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

**FULL PUBLIC REPORT**

**Polymer in Fadex ECS Liquid**

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**Director  
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## Polymer in Fadex ECS Liquid

### 1. APPLICANT AND NOTIFICATION DETAILS

#### APPLICANT(S)

Clariant (Australia) Pty Ltd (ABN 30 069 435 552) of 675 Warrigal Road, Chadstone, Vic, 3148.

#### NOTIFICATION CATEGORY

Limited: Polymer with NAMW  $\geq 1000$  (greater than 1 tonne per year).

#### EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication:

Chemical identity  
Polymer composition  
Purity and nature of impurities  
Spectral data  
Introduction volume  
Detailed use  
Identity of recipients

#### VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

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

Purity  
Residual monomers  
Adsorption/desorption  
Dissociation constant  
Flammability limits

#### PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

#### NOTIFICATION IN OTHER COUNTRIES

Canada: Schedule NSN # 7389 (May 1998)

USA: PMN passed review in June 1992

### 2. IDENTITY OF CHEMICAL

#### MARKETING NAME(S)

The notified polymer is imported as a component (concentration < 5%) of the product Fadex ECS Liquid. The polymer solution (containing 30-35% notified polymer) used in the formulation of this product is called Lyocol RDN liquid.

#### MOLECULAR WEIGHT (MW)

Number Average Molecular Weight (NAMW) >1000

#### METHODS OF DETECTION AND DETERMINATION

METHOD	IR Spectroscopy
Remarks	Spectra for Lyocol RDN Liquid provided. Peaks consistent with functional groups present.

### 3. COMPOSITION

#### DEGREE OF PURITY

Not determined

#### DEGRADATION PRODUCTS

No degradation occurs if the product is handled, stored and used according to recommendations and government regulations.

In case of fires, hazardous combustion gases are formed: carbon monoxide (CO), carbon dioxide (CO<sub>2</sub>), sulphur oxides.

#### LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES

No loss of monomers expected when handled, stored and used at ambient temperature and pressure.

## 4. INTRODUCTION AND USE INFORMATION

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

The notified polymer is to be imported as a component (< 5%) of the product Fadex ECS Liquid. The new polymer may be imported in the future in other textile chemical products or dyestuff products at concentrations < 5%. No quantities of the new polymer are to be manufactured in Australia.

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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	1-3	1-3	1-3	1-3	1-3

#### USE

Dispersing agent for textile industry.

## 5. PROCESS AND RELEASE INFORMATION

### 5.1. Distribution, transport and storage

#### PORT OF ENTRY

Melbourne or Sydney

#### IDENTITY OF MANUFACTURER/RECIPIENTS

The notified polymer will be used at two textile treatment facilities in Victoria.

#### TRANSPORTATION AND PACKAGING

Fadex ECS liquid containing < 5% notified polymer is transported in 110 kg polyethylene drums.

### 5.2. Operation description

A batch quantity of Fadex ECS liquid containing < 5% notified polymer will be weighed and added to open vessels for dissolving in water and blending with other materials if necessary. Transfer from the drums to the mixing vessel is via pumps or ladle. Approximately 12kg of Fadex ECS Liquid will be used for a batch size of 400kg of fabric. The diluted Fadex ECS liquid may then be manually poured via a delivery chute into the dyeing machine or poured into a holding tank for pumping into the dyeing machine.

Following dyeing the treated fabric enters a hydroextractor to remove the bulk of moisture before being placed on open frames for final drying.

### 5.3. Occupational exposure

*Number and Category of Workers*

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration</i>	<i>Exposure Frequency</i>
Stores personnel	4	1 hour per day	100 days per year
Weighing personnel	4	1 hour per day	225 days per year
Dye machine operators	8	1 hour per day	225 days per year

#### *Exposure Details*

##### *Import, transport and distribution*

During transport and storage, workers are unlikely to be exposed to the notified polymer except when packaging is accidentally breached. Warehouse/stores personnel will wear protective equipment (overalls/industrial clothing and gloves as appropriate) when receiving/handling consignments of Fadex ECS liquid.

##### *Dyeing Process*

Dermal and ocular exposure to the notified polymer at a concentration of < 5% could occur from drips, splashes and spills during weighing and the transfer of Fadex ECS liquid to mixing vessel. Following dilution, workers may be exposed to < 5% notified polymer during transfer of the diluted Fadex ECS liquid to the dyeing machine or holding tank. The operators will also wear appropriate skin, eye and respiratory protection

Dye machine operators are involved in controlling valves to pump dyes and auxiliaries into the machines and to remove wastewater at the end of the process. No contact with the dye machine contents occurs during this process and hence exposure to the notified polymer is not expected.

Exposure to residues of the notified polymer from contact with the treated fabric is not expected as the residue is expected to be removed from the fabric during the rinse phases.

#### **5.4. Release**

##### **RELEASE OF CHEMICAL AT SITE**

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

##### **RELEASE OF CHEMICAL FROM USE**

The new substance will be a component in the treatment of polyester fibres. The product Fadex ECS Liquid will be used at 3.0% by weight of goods being processed (polyester yarn or piece goods). The exhausted dyebath undergoes 4 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. The notified polymer is expected to remain in waste liquids after the treatment and washing processes.

Based on the annual import quantity, up to 3 tonnes of the chemical per year will be required to 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 equalized to below pH 10 and then temperature of the effluent is reduced to below 38°C. The waste water from treatment and washing processes (total 24000 litres per batch) passes through dosing tanks where pH is reduced to <10 (normally to pH 9-9.5). The pH of the waste liquid from the treatment and washing processes is always >10 (dye bath pH is approx. 11). Waste water is then moved to 250,000 litre holding tanks where a further dilution takes place (approximately 1:10 dilution per batch) before pumping to the sewerage system. Discharged waste water is released to the local waste treatment plant to undergo biological treatment before release to waterways.

Residues of the notified polymer in packaging after emptying will be minimal. Some of the liquid product will remain in drums after emptying. It is estimated that less than 0.1% of the product (up to 3 kg of the notified polymer) will be retained per drum. 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 the MSDS instructions.

#### **5.6. Public exposure**

The notified polymer will not be directly available to the public, however, the public will handle and

wear textiles treated with the notified polymer.

## 6. PHYSICAL AND CHEMICAL PROPERTIES

Limited physicochemical data has been provided for the product Lyocol RDN Liquid, a 30-35% aqueous solution of the notified polymer.

<b>Appearance at 20°C and 101.3 kPa</b>	Brown clear liquid
<b>Melting Point/Freezing Point</b>	-4 °C
Remarks	Data provided by notifier. Study report not provided.
<b>Boiling Point</b>	~100°C at 101.3 kPa
Remarks	Aqueous solutions of the notified polymer are expected to have a boiling point similar to that of water.
<b>Density</b>	1100 kg/m <sup>3</sup> at 20°C
Remarks	Data taken from MSDS. Study report not provided
<b>Vapour Pressure</b>	~2.3 kPa at 20°C
Remarks	An aqueous solution of the notified polymer is expected to have a vapour pressure similar to that of water. Based on its structure, the polymer itself is expected to have very low vapour pressure.
<b>Water Solubility</b>	≥350 g/L at 20°C (pH unadjusted) <50 mg/L at pH 1, at 20°C >1000 g/L at pH 10, at 20°C
METHOD	<p>The notified polymer was isolated from Lyocol RDN liquid by evaporation under vacuum. The water content of the dry powder was determined to be &lt;0.5% by Karl Fischer.</p> <p>The solubility of the notified polymer was tested without pH adjustment and at pH 1 and pH 10. A description of the protocol used for the solubility determinations is as follows:</p> <p><u>Test Protocol</u></p> <p><i>pH unadjusted and pH10:</i> 5g portions of the notified polymer were added to 100 mL of demineralised water. Where required the pH was adjusted using 30% caustic soda. The aspect of the solution was determined 5 min after each addition. The test was repeated.</p> <p><i>pH1:</i> 5 g of the notified polymer was added to 100 mL of demineralised water and the pH was adjusted to 1 with 35% hydrochloric acid (0.8 ml). The slurry was filtered (G4 glass filter) and the filtrate was adjusted to pH 8 and analysed for the notified polymer by UV Spectroscopy at 256 nm.</p>
Remarks	<p><i>pH unadjusted:</i> The solution remained clear after the addition of 35 g of the isolated notified polymer but a slightly turbid solution was observed following addition of a further 5g. A second test showed the same results. Therefore, the solubility was determined to be ≥350 g/L at 20°C.</p> <p><i>pH1:</i> The UV-VIS spectrum showed a concentration of 35 (40) mg/l of notified</p>

polymer at 256nm. The solubility was determined to be <50 mg/L at 20°C.

*pH 10:* The solution remains clear after addition of 120 g of the notified polymer. A second test showed the same result. The solubility was determined to be >1000 g/L at 20°C.

Information provided by notifier. The original study report was not reviewed.

**Fat (or n-octanol) Solubility** <50 mg/L in n-octanol at 20°C

METHOD	5 g of the notified polymer was added to 100 ml of n-octanol at 20°C. The mixture was stirred overnight (16 h) and filtered. The filtrate was evaporated (100°C, 1 mbar) and the residue (not visible) was dissolved in 100 mL demineralised water by heating to 50°C. The pH was adjusted to pH 8 and the solution was analysed for the notified polymer by UV Spectroscopy.
Remarks	UV-VIS spectrum showed a concentration of 30 or 35 mg/L of the notified polymer. The solubility of the notified polymer in n-octanol at 20°C was determined to be <50 mg/L.

Information provided by notifier. The original study report was not reviewed.

**Hydrolysis as a Function of pH**

Remarks	The notified polymer is unlikely to hydrolyse as there are no hydrolysable groups present in the notified polymer.
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**Partition Coefficient (n-octanol/water)** log Pow = <-4 at 20°C

Remarks	The calculation is based on the n-octanol solubility of <0.050 g/L and water solubility of ≥350 g/L.
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**Adsorption/Desorption** Not determined

Remarks	Based on the high water solubility of the notified polymer, it is unlikely to adsorb to soil
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**Dissociation Constant** Not determined

Remarks	The notified polymer is an anionic polymer which is expected to be fully dissociated under normal environmental conditions.
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**Particle Size** Not determined

Remarks	The notified polymer is introduced in a solution
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**Flash Point** >100°C at 101.3 kPa

Remarks	No flashpoint was observed up to the boiling point. Data taken from MSDS. Study report not provided
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**Flammability Limits** Not determined

Remarks	The notified polymer is imported as an aqueous solution. The notified polymer does not react with water.
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**Autoignition Temperature** Estimated to be >200°C

Remarks	Data provided by notifier. The notified polymer is imported as an aqueous solution and is not expected to self ignite in this form.
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**Explosive Properties**

Not predicted to be explosive

Remarks	There are no chemical groups that would imply explosive properties, therefore the result has been predicted to be negative
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**Reactivity**

Remarks	Expected to be stable under normal conditions of use.
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## 7. TOXICOLOGICAL INVESTIGATIONS

The following toxicological data was submitted for the product Lyocol RDN Liquid, a 30-35% aqueous solution of the notified polymer.

<i>Endpoint and Result</i>	<i>Assessment Conclusion</i>
Rat, acute oral	low toxicity, LD50 >5000 mg/kg bw
Rabbit, skin irritation	very slightly irritating
Rabbit, eye irritation	severely irritating

### 7.1. Acute toxicity – oral

TEST SUBSTANCE	Lyocol RDN Liquid
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
Vehicle	Test substance administered as supplied
Remarks - Method	No significant protocol deviations.

A range-finding study was conducted to establish a suitable dose level for the main study.

#### RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
I	5 per sex	5000 (test substance, equivalent to 1500 – 1750 notified polymer)	0/10

LD50	>5000 mg/kg bw (test substance), >1500 mg/kg bw (notified polymer)
Signs of Toxicity	Hunched posture, lethargy and pilo-erection were noted in all animals one and four hours after treatment. All animals appeared normal one day after treatment. No toxicologically significant effects on bodyweight were noted.
Effects in Organs	No abnormalities were noted at necroscopy.
Remarks - Results	

CONCLUSION	The notified polymer at a concentration of 30-35% is of low toxicity via the oral route.
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TEST FACILITY	SafePharm Laboratories (1989a)
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### 7.2. Irritation – skin

TEST SUBSTANCE	Lyocol RDN Liquid
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	Test substance administered as supplied
Observation Period	72 hours
Type of Dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations.

## RESULTS

<i>Lesion</i>	<i>Mean Score*</i> <i>Animal No.</i>			<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
	1	2	3			
<i>Erythema/Eschar</i>	0	0	0	1	1 hour	0
<i>Oedema</i>	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 confined to treated skin sites of two animals one hour after patch removal. No other adverse dermal effects were noted.
CONCLUSION	The notified polymer at a concentration of 30-35% is very slightly irritating to the skin.
TEST FACILITY	Safepharm Laboratories (1989b)

### 7.3. Irritation – eye

TEST SUBSTANCE	Lyocol RDN Liquid
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Observation Period	7 days
Remarks - Method	Following treatment of the first rabbit one drop of local anaesthetic was instilled into both eyes of the remaining two rabbits approximately 1-2 minutes before dosing.
	Deviation from protocol:
	Observation period was only 7 days (compared to 21 days) even though effects had not fully reversed at this time.

## RESULTS

<i>Lesion</i>	<i>Mean Score*</i> <i>Animal No.</i>			<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
	1	2	3			
<i>Conjunctiva: redness</i>	3	2.3	3	3	7 days	3
<i>Conjunctiva: chemosis</i>	2	2.7	2	3	7 days	2
<i>Conjunctiva: discharge</i>						
<i>Corneal opacity</i>	1.7	1.7	1.7	4	7 days	4
<i>Iridial inflammation</i>	1	1	1	1	7 days	1

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

Remarks - Results	<p>A dulling of the normal lustre of the corneal surface was noted in two treated eyes one hour after treatment. Diffuse corneal opacity was noted in the remaining treated eye at this time and in all treated eyes at the 24-hour observation. Translucent corneal opacity developed in all treated eyes at subsequent 48 and 72-hour observations. The cornea of two treated eyes appeared normal on day seven. Total corneal opacity with pus in the anterior chamber, developed in the remaining treated eye at this time. This may have developed as a result of infection and therefore may not totally be a result of damage by the test material.</p> <p>Iridial inflammation was noted in all treated eyes one hour after treatment, at subsequent 24, 48 and 72-hour observations and in one treated eye on</p>
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day seven.

Moderate to severe conjunctival irritation was noted in all treated eyes up to 72 hours after treatment. Severe conjunctival irritation persisted in one treated eye on day seven. Minimal conjunctival irritation was also noted in another treated eye at this time.

Due to the short observation time the reversibility of effects could not be fully determined.

The pH of the test substance as applied was 7-8, and therefore this was not considered to contribute to the irritant effect.

#### CONCLUSION

The notified polymer at a concentration of 30-35% is severely irritating to the eye based on the presence of ocular lesion at the end of the observation period.

#### TEST FACILITY

SafePharm Laboratories (1989c)

## 8. ENVIRONMENT

The following toxicological data was submitted for the product Lyocol RDN Liquid, a 30-35% aqueous solution of the notified polymer.

### 8.1. Environmental fate

#### 8.1.1. Inherent biodegradability

TEST SUBSTANCE	Lyocol RDN Liquid
METHOD	OECD TG 302 B Inherent Biodegradability: Modified OECD Zahn-Wellens Test.
Inoculum	Microorganisms from the secondary effluent of a domestic waste water sewage plant
Exposure Period	28 days
Auxiliary Solvent	Not applicable
Analytical Monitoring	DOC
Remarks – Method	The test material was dissolved in the test medium at a concentration of 771 mg/L corresponding to 86.3 mg DOC/L. The reference standard aniline was tested simultaneously under the same conditions.  At sampling intervals, one sample of 30 mL was taken and analysed for DOC in duplicate. Samples were taken at days 0 (0 and 3 h after treatment), 7, 14, 21, and 28 of the incubation period.

#### RESULTS

<i>Test substance</i>		<i>Aniline</i>	
<i>Day</i>	<i>% degradation</i>	<i>Day</i>	<i>% degradation</i>
3 h	<5	3h	-6
7	50	7	75
14	40	14	96
21	47		
28	46		

Remarks – Results	The notified polymer was degraded to 46% within 28 days. The standard compound aniline was degraded to 96% within 14 days.
CONCLUSION	The notified polymer is considered to be inherently biodegradable at 86.3 mg DOC/L.
TEST FACILITY	RCC Umweltchemie AG (1989)

#### 8.1.2. Bioaccumulation

Not determined. Given the high molecular weight and the calculated log  $P_{o/w}$  of <-4, the notified polymer is unlikely to bioaccumulate.

### 8.2. Ecotoxicological investigations

#### 8.2.1. Acute/Chronic toxicity to aquatic invertebrates

TEST SUBSTANCE	Lyocol RDN Liquid
METHOD	OECD TG 202 Part 1 Daphnia sp. Acute Immobilisation Test EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia
Species	<i>Daphnia magna</i>

Exposure Period	24 hours
Auxiliary Solvent	None
Water Hardness	Not given
Analytical Monitoring	None
Remarks – Method	The daphnids were exposed to Lyocol RDN Liquid in 50 mL beakers containing 20 mL test medium per 10 animals. All tests were run in duplicate. Test evaluations were done by visual inspection of the mobility of the daphnids after 24 hours (this is a protocol deviation, the standard test duration is 48 hours). The oxygen concentration and the pH were within acceptable limits during the test.

## RESULTS

<i>Concentration mg/L Nominal</i>	<i>Number of D. magna</i>	<i>Number Immobilised 24 h</i>
0	20	0
1	20	0
10	20	0
100	20	0

LC50 >100 mg/L based on Lyocol HPB 10.267 Liquid  
>30-35 mg/L at 24 h based on 30-35% notified polymer present

NOEC (or LOEC) = 30-35 mg/L at 24 h based on 30-35% notified polymer  
Remarks – Results The results indicate that none of the daphnia were immobilised at nominal test concentration up to 30-35 mg/L of the notified polymer.

CONCLUSION The notified polymer is at most harmful to *Daphnia magna*.

TEST FACILITY RCC Umweltchemie AG (1989)

### 8.2.3. Algal growth inhibition test

TEST SUBSTANCE Lyocol RDN Liquid

METHOD OECD TG 201 Alga, Growth Inhibition Test.

Species Green alga, *Selenastrum capricornutum*

Exposure Period 72 hours

Concentration Range 50-800 mg/L

Nominal

Auxiliary Solvent None

Water Hardness Not given

Analytical Monitoring

Remarks – Method Deionized water was used as the test medium enhanced with reagent-grade nutrients and filtered sterilised prior to use.

Two static range-finding tests were conducted at concentrations up to 1000 mg/L prior to performing the definitive test. Nominal test concentrations of 50, 100, 200, 400 and 800 mg/L were used.

A first definitive test was aborted due to poor growth in the control. In the second test, algal growth was measured and morphological observations were conducted on each test treatment to detect abnormal cell morphology and/or colouration compared with the control.

No chemical analysis of test solutions was conducted. Nominal test concentrations were used in all tests. The test temperature and pH were within acceptable limits.

## RESULTS

<i>Sample</i>	<i>Biomass</i>	<i>Growth</i>	
	<i>EbC50 (mg/L)</i> <i>at 0-72 h</i>	<i>ErC50</i> <i>mg/L at 24-48 h</i>	<i>NOEC</i> <i>(mg/L)</i>
Lyocol RDN Liquid	286 (CI: 231-346)	423 (CI: 362-498)	200

Lyocol RDN Liquid contains 30-35% notified polymer. The following values have been calculated for the notified polymer itself:

	<i>Biomass</i>	<i>Growth</i>	
	<i>EbC50 (mg/L)</i> <i>at 0-72 h</i>	<i>ErC50</i> <i>mg/L at 24-48 h</i>	<i>NOEC</i> <i>(mg/L)</i>
Notified polymer (if at 30%)	85.8 (CI: 69.3-104)	127 (CI: 109-149)	60
Notified polymer (if at 35%)	100 (CI: 81-121)	148 (CI: 127-174)	70

Remarks – Results	<p>After 72 hours of exposure to Lyocol RDN Liquid, the percentage inhibition of cell growth compared to the control ranged from 6% at 100 mg/L to 89% at 800 mg/L.</p> <p>Observations of cell morphology detected no changes in Lyocol RDN Liquid exposed cells as compared to cells in control media.</p> <p>The NOEC was 200 mg/L based on the lack of significant reduction in growth (cell density) at this and lower test concentrations of Lyocol RDN Liquid</p>
CONCLUSION	The notified polymer is considered harmful to algae.
TEST FACILITY	Toxikon Environmental Sciences (1997)

#### 8.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Lyocol RDN Liquid
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test.
Inoculum	Activated sludge from domestic waste water treatment plant
Exposure Period	3 hours
Concentration Range	10-100 mg/L
Nominal	
Remarks – Method	The study was performed in compliance with OECD TG 209 but only two concentrations were run.
RESULTS	
3 h IC50	>100 mg/L
Remarks – Results	The respiration rate of the activated sludge was not inhibited (-30.0%) at the highest concentration (100 mg/L) of Lyocol HPB 10.267 Liquid (= 30-35 mg/L based on notified polymer). Inhibition of over 90% was observed at the test concentration of 50 mg/L for the reference 3, 5-dichlorophenol sodium salt (3 h IC50 = 10.4 mg/L).
CONCLUSION	The notified polymer at a concentration of 30-35% was non-toxic to waste water bacteria under the conditions of the test.
TEST FACILITY	RCC Umweltchemie AG (1989)

## 9. RISK ASSESSMENT

### 9.1. Environment

### 9.1.1. Environment – exposure assessment

The notified polymer is used as a dispersing agent in dyeing baths. After treatment of the fabric the water-soluble notified polymer will be removed from the fabric during rinse phases. As a result of its water solubility, the notified polymer 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 dye containing the notified polymer is disposed of to landfill the residues may be mobile. The notified polymer is inherently biodegradable and will degrade 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 notified polymer released to the communal sewer via the dyehouse effluent discharge will be its major environmental exposure. All of the notified polymer (up to 3,000 kg per year) may be released to the environment from dyehouse waste and from the cleaning of residues in product drums. The notified polymer 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 notified polymer in the latter circumstances where the maximum amount entering STP would be  $0.67 \times 3,000 \text{ kg} = 2010 \text{ kg}$ . 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:

<i>Process or Dilution Factor</i>	<i>Dye House (STP discharge)</i>
Typical notified polymer use expected per day (based on 225 days of the notified polymer being used)	8.9 kg
Daily volume entering STP	50 ML
Concentration in effluent from sewage treatment plant	178 µg/L
<i>Predicted environmental concentrations (PECs) in receiving waters</i>	
PEC (Ocean (Dilution Factor 1:10))	17.8 µg/L
PEC (River (Dilution Factor 1:1))	178 µg/L

### 9.1.2. Environment – effects assessment

The results of the aquatic toxicity tests for the notified polymer are listed below. The most sensitive species were Daphnia with 24 hour EC<sub>50</sub> value of >30 mg/L based on the notified polymer.

<i>Organism</i>	<i>Duration</i>	<i>End Point</i>	<i>mg/L</i>
Daphnia	24 h	EC <sub>50</sub>	>30-35
Algae	0-72 h	E <sub>b</sub> C <sub>50</sub>	85.8
		E <sub>r</sub> C <sub>50</sub>	120

A predicted no effect concentration (PNEC - aquatic ecosystems) of > 30 µg/L has been derived by dividing the end point of > 30-35 mg/L for Daphnia by a worst-case scenario uncertainty (safety) factor of 1000 (as toxicity data are available only for two trophic levels).

### 9.1.3. Environment – risk characterisation

<i>Location</i>	<i>PEC*</i> µg/L	<i>PNEC</i> µg/L	<i>Risk Quotient (RQ)*</i>
Dyehouse Ocean outfall	17.8	>30	<0.6

(Regional city)	Inland River	178	>30	<6.0
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\* The worst-case PEC and the RQ values calculated assuming the notified polymer is not removed during the wastewater treatment at the dyehouses or the STP process.

The risk quotients indicate an acceptable risk ( $Q < 1$ ) for marine release but a potential risk for freshwater organisms. However, since it is expected that all will be released to ocean from the two dye houses, the risk is considered acceptable based on the maximum usage of 3 tonnes. However, if release to freshwater is proposed or the proposed usage volume exceeds 3 tonnes, then a secondary notification is stipulated as a result of the potential risk in the freshwater system.

## 9.2. Human health

### 9.2.1. Occupational health and safety – exposure assessment

Due to the largely automated nature of the dyeing process, minimal occupational exposure to the notified polymer is expected. However, dermal and ocular exposure to the notified polymer could occur from drips, splashes and spills during weighing and transfer of Fadex ECS liquid and diluted Fadex ECS liquid. This would be limited by the concentration of the notified polymer (<5%) and use of personal protective equipment (PPE).

As the notified polymer is expected to be removed from the fabric during rinsing, occupational exposure to the notified polymer from the handling of treated fabric is not expected.

### 9.2.2. Public health – exposure assessment

Public exposure to the notified polymer is expected to be negligible.

The notified polymer will only be used industrially and therefore direct exposure to the notified polymer is not expected. Based on the high water solubility of the notified polymer, any residual polymer is likely to be removed from the treated textile during rinsing. As such indirect exposure to the notified polymer from the handling and wearing of treated textiles is not expected.

### 9.2.3. Human health – effects assessment

Acute toxicity.

An aqueous solution containing 30-35% notified polymer was of low acute toxicity in rats. Based on this study it is not possible to definitively classify the notified polymer itself for acute toxicity, however, no mortality was observed in rats dosed with up to 1750 mg/kg bw of the notified polymer and therefore it is expected that the notified polymer would be of low acute toxicity.

Irritation and Sensitisation.

In a skin irritation study with an aqueous solution containing 30-35% notified polymer, the only sign of irritation observed was very slight erythema in two animals one hour after patch removal. Although the skin irritation potential of the notified polymer itself cannot be ascertained from this study, the notified polymer is not introduced to Australia in this form.

In an eye irritation study with an aqueous solution containing 30-35% notified polymer, observed signs of irritation included translucent corneal opacity, iridial inflammation and moderate to severe conjunctival irritation. Signs of irritation had not fully reversed in two of three animals at the end of a 7-day observation period and as such the notified polymer is considered to be severely irritating to eyes.

Hazard classification for health effects.

Based on the available data, the notified polymer is 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

The notified polymer is considered to be severely irritating to eyes. The potential for ocular exposure is only expected during the transfer of Fadex ECS liquid and diluted Fadex ECS liquid where the notified polymer is present at a concentration of <5%. At this concentration, the notified polymer is below the cut off for classification as an eye irritant according to NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004). Therefore, the risk of an adverse irritant response from exposure to the notified polymer at this concentration is considered to be low. In addition, workers are expected to wear eye protection which would reduce the potential for ocular exposure and hence the risk of eye irritation.

#### 9.2.5. Public health – risk characterisation

Public exposure to the notified polymer is expected to be negligible and therefore the risk to public health is also considered to be negligible.

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

#### 10.1. Hazard classification

Based on the available data the notified polymer is classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*. The classification and labelling details are:

Xi: R41 Risk of serious damage to eyes

and

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

<i>Hazard category</i>				<i>Hazard statement</i>
Serious eye irritation	eye	damage/eye	1	Causes serious eye damage

#### 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 Negligible Concern to public health when used in the proposed manner.

### 11. MATERIAL SAFETY DATA SHEET

#### 11.1. Material Safety Data Sheet

The MSDS for Fadex ECS Liquid 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 Fadex ECS Liquid 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 health hazard classification for the notified polymer:
  - Xi: R41 Risk of serious damage to eyes
- Use the following risk phrases for products/mixtures containing the notified polymer:
  - Conc $\geq$ 10%: R41
  - 5% $\leq$ conc<10%: R36

### CONTROL MEASURES

#### Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer as introduced:
  - Avoid contact with eyes
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced:
  - Protective eyewear

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

#### Disposal

- The notified polymer waste and contaminated packaging should be disposed of as chemical waste to an approved waste disposal facility in accordance with official regulations.

#### Emergency procedures

- Spills should be handled by dampening powder and scooping into marked containers for disposal as chemical waste in accordance with official regulations.

### 12.1. Secondary notification

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

- (1) Under Section 64(1) of the Act; if
  - the importation volume exceeds three tonne per annum notified polymer; or
  - if the notified polymer is released to freshwateror
- (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. For the two conditions described under subsection 64 (1) the following information will need to be submitted if a secondary notification is required:

- A full acute toxicity test result and report for fish.
- An acute toxicity test result and report for Daphnia over 48 h.

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