result of thermosol process used.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Warehouse and stores personnel	4	1	100
Weighing personnel	4	1	225
Dye machine operators	8	1	225

Exposure Details

Transport and warehousing

Transport, warehouse and stores personnel will wear protective equipment (overalls/ industrial clothing and gloves as appropriate) when receiving and handling consignments of the commercial product containing the notified chemical (at a concentration <30%). The product will be handled in the warehouse by forklift handling of pallets or manual handling of individual packages. During transport and warehousing, workers are unlikely to be exposed to the notified chemical except when packaging is accidentally breached.

Processing

The main routes of exposure to the notified chemical (at a concentration of <30%) are dermal and accidental ocular exposure during weighing and addition of commercial product to the machine and from splashes during preparation of the treatment bath.

Machine operators are involved in controlling valves to pump the notified chemical into the machine and it is possible that dermal exposure to leaks may occur. The concentration of the notified polymer in the machine prior to binding to the fabric will be <1%. Machine operators will have intermittent dermal exposure to the notified chemical when cleaning the equipment in general.

It is possible that dermal exposure to drips and spills may occur if manual intervention is required during rinse phases.

All workers involved in handling the commercial product containing the notified chemical and the treatment bath will wear protective equipment including safety glasses, impervious gloves, protective clothing and respiratory protection, if necessary.

5.4. Release

RELEASE OF CHEMICAL AT SITE

No manufacture or reprocessing of the notified substance will take place. Therefore, there will be no environmental exposure associated with this process in Australia.

RELEASE OF CHEMICAL FROM USE

The notifier has provided reports on the fixation rates on yarn and velour at 99.8 and 99.5%, respectively Clariant (1998). The notified chemical will be used at a level of less than 1% by weight fabric being processed (polyester yarn or piece goods). The exhausted dye bath typically undergoes four processes and dilutions. Based on batch treatment of 400 kg of fabric in 6000 L of water, the

process requires 24,000 L of water. 0.2% of the notified chemical is expected to remain in waste liquids after the treatment and washing processes.

Based on the annual import quantity, up to 10 tonnes of the notified chemical per year at a 99.8% fixation rate up to 0.2 tonnes per annum will be processed and diluted through the end-users' waste water treatment plants and through local sewerage systems. Current treatment processes at the end-user involves all discharged water being held in large effluent tanks. The effluent in tanks undergoes some processing before release to the local sewerage system. The pH is equalised to below pH 10 and then temperature of the effluent is reduced to below 38°C. The wastewater from treatment and washing processes (total of 24,000 L per batch) passes through dosing tanks where the pH is reduced to <10 (normally to pH 9 - 9.5). The waste liquid from the treatment and washing processes is always at a pH >10 (dye bath pH is approximately 11). Wastewater is then moved to 250,000 L holding tanks where a further dilution takes place (approximately 1:10 dilution per batch) before pumping to the sewerage system. Discharged wastewater is released to the local waste treatment plant to undergo biological treatment before release to waterways.

Residues of the notified chemical in packaging after emptying will be minimal. Some of the liquid product will remain in drums after emptying. It is estimated that <0.1% of the product (up to 10 kg of the notified chemical) will be retained per package. The drums will be sent to recycling companies for cleaning.

5.5. Disposal

Any solid waste generated at the dyehouse including the residue in empty import containers will be disposed of as chemical waste according to government regulations. It is recommended that waste substance should be disposed of via a licensed contractor or recycled if possible.

5.6. Public exposure

The notified chemical and the commercial product containing it are not for sale to the public.

The potential for exposure of the general public to the product during normal industrial storage, handling, transportation and manufacturing processes will be minimal. Only in cases of inappropriate handling or accidents during transportation would there be any likelihood of the notified chemical being released from the packaging and the public being exposed.

While public exposure may occur through dermal contact with fabrics treated with the notified chemical, leaching of the notified chemical from the fabric is not expected because of the nature of the thermosol process used to thermally bind the notified polymer to the polyester fibre.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa Off-white powder

Melting Point 151 to 154ºC

METHOD EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks Capillary method
TEST FACILITY SafePharm Laboratories Limited (1996a)

Boiling Point Decomposed at 275ºC at 101.6 kPa prior to boiling

METHOD EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks Distillation method
TEST FACILITY SafePharm Laboratories Limited (1996a)

Density 1337 kg/m^3 at 25ºC

METHOD EC Directive 92/69/EEC A.3 Relative Density.
Remarks A gas comparison pycnometer method was used.for determination in duplicate.

TEST FACILITY SafePharm Laboratories Limited (1996a)

Vapour Pressure <2.8 x 10^{-7} kPa at 25ºC (Estimated)

METHOD EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks The vapour pressure was determined using a vapour pressure balance and was measured over a range of temperatures (80-140ºC) to enable extrapolation to 298ºK. No statistical analyses were performed because the balance readings were too low and variable for a line of best fit to be drawn. Instead it was considered more appropriate to impose a regression slope on a chosen data point to provide an estimate of the maximum value for the vapour pressure.
TEST FACILITY SafePharm Laboratories Limited (1996b)

Water Solubility <0.0352 mg/L at 20ºC

METHOD EC Directive 92/69/EEC A.6 Water Solubility
Remarks The determination was performed using the column elution method. In the preliminary test 0.0905 g of the test material was diluted with 100 mL of distilled water. After shaking for 3 hours and standing at 20ºC for approximately 17 hours, the solution was filtered and analysed. In the definitive test, the sample dissolved in methanol was eluted through the column. The concentration of the sample collected was determined by HPLC in duplicate.

TEST FACILITY SafePharm Laboratories Limited (1996a)

Hydrolysis as a Function of pH Not determined

Remarks Because of the negligible water solubility of the notified chemical, a hydrolysis test was not performed. Based on the notified chemical's structure, it is expected that significant degradation by hydrolysis is not likely to occur in the environment.

Partition Coefficient (n-octanol/water) log P_{ow} >4.19 at 21ºC

METHOD EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks The test was performed using flask shake method. A preliminary assessment of the partition coefficient (log Po/w >2.55) was made based on the approximate solubilities of the notified chemical in n-octanol and water. In the definitive test, six partitions were performed and the concentration of the sample solutions was determined by HPLC.

It is unclear why this method was preferred for this insoluble substance over the OECD TG 117 HPLC method which is likely to have provided a more accurate estimate.
TEST FACILITY SafePharm Laboratories Limited (1996a)

Adsorption/Desorption Log K_{oc} >3.87 (unspecified temperature)

METHOD The procedure was based on the draft document "HPLC-Screening method for the determination of the adsorption-coefficient on soil-comparison of different stationary phases" Kordel W, Stutte J and Kotthoff G , Fraunhofer – Institut fur Umweltchemie and Okotoxikologie.
Remarks The determination was performed using the HPLC-screening method. The retention of the notified chemical was determined in duplicate with fenoxaprop-ethyl as the reference standard. The $\log_{10}$Koc of the sample was deduced by direct comparison of the retention time with that of the reference. The use of a single reference (cf a minimum of 6 in OECD TG 121) means only a limit value is available.
TEST FACILITY SafePharm Laboratories Limited (1996a)

Dissociation Constant Not determined

Remarks Due to the negligible water solubility of the notified chemical and the absence of an ionisable group in the notified chemical, dissociation is not expected in the aqueous environment.

Particle Size 10 μm (respirable range) = less than 1%

METHOD DIN 53 743 – Particle Size Distribution Determined Using Air-jet Sieve Method

Range (μm)	*Mass (%)*
10	0.005
20	1.49
45	26.9
75	51.7
125	61.7
250	79.1
355	91.0
425	97.5

Remarks Less than 1% of particles were within the respirable range (10 μm). The majority of particles were found to be distributed over the range 20 to 250 μm.
TEST FACILITY SafePharm Laboratories Limited (1996)

Surface Tension Not determined

Remarks The test was not conducted due to the low water solubility of the notified chemical (<1 mg/L)

Flash Point Not determined

Remarks The notified chemical is in a solid form. This test is not applicable to a solid.

Flammability Limits Not highly flammable.

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids).
Remarks The notified chemical failed to ignite in the preliminary screening test.
TEST FACILITY SafePharm Laboratories Limited (1996)

Autoignition Temperature >154°C

METHOD 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Remarks The substance does not have a self-ignition temperature below its melting temperature.
TEST FACILITY SafePharm Laboratories Limited (1996)

Explosive Properties Not explosive, not sensitive to shocks and not sensitive to friction

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks BAM Fall Hammer Test – Test for explosive properties
BAM Friction Test – Mechanical sensitivity to friction
Koenen Steel Tube Test – Test of thermal sensitivity
TEST FACILITY SafePharm Laboratories Limited (1996)

Oxidising Properties No oxidising properties

METHOD EC Directive 92/69/EEC A.17 Oxidising Properties (Solids).
Remarks The test material/ cellulose mixtures failed to propagate combustion at a rate

greater than or equal to that of the barium nitrate/ cellulose mixtures (reference mixture).

TEST FACILITY SafePharm Laboratories Limited, Derby, Derbyshire, UK

Reactivity

Remarks There are no hazardous reactions known. The notified chemical is expected to be stable under normal environmental conditions.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50 > 2000 mg/kg bw	low toxicity
Rat, acute dermal LD50 > 2000 mg/kg bw	low toxicity
Rat, acute inhalation	no data available.
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – adjuvant test.	no evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days.	NOEL 1000 mg/kg bw/day
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro CHL	non-genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE

METHOD OECD TG 401 Acute Oral Toxicity.
Species/Strain Rat/Sprague-Dawley CD
Vehicle Fadex He 1819 PK
Remarks - Method No protocol deviations were reported.
Compliance with GLP Standards was reported.

A range finding study was performed using one male and one female rat dosed at 2000 mg/kg bw by means of oral gavage to determine a dosing regime for the main study. On the basis of no deaths or clinical signs of toxicity in the range-finding study, a dose level of 2000 mg/kg bw was selected for the main study.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 males/5 females	2000	0

LD50 >2000 mg/kg bw
Signs of Toxicity There were no deaths or test substance related clinical signs during the study period. All animals showed expected gain in body weight during the study.
Effects in Organs No abnormalities were noted at necropsy

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

TEST FACILITY SafePharm Laboratories Limited (1996c)

7.2. Acute toxicity – dermal

TEST SUBSTANCE Fadex He 1819 PK

METHOD OECD TG 402 Acute Dermal Toxicity.
Species/Strain Rat/ Sprague-Dawley CD
Vehicle Nil
Type of dressing Semi-occlusive.
Remarks - Method No protocol deviations were reported.
Compliance with GLP Standards was reported.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 males/5 females	2000	0

LD50 >2000 mg/kg bw
Signs of Toxicity - Local There were no signs of skin irritation noted during the study.
Signs of Toxicity - Systemic There were no deaths or test substance related clinical signs during the study period. All animals showed expected gain in body weight during the study.
Effects in Organs No abnormalities were noted at necropsy
Remarks - Results

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

TEST FACILITY SafePharm Laboratories Limited (1996d)

7.3. Acute toxicity – inhalation

Remarks The test was not conducted. The notified chemical is a non-volatile powder of non-respirable particle size, hence is not expected to be an inhalation hazard when imported as a component of a liquid product.

7.4. Irritation – skin

TEST SUBSTANCE Fadex He 1819 PK

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain Rabbit/New Zealand White
Number of Animals 3
Vehicle Nil
Observation Period 72 hours
Type of Dressing Semi-occlusive.
Remarks - Method No protocol deviations were reported.
Compliance with GLP Standards was reported.

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	1 hour	0
Oedema	0	0	0	0	0	0

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

Remarks - Results Very slight erythema was observed at two treated skin sites one hour after patch removal. No other evidence of erythema was observed during the study. No evidence of oedema or corrosive effects was observed during the study. The test material produced a primary irritation index of 0.0.

CONCLUSION The notified chemical is not irritating to the skin.

TEST FACILITY SafePharm Laboratories Limited (1996e)

7.5. Irritation – eye

TEST SUBSTANCE Fadex He 1819 PK

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain Rabbit/New Zealand White
Number of Animals 3
Observation Period 72 hours
Remarks - Method No protocol deviations were reported.
Compliance with GLP Standards was reported.

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	0.3	0	0.3	2	24 hours	0
Conjunctiva: chemosis	0	0	0	1	1 hour	0
Conjunctiva: discharge	0	0	0	1	1 hour	0
Corneal opacity	0	0	0	0	–	0
Iridial inflammation	0	0	0	0	–	0

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

Remarks - Results No corneal or iridial effects were noted. Moderate conjunctival irritation was noted in one treated eye with minimal conjunctival irritation in two treated eyes one hour post instillation. Minimal conjunctival redness was noted in two treated eyed at the 24-hour observation period. Treated eyes appeared normal at the 24 and 48-hour observation periods.

CONCLUSION The notified chemical is slightly irritating to the eye.

TEST FACILITY SafePharm Laboratories Limited (1996f)

7.6. Skin sensitisation

TEST SUBSTANCE Fadex He 1819 PK

METHOD OECD TG 406 Skin Sensitisation – Magnusson & Kligman Maximisation Study in the Guinea pig.
Species/Strain Guinea pig/Dunkin Hartley
PRELIMINARY STUDY Maximum Non-irritating Concentration:
intradermal: 5% (w/v) in arachis oil.
topical: 25% (w/w) in arachis oil
MAIN STUDY
Number of Animals Test Group: 10 Control Group: 5
INDUCTION PHASE Induction Concentration:
intradermal: 5% (w/v) in arachis oil
topical: 25% (w/w) in arachis oil

Signs of Irritation	Well-defined or moderate to severe erythema was noted at the intradermal induction sites of all test group animals at the 24 and 48-hour observation periods with very slight to well-defined erythema confined to one intradermal induction site at the 48-hour observation period. Very slight erythema was noted at the intradermal induction sites of all control animals as the 24-hour observation period and in the three control group animals at the 48-hour observation period. Very slight to well-defined erythema and incidents of very slight oedema were noted at the topical induction sites of test animals at the 1-hour observation period. Incidents of bleeding from the intradermal injection sites were also noted. No adverse reactions were noted at the 24-hour observation or in the control groups.
CHALLENGE PHASE	
1st challenge	topical application: 5% (w/w) topical application: 10% (w/w)
Remarks - Method	No protocol deviations were reported. Compliance with GLP Standards was reported.

RESULTS

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

Remarks - Results	No deaths occurred in the control group or the test group animals. Body weight gains in the test group between study day 0 and study day 24 were comparable to those observed in the control group animals over the same period.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	SafePharm Laboratories Limited (1996g)

7.7. Repeat dose toxicity

TEST SUBSTANCE	Fadex He 1819 PK
METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents. EC Directive 92/69/EEC B.7 Repeated Dose (28 Days) Toxicity (Oral). Japanese Ministry of Health and Welfare (MHW) Guidelines 1986 for a twenty-eight day repeat dose oral toxicity study as required by the Japanese Chemical Control Law 1973 of Japanese Ministry of International Trade and Industry (JMITI) amended 1986.
Species/Strain	Rat/Sprague-Dawley.
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 7 days per week The recovery group animals were maintained for an additional 14-day treatment-free observation period following the end of the treatment.

Vehicle	1% carboxymethylcellulose.
Remarks - Method	No protocol deviations were reported. Compliance with GLP Standards was reported.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5/sex	0	1 [a]
II (low dose)	5/sex	150	0
III (intermediate dose)	5/sex	400	0
IV (high dose)	5/sex	1000	1 [b]
V (control recovery)	5/sex	0	0
VI (high dose recovery)	5/sex	1000	0

[a] One control male rat was euthanased *in extremis* on study day 6 because of a fractured left forepaw. [b] One male rat dosed at 1000 mg/kg/ bw/day was euthanasiad *in extremis* on study day 6 follow a sudden and severe deterioration in condition. The animal's condition was attributed to a mal-administration of the dose on study day 5.

Mortality and Time to Death: There were no deaths attributed to the toxicity of the test material.

Clinical Observations: No clinical observable signs of toxicity were detected in test or control animals through out the study period. One male and two female rats dosed at 1000 mg/kg bw/day showed red/brown staining on the dorsal fur which resolved during the first week of treatment. This observation was regarded as incidental and did not persist beyond study day 7 and therefore was not considered indicative of test material toxicity. No adverse effect on body weight development, dietary intake or water consumption was detected.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis: No treatment related effects on haematology, blood chemistry or urinalysis were detected.

Incidentally statistically significant changes ($p < 0.05$ or $p < 0.001$) in urea (increase in females at 400 mg/ke/ bw/day), glucose (decrease in males at 400 mg/kg bw/day), albumin (increase in females at 150 mg/kg bw/day) and bilirubin (decrease in males at 150 and 400 mg/kg bw/day) were observed between treatment groups compared to controls. However, in the absence of any dose response relationship and/or associated changes in parameters that might demonstrate a toxicologically relevant effect, these inter-group differences were considered not to be toxicologically significant.

Clinical chemistry in recovery group: Female rats dosed at 1000 mg/kg bw/day showed a statistically significant reduction ($p < 0.001$) in lymphocyte count at the end of the dosing period compared with controls. This was not considered toxicologically significant because none of the individual values were outside the expected range of rats of the strain and age used in the study and there was no other evidence of an adverse effect with which such a reduction. In addition, there was no histopathological evidence of an adverse effect on haematopoiesis in the spleen.

Effects in Organ: No toxicologically significant macroscopic abnormalities were detected nor treatment related microscopic changes observed. All morphological changes were those commonly observed in laboratory maintained animals of the age and strain employed and there were no differences in incidence or severity between control and treatment groups that were considered to be toxicologically significant.

CONCLUSION

With no changes detected at 1000 mg/kg bw/day which could be considered indicative of a treatment related effect, the No Observed Adverse Effect Level (NOAEL) for males and females may be considered to be 1000 mg/day/day.

TEST FACILITY SafePharm Laboratories Limited (1996h)

7.8. Genotoxicity – bacteria

TEST SUBSTANCE	Fadex He 1819 PK
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. Plate incorporation procedure
Species/Strain	*S. typhimurium*: TA1538, TA1535, TA1537, TA100 *E. coli*: WP2uvrA
Metabolic Activation System	Rat liver S9 microsomal fraction from Aroclor 1254 treated rats.
Concentration Range in Main Test	a) With metabolic activation: 0 - 5000 µg/plate b) Without metabolic activation: 0 - 5000 µg/plate
Vehicle	Dimethylsulfoxide (DMSO).
Remarks - Method	No protocol deviations were reported. Compliance with GLP Standards was reported.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 5000	> 5000	1500	negative
Present				
Test 1	> 5000	> 5000	1500	negative

Remarks - Results	A precipitate at and above 1500 µg/plate was observed however was not regarded as interfering with the scoring of revertant colonies. No cytotoxicity was observed at any dose level. Negative and positive controls gave expected responses. No increase in revertant numbers was observed at any dose level either with or without S9.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	SafePharm Laboratories Limited (1996i)

7.9. Genotoxicity – in vitro

TEST SUBSTANCE	Fadex He 1819 PK
METHOD	EC Directive 2000/32/EC B.10 Mutagenicity - In vitro Mammalian Chromosome Aberration Test.
Species/Strain	Chinese Hamster Lung cell line isolated by Koyama et al (1970) and cloned by Ishidate and Sofuni (1958).
Metabolic Activation System	Rat liver microsomal S9 fraction from Aroclor 1254 treated rats.
Vehicle	Dimethylsulfoxide
Remarks - Method	No protocol deviations were reported. Compliance with GLP Standards was reported.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0, 10, 20, 40, 60*, 80*, 120*	12 hours	12 hours
Test 2	0, 5, 10, 20, 40, 60^{+}	12 hours	12 hours
	0, 10, 20, 40, 80°, 120°, 160^{+}	6 hours	24 hours
	0, 10, 20, 40, 80^{+}, 120^{+}, 160^{+}	24 hours	24 hours
	0, 2.5, 5, 10, 20, 30^{+}, 40^{+}	48 hours	48 hours
Present			

Test 1	0, 20*, 40*, 80*, 120, 160+, 240+	4 hours	12 hours
Test 2	0, 40, 80, 120, 160+, 240+	4 hours	12 hours
	0, 40, 80, 160, 240+, 320+, 480+	6 hours	24 hours

*Cultures not selected for metaphase analysis.
+ No scorable metaphases.
° Very few metaphases

RESULTS

Metabolic Activation	*Test Substance Concentration (μg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	75.63	20	≥120	negative
Test 2	75.63	10	≥20	negative
	151.25	20	≥40	negative
	75.63	80	≥40	negative
	18.91	30	≥40	negative
Present				
Test 1	302.5	120	≥160	equivocal
Test 2	302.5	120	≥160	negative
	302.5	240	≥160	equivocal

*Cultures selected for metaphase analysis.

Remarks - Results

The preliminary cytotoxicity tests showed evidence of a dose-related increase in cell toxicity with and without activation in every exposure case. The notifier states the presence of a precipitate may have affected the electronic cell counter resulting in falsely elevated counts in some cases.

Experiment 1 showed the expected level of toxicity similar to that seen in the preliminary toxicity study. The results of the mitotic index demonstrated a clear dose-related increase in toxicity with increasing dose of the test material resulting in a higher level of toxicity than shown by the cell counts. The results of the cell counts at 12-hours harvest showed a mean percentage compared with solvent control for 12 hours treatment of 85, 102, 128, 137, 135 and 159% at 10, 20, 40, 60, 80 and 120 μg/mL, respectively, without activation and for 4-hours treatment showed a mean percentage compared with solvent controls of 94, 89, 102, 112, 123, and 164% at 20, 40, 80, 120, 160 and 240 μg/mL, respectively, with activation.

The test material induced a small but statistically significant increase ($p \leq 0.001$ with gaps and $p \leq 0.05$ without gaps) in the frequency of cells with aberrations at 240 μg/mL in the presence of S9 (i.e., with activation) with a mean mitotic index of 30% of control. The total percentage of cells at 240 μg/mL showing structural chromosomal aberrations with and without gaps was 11±5.5% and 5±2.5%, respectively, compared to 1±0.5% and 0%, respectively, in the solvent control cells. In all treatment cases with and without activation, there was no significant change in the mean frequency of polyploid cells observed at any dose level across the treatment groups compared to solvent control cells.
Experiment 2 showed expected levels of toxicity similar to that seen in the preliminary toxicity study and Experiment 1. As in Experiment 1, the mean mitotic indices showed a higher and more accurate level of toxicity than that shown by the cell counts.

The mean mitotic index at 12-hours harvest showed a percentage of control for 12 hours treatment of 65, 50, 44 and 0% at 10, 20, 40 and 60 μg/mL, respectively, in the absence of S9 and for 4 hours treatment of 108, 117, 75 and 0% at 40, 80, 120 and 160 μg/mL, respectively, in the presence of S9. The mean mitotic index at 24-hours showed a percentage of control for 6 hours treatment of 87, 67, 61, 52 and 0% at 20, 40, 80, 120 and160 μg/mL, respectively, in the absence of S9 and of 75, 76, 98 and 0% at 40, 80, 160 and 240 μg/mL, respectively, in the presence of S9. The mean mitotic index at 24-hours continuous treatment showed a percentage of control of 96, 78, 61, 82 and 0% at 10, 20, 40, and 80 μg/mL and for 48-hours continuous treatment of 66, 125, 98 and 0% at 5, 10, 20 and 30 μg/mL, respectively, in the presence of S9.

There were no statistically significant increases in the total number of cells showing chromosomal aberrations compared to controls. In the presence of S9, however, the total percentage of cells with and without gaps of 10±5% and 9±4.5%, respectively, observed at 160 μg/mL at 6 hours treatment was comparable in values observed in Experiment 1 at 240μg/mL at 4 hours treatment. It is noted in the Experiment 2 solvent control cells, the cases of aberration with and without gaps were 10±5% and 6±3%, respectively, and were higher than that observed in Experiment 1 solvent control cells.

The statistically significant increase in chromosomal aberrations observed at 240 μg/mL in the presence of S9 (with a mean mitotic index of 30% of controls) in Experiment 1, which was not reproduced in the same exposure group of Experiment 2 albeit the test material was more toxic in Experiment 2, may be attributed to a lower than expected number of chromosomal aberrations in the solvent controls compared to historical solvent control cells. The vehicle control data for all of the exposure groups in Experiment 1 and 2 were within the historical range for CHL cells. In the absence of S9, the test material induced a significant ($p < 0.05$) increase (6±2.9%) in the numbers of polyploid cells at 20μg/mL in the 48-hour treatment group compared to solvent controls.

CONCLUSION

The notified chemical was not clastogenic to CHL cells treated *in vitro* under the conditions of the test.

TEST FACILITY

SafePharm Laboratories Limited (1996j).

7.10 Endocrine Disruption

Using the Quantitative Structure Activity Relationship (QSAR) modelling program OASIS TIMES (v1.14), Environment Canada predicted the binding of the notified chemical to the rat oestrogen receptor (ratER). The data is reported as relative binding affinity (RBA) in reference to 17β-estradiol (E2) expressed in percent (e.g. a RBA = 100% represents equal potency of E2 to the ratER). RBA values are reported with confidence levels from 3 to 0 in order of greater to lower confidence. The results of the predictions are given in the table below.

Notified chemical	RatER binding affinity predictions for the notified chemical (OASIS)					
Relative Binding Affinity (RBA)	0.001%	0.01%	1%	10%	100%	150%
Confidence interval (CI)	No data	3	3	3	3	0

QSAR modelling of the notified chemical for oestrogen receptor binding affinity revealed a high ratER affinity (RBA = 100% with a CI of 3).

There is equivocal evidence of the potential for endocrine disruption. Therefore, on the basis of inadequate evidence, no conclusion is made.

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE: Fadex He 1819 PK

METHOD: OECD TG 301 C Ready Biodegradability: Modified MITI Test (I).

- Inoculum: Mixed population of activated sewage sludge micro-organisms from 10 sites including domestic and industrial sewage plants and river, lake and sea water samples.
- Exposure Period: 28 d
- Auxiliary Solvent: None
- Analytical Monitoring: DOC and HPLC analysis
- Remarks – Method: The test material was prepared as an aqueous dispersion at a final concentration of 100 mg/L. The sample was inoculated with micro-organisms in the dark for 28 days at 25ºC. The degradation of the notified chemical was assessed by oxygen consumption and HPLC on days 0 and 28.

RESULTS

Test substance		*Reference Substance- Aniline*	
Day	*% degradation*	*Day*	*% degradation*
7	-0.7	7	60
14	0	14	66
28	-1.3	28	67

- Remarks – Results: The 3 replicates for the notified chemical attained 1, -3 and 0% with a mean of –1.3% degradation calculated from oxygen consumption values after 28 days. The degradation rates from the residual test material analyses by HPLC were -4, -4 and -7% with a mean value of -5%. The degradation of the reference met validation criteria.

CONCLUSION The notified chemical cannot be classed as ready biodegradable.

TEST FACILITY SafePharm Laboratories (1997a)

8.1.2. Bioaccumulation

The notified substance has a high log Pow value (>4.19) indicating a potential for bioaccumulation in aquatic organisms. Due to the negligible water solubility (<35 µg/L) and the high soil adsorption coefficient (log K_{oc} = >3.87), its adsorption to soils/solids in sewage treatment processes or in natural waterways may reduce the potential for bioaccumulation.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE Fadex He 1819 PK

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 h
Auxiliary Solvent	Dimethylformamide in dechlorinated tap water
Water Hardness	100 mg $CaCO_3$/L
Analytical Monitoring	HPLC
Remarks – Method	Following preliminary range-finding studies, fish were exposed in 2 groups of 10 to an aqueous dispersion of the test material at a single concentration of 0.1 mg/L for a period of 96 hours under semi-static conditions. The test concentration of 0.1 mg/L used in duplicate during the study was prepared with the aid of dimethylformamide. The concentration of 0.1 mg/L was considered to be close to the true limit of water solubility for the test material given that the test preparations at this concentration were observed to be clear colourless solutions when freshly prepared and after 24 hour exposure. Test evaluations were done by visual control of the mortality of fish. The pH, temperature and dissolved oxygen were within acceptable limits throughout the test.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control		10	0	0	0	0	0
Solvent control		10	0	0	0	0	0
0.10		20	0	0	0	0	0

LC50	>0.10 mg/L at 96 hours.
NOEC	≥0.10 mg/L at 96 hours.
Remarks – Results	Analysis of the test solutions at 96 hours showed the overall mean measured test concentration, calculated from the results of all sampling occasions, to be near nominal (91%). Thus the results are based on nominal test concentrations only. There were no sub-lethal effects observed in the fish over the 96 hours. The analysis of the solvent control samples showed a “peak” which eluted at a similar retention time to the test material. However, this “peak” was of a different “peak” shape and was considered not due to the presence of test material. As all test sample results have been corrected for this interference (as determined in the solvent control samples), the low values at 24 hours were not the true dose concentration due to

interference from the co-eluted peak.

CONCLUSION The notified chemical is considered to be non-toxic to rainbow trout close to the limit of its water solubility.

TEST FACILITY SafePharm Laboratories Limited (1997b)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Fadex He 1819 PK

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

Species	*Daphnia magna*
Exposure Period	48 h
Auxiliary Solvent	Dimethylformamide
Water Hardness	ca. 270 mg $CaCO_3$/L
Analytical Monitoring	HPLC
Remarks – Method	Following preliminary range-finding studies, 40 Daphnids were exposed in 4 replicates of 10, to an aqueous dispersion of the test material and DMF, at a concentration of 0.1 mg/L for a period of 48 hours. The concentration of 0.1 mg/L was considered to be close to the limit of water solubility and the test preparations were observed to be clear colourless solutions. Duplicate control and solvent control vessels were also prepared. Immobilisation and any adverse reactions to exposure were recorded after 24 and 48 hours. The pH, temperature and dissolved oxygen were within acceptable limits throughout the test.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
Control		10	0	0
Control		10	0	0
0.10		20	0	0

EC50 >0.1 mg/L at 48 hours

NOEC ≥0.1 mg/L at 48 hours

Remarks – Results Analysis of the test solutions at 0 and 48 hours showed the overall mean measured test concentration, calculated from the results of all sampling occasions to be near nominal (86%). Thus the results were based on nominal test concentrations.

No immobilisation or adverse reactions to exposure were observed.

Similar interference of peak was observed as above. As all test sample results have been corrected for this interference (as determined in the solvent control samples), the low values at 48 hours were not the true dose concentration due to interference from the co-eluted peak.

CONCLUSION The notified chemical is considered to be non-toxic to *Daphnia magna* close to the limit of its water solubility.

TEST FACILITY SafePharm Laboratories Limited (1997c)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE Fadex He 1819 PK

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	0.1 mg/L
Auxiliary Solvent	Dimethylformamide
Water Hardness	Not given
Analytical Monitoring	HPLC
Remarks – Method	Following preliminary range-finding studies, *Scenedesmus subspicatus* was exposed to an aqueous dispersion of the test material and DMF, at a concentration of 0.10 mg/L (six replicate flasks) for 72 hours under constant illumination and shaking. Samples of the algal populations were removed daily and absorbance values determined for each control and treatment group. The pH, temperature and dissolved oxygen were within acceptable limits throughout the test.

RESULTS

Biomass		*Growth*	
EbC50	*NOEC*	*ErC50*	*NOEC*
mg/L at 72 h	*... mg/L*	*mg/L at 0-24 h*	*... mg/L*
>0.10	≥0.10	>0.10	≥0.10

Remarks – Results

The test concentration was the highest attainable test concentration that could be prepared due to the limited solubility of the test material in water. There were no abnormalities detected in any of the test or test cultures and no effects on growth were observed at the test concentration used. The overall mean test concentration from all samplings was shown to be 97% of the nominal. The apparently high value obtained at 0 hours was not the true concentration as the co-eluted peak interfered with the test peak. No abnormalities were detected in any of the control or test cultures.

CONCLUSION The notified chemical is considered to be non-toxic to alga close to the limit of its water solubility.

TEST FACILITY SafePharm Laboratories Limited (1997d)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE Fadex He 1819 PK

METHOD OECD TG 209 Activated Sludge, Respiration Inhibition Test.
EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test.

Inoculum	Activated sludge from domestic sewage treatment plant
Exposure Period	3 hours
Concentration Range Nominal	1000 mg/L

Remarks – Method	The test concentration to be used in the definitive study was determined by a preliminary range-finding study using a series of nominal test concentrations of 10, 100 and 1000 mg/L. These concentrations were prepared by dispersing the test material in water and subjecting to ultrasonification for approximately 30 minutes prior to additions of other components. A single test concentration, in triplicate, of 1000 mg/L was selected for the definitive study. The test material was aerated for a period of 3 hours at 21ºC in the presence of activated sewage sludge with the addition of a synthetic sewage as a respiratory substrate. The rate of respiration was determined after 30 minutes and 3 hours contact times and compared to data for the control and a reference material, 3,5-dichlorophenol.

RESULTS

IC50	>1000 mg/L
Remarks – Results	No significant effect on respiration was observed at all of the range-finding study test concentrations. The validation criteria for the control respiration rates and reference material IC50 values were satisfied.
CONCLUSION	The effect of notified chemical on the respiration of activated sewage sludge microorganisms gave a 3 hour IC50 of >1000 mg/L.
TEST FACILITY	SafePharm Laboratories Limited (1997e)

ADDITIONAL TESTS

8.5 Fish Early Life-stage Toxicity Test

TEST SUBSTANCE	Fadex He 1819 PK
METHOD	US EPA OPPTS Ecological Effects Guideline 850.1400
Species	Rainbow trout (*Oncorhynchus mykiss*)
Exposure Period	97 days
Auxiliary Solvent	Dimethylformamide
Water Hardness	130-160 mg $CaCO_3$/L
Analytical Monitoring	HPLC

METHOD

Remarks – Method	A 10 day range finding test was conducted to estimate the concentration range for the definitive test using survival as the primary endpoint. Based on these results and water solubility of approximately 50 µg/L, target nominal concentrations for the definitive test were 0 (control, 0 (DMF control), 3.1, 6.3, 13, 25, and 50 µg/L. Each treatment consisted of four replicate test chambers containing 100 eggs per treatment. On day 25 the developing embryos were thinned to 15 per replicate. The 60 day post-hatch growth period began on day 37 when >95% of the embryos in the control had hatched. During the growth phase of the test, observations of abnormal behaviour, physical change and mortality were recorded daily. Positive counts of surviving fry were made periodically during the test and at test termination. Fry growths were measured by standard length and blotted wet weight. These data were analysed using analysis of variance methods (ANOVA). A one-tailed Dunnett's multiple comparison procedure was used to assess differences between the control and the treatment groups. Water quality characteristics of pH, temperature and dissolved oxygen were within acceptable limits throughout the test.

RESULTS	
NOEC	97 days >39 µg/L (mean measured concentration)
Remarks – Results	Mean measured concentrations of the test substance during the 97 day represented 77 to 84% of the nominal concentrations. The test substance appeared to be stable under the conditions of the test. Within individual replicates of the notified chemical (4 per treatment), egg hatchability ranged from 93 to 100%. Survival was calculated for the interval between thinning on day 25 and test termination. Overall percent survival was 85 to 90% at all treatment levels. Growth was assessed at test termination (study day 97) through standard length and blotted wet weight measurements. No statistically significant reduction in mean blotted wet weight occurred at any concentration tested when compared to the pooled control group. No significant behavioural abnormalities were observed during the test.
CONCLUSION	Egg hatchability, fry survival and growth exhibited no statistically significant reductions at any concentration tested when compared to the pooled control group. The NOEC for all parameters was ≥39 µg/L.
TEST FACILITY	ABC Laboratories Inc. (2000)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The high Koc and the negligible solubility indicate that the notified chemical is likely to be adsorbed to sludge. After treatment of the fabrics, the notified chemical is assumed to have 99.8% fixation on the fabric and the remaining 0.2% will be removed from the fabric during the rinse phases. As a result the notified chemical is expected to remain in waste liquids after treatment and washing processes. Discharged waste water is released to the local waste treatment plant to undergo biological treatment before release to waterways.

If the notified chemical is disposed of to landfill the residues are likely to be adsorbed to soil and remain immobile. The notified polymer is not ready biodegradable and will degrade slowly via biotic and abiotic processes. Disposal to landfill if any, will be as chemical waste, therefore, the risk of leaching to the water table is significantly reduced. The fate of the notified chemical bound to the fabrics would be the same as that of the fabrics. The fabrics may be disposed of to landfill, where the notified chemical would remain inert.

The notified chemical released to the communal sewer via the dyehouse effluent discharge will be its major environmental exposure. Approximately 0.2% of the notified chemical (up to 20 kg per year) may be released to the environment from Dyehouse waste and from laundering of residues in product drums. The notified chemical will be used mainly in a capital city (33%) and in a regional city (67%). The worst case scenario will be based on discharge of the latter where the maximum amount entering STP would be 0.67 x 0.002 x 10,000 kg = 13.4 kg. Based on the assumption that the substance is not removed with solids or sludge and not degraded, then the Predicted Environmental Concentration (PEC) can be calculated as follows:

Process or Dilution Factor	Dye House (STP discharge)
Typical amount of notified chemical expected to be discharged per day (based on 225 days of the notified chemical being used)	60 g
Daily volume entering STP	50 ML

Concentration in effluent from sewage treatment plant	1.2 µg/L

Using the SIMPLETREAT model for modelling partitioning and losses in sewage treatment plants (European Communities, 2003), the percentage removal from solution by sewage treatment plants (STP) approximates 1% through volatilisation and 21% adsorption in sludge. This is based on the Henry's Law Constant Log H of <0.59, log K_{0w} of >4.19 and no biodegradability. Hence, approximately 77% of the inflow concentration of the notified chemical may potentially remain in solution, passing through the STP. The resulting PEC concentrations in treated effluents will be reduced to 1.2 µg/L X 0.77 = 0.92 µg/L.

However, these values are based on the highest possible for volatility and the lowest for log Pow and should be treated with caution. For example, it is difficult to accept only 21% adsorbing to sludge and 77% remaining in water column for such an insoluble substance. If we assume 90% adsorption as supported by the results the PEC is reduced to 0.12 µg/L.

Based on the respective dilution factors of 1 and 10 for rural areas and coastal discharges of effluents, the PECs of the notified chemical in rural areas and coastal water may approximate 9 and 0.9 µg/L, respectively.

The notified chemical has the potential to bioaccumulate based on its high log Pow value of >4.19. However, given that very small amount of the notified chemical will be discharged to sewer, bioaccumulation is unlikely to occur. However, bioaccumulation potential will need to be re-assessed if fixation rates from other textiles are lower than polyesters and/or the maximum usage volume exceeds 10 tonnes.

9.1.2. Environment – effects assessment

The results of the aquatic toxicity tests for the notified polymer are listed below. As all the species of the three trophic levels show similar toxic effects, concentration at >0.1 mg/L based on the notified chemical will be used as the toxicological end point.

Organism	*Duration*	*End Point*	*mg/L*
Rainbow trout (acute)	96 h	LC50	>0.1
Rainbow trout (chronic)	97 days	NOEC	>0.039
Daphnia	48 h	EC50	>0.1
Algae	72 h	E_bC50	>0.1
	24 h	E_rC50	>0.1
Sludge micro-organisms	3 h	IC50	>1000

A predicted no effect concentration (PNEC – aquatic ecosystems) of >1 µg/L has been derived by dividing the end point of >0.1 mg/L for Daphnia by a worst-case scenario uncertainty (safety) factor of 100 (as toxicity data are available for three trophic levels). Note this value is preferred to using a factor of 50 on the chronic fish test result of >0.039 mg/L ie >0.78 µg/L. It should be noted that no effects were observed in any of the four aquatic toxicity tests for which limit values are available.

9.1.3. Environment – risk characterisation

	Location	PEC µg/L	PNEC µg/L	Risk Quotient (RQ)
Dyehouse	Ocean outfall	0.012	>1	<0.012
	Inland River	0.12	>1	<0.12

The risk quotients indicate an acceptable risk for marine and freshwater release.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Due to the largely automated nature of the fabric treatment process, minimal occupational exposure to the notified chemical (at a concentration <30%) is expected. However, dermal and accidental ocular exposure to the notified chemical could occur from inadvertent drips, splashes and spills during weighing and addition of the commercial product to the fabric treatment machine or via incidental leaks from the machine transfer hoses, fittings, and/or pumps (at a

concentration less than 1%). Given the molecular weight of the notified chemical, absorption through intact skin cannot be excluded.

Transport, Warehouse and Storage
Exposure to the notified chemical is not expected during transport, warehousing and storage provided the 110 kg polyethylene drums containing the commercial product remains intact. Transport, warehousing and storage workers would only be exposed to the notified chemical (at a concentration <30%) in the event of an accidental spill or breach of the drums.

Processing
While minimal occupational exposure is expected, such exposure (albeit of short duration of approximately 1 hour) will be frequent exposure (at a concentration <30%) during the weighing and transferring of the commercial product into the machine.

Exposure to the notified chemical is limited during the thermosol process as the process is controlled through the use of enclosed automatic equipment. Exposure is further limited by the use of PPE such as safety glasses, impervious gloves and protective clothing. Inhalation exposure is expected to be low given the notified chemical's low vapour pressure.

Exposure to the notified chemical is expected to be negligible when handling the finished dry fabric as the chemical is thermally bound to the fabric and at a very low level (<1% by weight fabric) and negligible residue is expected.

Maintenance, Cleaning and Disposal
Maintenance, cleaning and disposal workers will have limited exposure to the notified chemical by skin contact as they are required to maintain and repair equipment and dispose of spent items, respectively. Any dermal exposure as a result of contaminated equipment will be mediated by the use of personal protective equipment (PPE) such as safety glasses, impervious gloves and protective clothing.

Any exposure in general to the notified chemical would be limited use of PPE. All workers handling the notified chemical will wear PPE such as safety glasses, impervious gloves, protective clothing and respiratory protection if necessary and have access to the Material Safety Data Sheet.

9.2.2. Public health – exposure assessment

The notified chemical will not be sold to the public except in the form of finished automotive textiles. There is potential for extensive public exposure to such treated fabrics. While members of the public are expected to make dermal contact with fabrics treated with the notified chemical, such contact is not via a bioavailable form. This is because the notified chemical is thermally bound to the fabric and hence not bioavailable and as such unlikely to penetrate biological membranes. Exposure to the notified chemical is, therefore, assessed as low due to the inert nature of the notified chemical in its final fabric form and inability to leach from the fabric.

9.2.3. Human health – effects assessment

Toxicological data for the notified chemical for the following health end points were submitted:

- acute oral and dermal toxicity
- primary dermal irritation
- eye irritation
- skin sensitisation
- 28-day subacute oral toxicity (gavage); and
- genotoxicity

An acute oral and dermal toxicity study in the rat and rabbit, respectively, indicated the notified chemical is of low toxicity via the oral and dermal routes. A primary dermal irritation test in

rabbits showed the notified chemical is non-irritating to skin. An eye irritation study in the rabbit showed minimal to moderate symptoms of conjunctival irritation which were fully resolved in all animals by the 48-hours observation period and indicated the notified chemical is slightly irritating to the eye.

A skin sensitisation (Magnusson & Kligman Maximisation) test in guinea pigs showed no evidence of reactions indicative of sensitisation. Based on a 28-day subacute oral toxicity study in rats, a NOAEL in male and female rats of 1000 mg/kg/day was indicated based no changes considered indicative of a treatment related effect.

A reverse mutation test in *Salmonella typhimurium* indicated the notified chemical was not mutagenic to bacteria. A chromosomal aberration tests in Chinese Hamster Lung Cells (*in vitro*) showed the notified chemical was not clastogenic to CHL cells treated in vitro under the conditions of the test.

Quantitative Structure Activity Relationship (QSAR) modelling of the notified chemical for oestrogen receptor binding affinity revealed a high ratER affinity (RBA = 100% with a CI of 3). As the evidence of the potential for endocrine disruption is equivocal, no conclusion is made.

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

Incidental dermal and accidental ocular exposure to the notified chemical (<30% notified chemical) may occur during manual weighing and transferring of the commercial product and during any machine maintenance and disposal activities. Exposure to the notified chemical during the fabric treatment process is not expected as the process is automated and enclosed and the exposure is limited by the low concentration (<1% notified chemical) and use of PPE. Exposure to the notified chemical during transport and storage is not expected unless the packaging is accidentally breached. Therefore, on the basis of good work practices and safety-handling measures and the non-hazardous nature of the notified chemical, the notified chemical is unlikely to pose a significant occupational health and safety risk when used in the proposed manner.

9.2.5. Public health – risk characterisation

The notified chemical is not available to the general public and negligible residue and leaching of the notified chemical is expected in and from the finished automotive fabric.

There will be significant public exposure by dermal exposure to fabric treated with the notified chemical. However, the concentration of the notified chemical used is at low concentrations in polyester automotive fabrics (<1% by weight fabric) and is thermally bound to the polyester fabric, not bioavailable and as such not available for skin contact nor skin penetration. Therefore, the notified chemical is unlikely to pose a significant public health risk when used in the proposed manner.

The notified chemical has the potential to bioaccumulate based on its high log Pow value of >4.19. Predicted data suggest that the notified chemical will show high ratER affinity (or oestrogenicity). However, given that the notified chemical is thermally bound to the fabric and hence not bioavailable and as such unlikely to penetrate biological membranes, bioaccumulation and any potential for endocrine disruption is unlikely to occur. However, bioaccumulation and endocrine potential will need to be re-assessed if fixation rates from other textiles are lower than polyesters and/or the maximum usage volume exceeds 10 tonnes.

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*.

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.

Based on the available data, the notified chemical does not meet the criteria for the Classification and Labelling of Chemicals according to the United Nations (2003) Globally Harmonised System.

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 Low Concern to public health when used in the treatment of automotive textiles in the pattern described.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the product containing 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 product containing 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

REGULATORY CONTROLS

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, 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.

Environment

Disposal

- The notified chemical should be disposed of by landfill

Emergency procedures

- In case of spillage prevent the material from entering drains or water courses. Remove with liquid binding material (eg sand, soil or diatomaceous earth). Wash the residue and small amounts from the contaminated area with water.

Annotation on the Australian Inventory of Chemical Substances

- Annotation on the Australian Inventory of Chemical Substances (AICS):

(a) for use as a UV absorber for automotive textiles.
(b) modelling for oestrogen receptor binding affinity show significant binding potential

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:

1. if the import volume exceeds 10 tonnes per annum or if manufactured or reformulated locally:
(a) more accurate log Pow or adsorption/desorption values based on OECD TG 117 and 121, respectively.
(b) a suitable *in vitro* oestrogen receptor-α (ER-α) and estrogen receptor-β (ER-β) reporter gene assay conducted in conformity with the OECD Principles of Good Laboratory Practice.

2. if adverse reporting for the environment and human health becomes available.

3. if fabric other than polyester is used:
(a) information and supporting data on the fixation rate; and
(b) information and supporting data on the nature and extent of the fixation rate and non-leaching potential.

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.

13. BIBLIOGRAPHY

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