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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Chemical in Additol XL 270

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health and Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment, Water, Heritage and the Arts.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at 334-336 Illawarra Road, Marrickville NSW 2204.

This Full Public Report is also available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

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Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Cytec Australia Holdings Pty Limited (ABN: 45 081 148 629) of Suite 1, Level 1 Norwest Quay, 21 Solent Circuit, Norwest Business Park, Baulkham Hills, NSW 2153

AND

Pacific Resins Pty Ltd (ABN: 92 520 305 379) of 3/7 Jannali Avenue, Jannali, NSW 2226

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical name, Other names, CAS number, Molecular formula, Structural formula, Molecular weight, Spectral data, Purity, Impurities, Additives/Adjuvants, Import volume, Use details.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Melting Point, Boiling Points, Density, Vapour Pressure, Hydrolysis as a Function of pH, Partition Co-efficient, Absorption/Desorption, Dissociation Constant, Flash Point, Flammability Limits, Autoignition Temperature, Explosive Properties, Reactivity, Acute Oral Toxicity, Acute Dermal Toxicity, Acute Inhalation Toxicity, Skin Irritation, Eye Irritation, Skin Sensitisation, Repeated Dose Toxicity, Genetic Toxicity, Induction of Point Mutations, Induction of Germ Cell Damage, Chromosome Damage, Acute Toxicity (Fish), Acute Immobilisation/Reproduction (Daphnia sp.), Growth Inhibition Test (Alga), Biodegradation, Ready Biodegradation, Bioaccumulation.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
CEC/727 - CEC Permit No. 690, Duration of Permit: 17 April 2007 – 17 April 2008
CER/22 - CER Permit No. 723, Duration of Permit: 30 April 2008 – 30 April 2009

NOTIFICATION IN OTHER COUNTRIES
USA (2002); Canada (2005)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Additol XL 270 (containing <60% of the notified chemical)

MOLECULAR WEIGHT
>1000 Da

ANALYTICAL DATA
Reference GPC spectra was provided.

ADDITIVES/ADJUVANTS
(For product Additol XL 270)

Chemical Name	Benzene, dimethyl-		
CAS No.	1330-20-7	*Weight %*	42.87

Chemical Name	Benzene, ethyl-		
CAS No.	100-41-4	*Weight %*	10.7
Chemical Name	Benzene, methyl-		
CAS No.	108-88-3	*Weight %*	1.81
Chemical Name	Additive 11 (silicone from Dow Corning)		
CAS No.	Unknown	*Weight %*	0.2

3. COMPOSITION

DEGREE OF PURITY >95%

4. PHYSICAL AND CHEMICAL PROPERTIES

Only data on water solubility of the notified chemical are available. The information below are based on 1) the imported product, Additol XL 270, containing < 60% of the notified chemical in solvents xylene (~30%), toluene (~2%), and ethylbenzene (~10%); 2) Component 1; and/or 3) the accepted analogue [refer section 6.2. for details on 2) and 3)].

APPEARANCE AT 20°C AND 101.3 kPa: Brown liquid (for Additol XL 270)

Property	Value	Data Source/Justification
Melting Point	25-35 °C	Analogue data
Boiling Point	100-200 °C	MSDS for Additol XL 270
	> 200 °C	Analogue data
Density	911 kg/m^3 at 20 °C	Measured for Additol XL 270
	~850 kg/m^3 at 75 °C	Analogue data
Vapour Pressure	Not determined	Based on the high molecular weight of the notified chemical, this is expected to be low.
Water Solubility	>3.07 g/L at pH 4 and 20°C	Measured for the notified chemical
Hydrolysis as a Function of pH	Not determined	The notified chemical does not contain hydrolysable functionality.
Partition Coefficient (n-octanol/water)	log P_{OW} = 1 – 4.9	Based on the range of results from Component 1 and the analogue. Their salts would be expected to have a much lower log P_{OW}.
Adsorption/Desorption	Not determined	Based on the high solubility and anionic nature of the notified chemical, it is not expected to adsorb to organic matter.
Dissociation Constant	Not determined	The notified chemical is expected to have a pK_a value of 3 – 5 since it contains anionic functionalities, and is predicted to be ionised in the environmental pH range of 4 – 9.
Particle Size	Not applicable	The notified chemical is in liquid form.
Flash Point	26 °C	Measured for Additol XL 270
Flammability	Not expected to be flammable	Based on the chemical structure
Autoignition Temperature	Not expected to autoignite	Based on the chemical structure
Explosive Properties	Not expected to be explosive	Does not contain any structural alerts for explosive properties.

DISCUSSION OF PROPERTIES
For full details of tests on physical and chemical properties, please refer to Appendix A.

Reactivity
Stable under the normal conditions of use. No hazardous reactions when stored and handled according to prescribed instructions. No decomposition should occur if used as intended.

Dangerous Goods classification
The flash point of the imported product containing the notified chemical, Additol XL 270, meets the classification criteria for its flammability according to the Australian Dangerous Goods Code (FORS, 1998). However, the flammability of the notified chemical is expected to be low based on its structure.

5. 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 Additol XL 270 containing <60% of the notified chemical in solvent solution.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	2-3	2-3	2-3	4-5	<15

PORT OF ENTRY
Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
Paint manufacturers

TRANSPORTATION AND PACKAGING
The imported product containing the notified chemical will be imported in 200 L metal drums by ships and transported by road to the formulators. Following reformulation, the final paint products will be packaged in either 200 L drums for coating companies or 1000 L holding tanks for the road marking industry and will be transported to end users by road.

USE
The imported product containing the notified chemical will be used as an additive in the manufacture of industrial paints (containing ≤1% of the notified chemical). The industrial applications of the paint will be in road marking (70%), automotive coatings (15%), and board coatings (15%).

OPERATION DESCRIPTION
Paint Formulation
Formulation processes will involve transfer of the product containing the notified chemical by metered dosing to a mixing vessel and mixing with other ingredients in the sealed vessel fitted with a high-speed mixer and local exhaust ventilation systems. Each batch will be quality checked and adjustments made as required. The resulting paint will be filtered prior to being dispensed into closed head drums or holding tanks under exhaust ventilation for supply to end users. The system will be flushed using a solvent and washings will be collected into holding tanks, which will be emptied on a regular basis by licensed contractors for disposal.

End-uses –Road Marking
The paint containing ≤1% of the notified chemical will usually be applied immediately after the road has been paved. The road is marked commonly by a truck. Workers will drive the road marking truck to the area where the holding tank of the paint is situated. A plant operator will then connect a hose from the holding tank to the truck holding drums. The markings will be controlled automatically by the controller who sits at the back of the truck. Paint will be run through a series of hoses under air pressure and applied to the roadway surface. After application, the paint will air-dry. The spray nozzles will be cleared under pressure at the beginning of a run. The truck carries a tank of water that will be used to supply water for washing equipment and the washwaterwill be stored and disposed of in accordance with EPA and local council regulations. The waste material will be collected in a can, which will be allowed to dry and disposed of to landfill.

End-uses – Industrial Coatings (automotive and board coating)
Application of the paint will be mostly by robotic spray for the automotive industry and curtain coating techniques for the wood board industry.

The paint containing ≤1% of the notified chemical will be used either undiluted or manually mixed with the other components (diluted up to 50%). The final paint will be loaded into a spray gun (for electrostatic spraying) and spray application will be carried out using a robotic system. Overspray will be collected in a pool of water below the grill floor or in a wet scrubber in the exhaust, and will ultimately be removed using a filter. The residual solids will be disposed of to secure landfill. Once spraying is completed or coating has been exhausted, the equipment will be drained and cleaned using solvents and rags. The rinsates and used rags are collected for disposal. Empty cans will be drained onto absorbent material and the cans disposed of to landfill. Spray booth filters will be removed by workers for disposal every 2-4 months.

The curtain method involves a continuous film of the paint, which falls over the board as it passes on the conveyor. The curtain is created by pumping the paint through a wide trough, which has a narrow opening in the bottom. Boards are coated by passing them through the curtain of paint. Excess paint will be collected and returned to the paint reservoir. The application will be a non-contact method and gives a smooth, even distribution of coating across the whole board. The equipment will be used continuously, but may occasionally be shut down for maintenance. During maintenance, the equipment will be cleaned with a solvent which will be collected and sent off site to a liquid waste treatment facility.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration (hrs/day)*	*Exposure Frequency (days/yr)*
Transport and storage	2	2-3	10-15
Paint formulation			
Weighing and mixing	6	30 min – 6	30
Drum filling	4	3	30
Quality control	4-8	1	30
Cleaning	2	30	30
End-Use			
Road marking industry	~ 1000	8	220
Automotive painting industry	~ 1000	8	220
Curtain coating industry	50	8	220

EXPOSURE DETAILS
Waterfront, transport and warehouse workers are not expected to be exposed to the notified chemical unless an accidental spill or release occurs during transport.

Paint Formulation
Occupational exposure to the notified chemical is expected to be greatest for workers involved in paint reformulation as they will be exposed to the notified chemical at <60%.

During paint formulation, workers may be exposed to the chemical via dermal and ocular exposure to drips, spills and splashes during transfer, quality control testing and during drum filling where the enclosed system is expected to be breached. However, exposure will be minimised by workers wearing personal protective equipment (PPE) such as coveralls, goggles, and impervious gloves. Inhalation exposure is expected to be minimal as an enclosed mixing and exhaust ventilation system will be used.

The estimated dermal exposure is 25.2 mg/day, based on an EASE model using reasonable worst case defaults for the exposure scenario 'coupling and decoupling of a transfer line/quality control sampling (pre-mixing)' (European Commission, 2003) and assuming the notified chemical is present at typical concentration of up to 60%. Therefore, for a 70 kg worker and a 100% dermal absorption factor, systemic exposure is estimated to be

0.36 mg/kg bw/day. Workers' exposure would be further limited by the use of automated/enclosed processes and PPE. Inhalation exposure is not estimated due to the low likelihood of gas/vapour/aerosol formation. The potential exposure during post-mixing quality control testing and drum filling is expected to be lower, as workers will handle products containing low concentration (≤1%) of the notified chemical.

End-uses - Road Marking
Accidental dermal and ocular exposure may be possible due to drips and spills during truck holding drum filling, although the filling process will be conducted under local exhaust ventilation.

There will be no contact with the notified chemical by the operator during road marking process as it will be fully automated. Dermal and accidental ocular exposure to the notified chemical may be possible during maintenance and cleaning. However, workers' exposure to the notified chemical is expected to be low due to the low concentration of the notified chemical in the paint and use of PPE such as coveralls, goggles and gloves. Once the paint is dry the notified chemical will be bound in an inert matrix and unavailable for exposure.

End-uses – Industrial Coatings
Workers' exposure to the notified chemical is expected to be low during industrial coating as both automotive and board coatings are automated and/or non-contact processes. However, accidental dermal and ocular exposure cannot be ruled out, especially during manual mixing, maintenance and equipment cleaning. The potential exposure is expected to be minimised by use of appropriate PPE.

An exposure estimation for end uses has not been conducted, as the exposure level during formulation is estimated to be low (see above).

6.1.2. Public exposure
Exposure of the public to the product containing the notified chemical would only be possible if an accidental spill or release occurs during transport.

Products containing the notified chemical will not be available for sale to the public and will only be used by professional users. Members of the public may make dermal contact with substrates that are coated with products containing the notified chemical. However, such exposures will be negligible because the notified chemical will be bound within a cured paint film.

6.2. Human health effects assessment

No toxicity data is available for the notified chemical. Information on two major components of the notified chemical and one analogue was provided. **Component 1** is the parent acid and **Component 2** is the parent base of the notified chemical. It is expected that the notified chemical will dissociate into the two major components within biological systems based on its structure and high water solubility. Therefore, the data on the two components is considered to be appropriate for the purpose of hazard identification.

The structure of the **analogue** is closely similar to the Component 1, thus, it is also considered to be acceptable for hazard identification.

The results from toxicological investigations conducted on Component 1 and the analogue are summarised in the Table 6.1 below. A review of toxicological literature on Component 2 is available and also summarised in the Table 6.1. Details of these studies/review can be found in Appendix B.

Table 6.1: Summary of toxicity data on the two major components of the notified chemical and one analogue.

Endpoint and Result	*Assessment Conclusion*
Acute oral toxicity	
Component 1	
Study 1 in rats	LD50 > 5000 mg/kg bw (low toxicity)
Study 2 in rats	LD50 > 2000 mg/kg bw (low toxicity)
Analogue	
Study 1 – in rats	LD50 > 21.5 ml/kg (low toxicity)
Study 2 – in rats	LD50 > 2000 mg/kg (bw low toxicity)
Component 2 (a number of studies)	Slightly toxic to low toxicity
Acute dermal toxicity	
Component 2 (a number of studies)	Low to moderate toxicity
Acute inhalation toxicity	
Component 2 (a number of studies)	Low to moderate toxicity
Skin irritation	
Analogue	
Study 1 – Rabbit	Non-irritating
Study 2 – Rabbit	Non-irritating
Component 2 (a number of studies)	Severely irritating to Corrosive
Eye irritation	
Analogue	
Study 1 – Rabbit	Non-irritating
Study 2 – Rabbit	Non-irritating
Component 2 (a number of studies)	Severely irritating
Skin sensitisation	
Analogue	
In humans	Non-sensitising
Component 2 (a number of studies)	Potential skin sensitiser (positive LLNA, but negative Guinea pig test and human data)
Repeat dose toxicity	
Component 1	
Rat, diet repeat dose toxicity - 90 days	NOAEL = ~100 mg/kg bw/day
Component 2 (a number of studies)	NOAEL = 180 mg/kg bw/day
Genotoxicity - bacterial reverse mutation	
Component 1	
Ames *Salmonella* Assay	Non-mutagenic
Component 2 (a number of studies)	Non-mutagenic

Genotoxicity – in vitro	
Component 1	
In vitro – Mammalian cell gene test – mouse lymphoma L5178Y cells	Non-mutagenic
In vitro – Mammalian cytogenetic test – human Lymphocytes	Non-clastogenic
Component 2 (a number of studies)	Non-genotoxic
Carcinogenicity	
Component 2 (2 long-term oral studies)	Non-carcinogenic
Developmental and reproductive effects	
Component 1	
One-generation oral study	NOEL = ~180 mg/kg bw/day (parental) NOEL = ~1858 mg/kg bw/day (F1)
Component 2	
One inhalation one-generation study	NOAEL = 10 ppm (parental) NOEL ≥ 100 ppm (F1)

Toxicokinetics
No information on toxicokinetics of the notified chemical is available. However, absorption of the notified chemical via oral and dermal exposure is expected based on its properties such as moderate to high water solubility (measured for the notified chemical) and low melting point of the analogue. This is supported by the systemic effects observed in the repeated dose toxicity studies using Component 1 and 2 and the acute dermal toxicity studies.

Acute and repeated inhalation studies using Component 2 indicate some absorption and effects via inhalation. However, the possibility of vapour formation from use of the notified chemical is expected to be low because of its predicted low vapour pressure based on its high molecular weight (the molecular weight of the notified chemical is 8 to 10 times higher than that of Component 2).

Acute toxicity
Component 1 and the analogue did not exhibit acute toxicity via oral exposure based on the high LD50s found in the acute animal studies. No acute inhalation study is available using these two chemicals. However, low to moderate toxicity was shown via all routes of exposure and a number of local and systemic effects were observed in acute inhalation studies using Component 2, which has been classified as 'Harmful by inhalation, in contact with skin and if swallowed' (R20/21/22).

Irritation and sensitisation
Both Component 1 and the analogue are not considered skin and eye irritants. However, Component 2, the parent base of the notified chemical, demonstrated significant skin and eye irritation and it is classified as a Corrosive substance. It is classified as 'Causes burn' (R34).

Skin sensitisation data is only available on the analogue and Component 2. The limited human data on the analogue indicates that it is not a skin sensitiser. Component 2 showed positive LLNA data, which indicated a linear dose-related positive result. However, this is not supported by negative human studies and guinea pig maximum test.

Repeated dose toxicity
Based on minimal increases in clinical chemistry parameters and histopathological findings at the higher doses, a NOAEL of 100 mg/kg bw/day was identified in a 90 day oral study in rats using Component 1.

A number of inhalation studies using Component 2 indicated local effects of irritation to the respiratory tract, effects to the lung, and some hematological parameters, but no NOAEL was identified. A dermal repeated dose study did not exhibit systemic effects apart from severe skin irritation. A NOAEL of 180 mg/kg bw/day was identified in a 90 day feeding study.

The systemic effects of Component 2 were observed at higher concentrations (NOAEL of 180 mg/kg bw/day)

than those of Component 1 (100 mg/kg bw/day). The likely toxicity of the notified chemical following repeated exposure would be similar to Component 1.

Mutagenicity
Negative results were found in a number of studies in both bacteria and in vitro studies with various test assays on Component 1 and 2, indicating a low potential to induce genotoxicity by the notified chemcial.

Carcinogenicity
No study is available for Component 1 and the analogue. Component 2 did not increase incidence of neoplasms in two long-term oral studies in mice.

Toxicity for reproduction
No reproductive and teratological effects were seen at the highest doses tested (1858 mg/kg bw/day and 100 ppm) in a one-generation oral study using Component 1 and in an inhalation study using Component 2.

Summary
Toxicity data on Component 1 and the analogue did not indicate significant local or systemic effects (NOAEL of 100 mg/kg bw/day using Component 1).

However, Component 2 induced low to moderate acute toxicity via all routes of exposure. Severe local effects of irritation and positive LLNA results were also found.

No information is available on extent of the dissociation of the notified chemical into the 2 major components. However, based on the high pKa (dissociation constant) value of the Component 2 and high water solubility of the notified chemical, the dissociation in aqueous solution (in situations such as workers' sweat at workplaces) is expected. Therefore, a precautionary hazard classification for skin sensitisation based on the data on Component 2 should be made.

Assuming 100% dissociation, the proportion of Component 2 in Additol XL 270 after the dissociation is estimated to be 15% based on molecular weight of this component and concentration of the notified chemical in Additol XL 270 (up to 60%). Therefore, the imported product Additol XL 270 also exceeds the concentration cut-off levels for hazard classification.

Health hazard classification
Based on the available data on Component 2 and the possibility of dissociation of the notified chemical into Component 1 and 2, the notified chemical should be classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

- R20/21/22 - Harmful by inhalation, in contact with skin and if swallowed'
- R34 - Causes burn
- R43 – May cause sensitisation by skin contact

6.3. Human health risk characterisation

6.3.1. Occupational health and safety
Based on the low level of exposure to the notified chemical by workers who handle the end use products containing low concentration (≤1%), the notified chemical is not considered to pose an unacceptable risk to workers.

The major concerns are the possible risk of irritation/corrosion, potential skin sensitisation and the systemic effects after repeated exposure for workers who handle the imported product containing <60% of the notified chemical.

Risk of irritation/corrosion and potential skin sensitisation
Potential dermal and ocular exposure may occur during transfer, quality control testing and drum filling where the enclosed system is expected to be breached and spills and splashes are possible. Although the proposed control measures will reduce the likelihood of the exposure, every attempt in minimising the incidences of spills and splashes should be made wherever feasible.

Risk of systemic effects following repeated exposure
Based on a NOAEL of 100 mg/kg bw/day, derived from a 90-day rat oral study and the reasonable worst-case

worker exposure estimation during formulation, the margin of exposure (MOE) is calculated as 100/0.36 = 278. MOEs greater than or equal to 100 are considered acceptable to account for intra- and inter-species differences. Therefore, the risk of systemic effects based on the modelled data is expected to be acceptable for formulation workers who handle products containing <60% of the notified chemical. Due to their lower expected exposure to the notified chemical, the risk of systemic effects is considered low for end use workers.

6.3.2. Public risk

Baaed on the negligible public exposure, the notified chemical is not considered to pose an unacceptable risk to public health.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

Release to the environment during shipping, transport and warehousing will only occur in the unlikely event of accidental spills or leaks of the 200 L import drums.

There is a potential for release during formulation of the paint. In the unlikely event that a spill occurs, it is expected to be contained by existing plant bunding and collected for disposal to landfill. It is estimated that up to 0.75% of the annual introduction volume of notified chemical may be lost due to spills and leaks.

Equipment washings from formulation processes may result in up to 1.5% of the annual volume of introduced notified chemical being released to the environment. Washings are expected to be collected into holding tanks, which are emptied on a regular basis by licensed contractors for disposal to landfill. Some residues will also remain in the empty import drums after use. It is estimated that up to 0.75% of the annual introduction volume of notified chemical may remain as residues. Drums are expected to be disposed of to landfill.

Summary of release from formulation

Source	*Quantity*	*Disposal method*
Spills	0.75%	Landfill
Cleaning of equipment	1.5%	Landfill
Residues in empty containers	0.75%	Landfill

RELEASE OF CHEMICAL FROM USE

Road Marking Industry – 70% of annual volume of introduced notified chemical

Road marking will be carried out by truck mounted units for highway marking. The spray equipment is cleaned at the beginning of a run under pressure. The waste material is collected in a can, which is allowed to dry and is disposed of to landfill. It is estimated that a maximum of 70% x 0.5% = 0.35% of the annual introduction volume of notified chemical will be lost due to the cleaning of spray nozzles.

The truck carries a tank of water that is used to supply water for washing and store the resultant wash-water. The wash-water will be disposed of in accordance with EPA and local council regulations. The amount of waste notified chemical generated via washings is estimated to be 70% x 1% = 0.7% of the annual introduction volume.

It is estimated that 70% x 1% = 0.7% of the annual introduction volume of the notified chemical may be lost from accidental spills. Spills are expected to be covered with some inert absorbent material and collected in a waste disposal container for disposal to landfill.

Cured road paint incorporating the notified chemical will deteriorate upon exposure to the elements and traffic, however, the notified chemical is expected to remain bound in the paint matrix. Once the paint has dried the matrix is expected to be stable.

Summary of release from the road marking industry

Road Marking industry	*Quantities*	*Disposal method*
Cleaning of equipment	0.35%	Landfill
Waste notified chemical generated via washings	0.7%	Liquid waste treatment facility

Accidental spills	0.7%	Landfill

Automotive industry coating – 15% of annual volume of introduced notified chemical
A piston pump using an air pressure of around 3-4 bars operates the airless spray guns. It is expected to be approximately 30% overspray from this process but it will be performed in a spray booth. The engineering controls for overspray are typically spray booth filters. The spray booth filters are usually renewed every 2-4 months. The filters are disposed of to landfill. The annual percentage of notified chemical released to landfill as a result of overspray has been calculated as being 15% x 30% = 4.5% of the annual introduction volume.

It is estimated that approximately 1% of the annual introduction volume of notified chemical contained in paint products would remain as residue in the steel containers after emptying. This will be ultimately be disposed of to landfill along with the containers and will account for a total of 15% x 1% = 0.15% of the annual introduction volume.

Once spraying is completed, the equipment is drained and cleaned using solvents and rags. The rinsates and used rags are collected for ultimate disposal to landfill. It is estimated that this will account for approximately 1% of the annual introduction volume of notified chemical and will account for a total of 15% x 1% = 0.15% of the annual introduction volume.

Summary of release from the automotive coating industry

Source	*Quantity*	*Disposal method*
Overspray	4.5%	Landfill
Residues in empty containers	0.15%	Landfill
Cleaning of equipment	0.15%	Landfill

Board coating industry – 15% of annual volume of introduced notified chemical
The coating is applied to the wood boards at the end-users site using the curtain method and any excess paint is collected and returned to the paint reservoir. The equipment is used continuously, but may be shut down for maintenance from time to time. The equipment is cleaned with a suitable solvent which is collected and sent off site to a liquid waste treatment facility. It is estimated that 15% x 1% = 0.15% of the annual introduction volume may be lost from the cleaning of equipment. There will be no release to sewer during this end-use of products containing the notified chemical.

It is estimated that 15% x 1% = 0.15% of the annual introduction volume of the notified chemical may be lost from accidental spills. Spills are expected to be covered with some inert absorbent material and collected in a waste disposal container for disposal to landfill.

The drums are rinsed with solvents before collection by waste disposal contractors. Residues in drums are expected to account for up to 15% x 2.5% = 0.375% of the annual introduction volume.

Summary of release from the timber coating industry

Source	*Quantity*	*Disposal method*
Residues in empty containers	0.375 %	Waste disposal contractors
Cleaning of equipment	0.15%	Liquid waste treatment facility
Accidental spills	0.15%	Landfill

RELEASE OF CHEMICAL FROM DISPOSAL
Unformulated notified chemical that is disposed of to landfill is expected to associate with soil and organic matter. Over time, the notified chemical should degrade via abiotic and biotic means to form various simple organic compounds. Formulated notified chemical that is disposed of directly to landfill is expected to be entrapped within a stable coatings matrix. However, over time, the notified chemical should eventually degrade via abiotic and biotic means to form various simple organic and nitrogenous based compounds. The notified chemical disposed of by licensed waste disposal companies is expected to be cured in the associated coating matrix, and then be disposed of to landfill. Overall, it is expected that up to 10% of the annual introduction volume will be disposed of directly to landfill.

The notified chemical that will be applied to roads in road marking paint is expected to remain entrapped within the stable paint matrix. As it is abraded due to traffic, which is expected to associate with roadside soil, or if washed into drains, associate with sediments, it should eventually degrade over time to various simple organic and nitrogenous based compounds.

The notified chemical applied to automobiles is expected to share the fate of the substrate, and is expected to be thermally decomposed during metal reclamation to form various carbon and nitrogen oxides and water vapour. The notified chemical applied to timber is expected to eventually be disposed of to landfill, and will share the fate of the formulated notified chemical mentioned above.

7.1.2 Environmental fate

Environmental fate data for the notified chemical is not available. However, data for Component 1 and the analogue has been supplied with results ranging from approximately 6% biodegradation after 28 days for Component 1 to up to 88% biodegradation in 28 days for the analogue. Component 2, the parent base of the notified chemical, was also reported to be readily biodegradable. Based on the structure of the notified chemical, it is expected to be, at the very least, inherently biodegradable. For the details of the environmental fate studies please refer to Appendix C.

7.1.3 Predicted Environmental Concentration (PEC)

As direct release of unformulated or un-entrapped notified chemical is not expected at any time under the proposed use patterns, a Predicted Environmental Concentration in the aquatic compartment cannot be derived.

7.2. Environmental effects assessment

Environmental effect data for the notified chemical is not available. However, results from ecotoxicological investigations conducted on the two major components and an accepted analogue of the notified chemical are summarised in the table below, using the GHS classification scheme. Details of these studies can be found in Appendix C.

Component/ Analogue	*Endpoint*	*Result*	*Assessment Conclusion*
Component 1	Fish Toxicity	LLR50 > 1000 mg/L WAF	Not classifiable
Analogue	Fish Toxicity	LC50 > 1000 mg/L WAF	Not classifiable
Analogue	Fish Toxicity	LC50 13.4 mg/L	Harmful
Component 2	Fish Toxicity	LC0 107-167 mg/L	Not classifiable
Component 2	Fish Toxicity	LC0 88-131 mg/L	Not classifiable
Component 2	Fish Toxicity	LC50 100-200 mg/L	Not classifiable
Component 2	Fish Toxicity	LC50 81 mg/L	Harmful
Component 1	Daphnia Toxicity	LLR50 > 1000 mg/L WAF	Not classifiable
Analogue	Daphnia Toxicity	EC50 ≥ 1000 mg/L WAF	Not classifiable
Component 2	Daphnia Toxicity	EC50 98.77 mg/L	Harmful
Component 2	Daphnia Toxicity	EC50 105.42 mg/L	Not classifiable
Component 2	Daphnia Toxicity	EC50 98.37 mg/L	Harmful
Component 1	Algal Toxicity	EC50 > 1000 mg/L WAF	Not classifiable
Analogue	Algal Toxicity	EC50 ≥ 1000 mg/L WAF	Not classifiable
Component 2	Algal Toxicity	EC50 35 mg/L	Harmful
Component 2	Inhibition of Bacterial Respiration	EC10 > 8000 mg/L	Not classifiable

The above data show considerable variation, and this is possibly due to the difficulty in solubilising the notified chemical in test media, reflected in the different preparation methods. As the above results are for the major components and the analogue, they should be considered to be indicative only, and it is therefore, not possible to definitively classify the notified chemical. Also it should be noted that Component 2 is the parent base of the notified chemical.

7.2.1 Predicted No-Effect Concentration

Given the lack of effects data for the anionic notified chemical, it is not possible to calculate a substantive Predicted No-Effect Concentration.

7.3. Environmental risk assessment

As neither PEC nor PNEC were able to be derived, it is not possible to calculate a Risk Quotient (Q) value. However, given the lack of aquatic exposure at any point in the life-cycle of the notified chemical in Australia, the risk to the aquatic environment, under the proposed use patterns, is therefore, considered to be low.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available data on the major components and an analogue, the notified chemical is classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

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

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

Environmental risk assessment
On the basis of the proposed uses and associated environmental releases, the notified chemical is not considered to pose an unacceptable risk to the environment.

Recommendations

REGULATORY CONTROLS
Hazard Classification and Labelling

- The Office of the ASCC, Department of Employment and Workplace Relations (DEWR), should consider the following health hazard classification for the notified chemical:
  - *R20/21/22 - Harmful by inhalation, in contact with skin and if swallowed'*
  - *R34 - Causes burn*
  - *R43 – May cause sensitisation by skin contact*

and

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

	Hazard category	***Hazard statement***
Corrosive	1C	Danger: Causes severe skin burns and eye damage
Acute toxicity	4	Warning: Harmful if swallowed and in contact with skin
	3	Danger: Toxic in inhaled
Corrosion/Irritation	1C	Danger: causes severe skin burns and eye damage
Skin sensitisation	1	May cause an allergic reaction

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - ≥ 25%: R21/22/23, R34, R43
  - ≥ 10%: R34, R43
  - 5% ≤ conc <10%: R36/38, R43
  - ≥ 1%: R43

Health Surveillance

- The notified chemical should be considered by the ASCC for development of health surveillance guidelines.

- As the notified chemical is a potential skin sensitiser, employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of skin sensitisation.

Material Safety Data Sheet

The MSDS for Additol XL 270 provided by the notifier should be amended according to the recommended hazard classification.

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical as introduced:
  - *Prevent leaks and spills.*
  - *Wherever possible, direct handling of the notified chemical should be avoided; rather, some remote handling apparatus should be used.*

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced:
  - *Avoid contact with skin, eyes and clothing.*
  - *A shower and eyewash station should be available.*
  - *Avoid spills and splashing during use.*
  - *After exposure, any contaminated PPE should be thoroughly cleaned before re-use.*

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced:
  - *Chemical resistant gloves.*
  - *Face-shield.*
  - *Chemical resistant clothing which protects the body, arms, legs and feet.*

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

- Only workers with sufficient education on the hazards of the notified chemical should handle it in any concentrated form, such as the imported product.

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

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

Environment

Disposal

- The notified chemical should be disposed of to landfill.

Emergency procedures

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

Regulatory Obligations

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

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

(1) Under Section 64(2) of the Act; if
  - the function or use of the chemical has changed from road marking and industrial coating, or is likely to change significantly;
  - the amount of chemical being introduced has increased from 15 tonnes per year, or is likely to increase, significantly;
  - if the chemical has begun to be manufactured in Australia;
  - additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

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

No additional secondary notification conditions are stipulated.

Material Safety Data Sheet
The MSDS of the product containing the notified chemical provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Only data on water solubility of the notified chemical are available. The information below are based on 1) the imported product, Additol XL 270, containing < 60% of the notified chemical in solvents xylene (~ 30%), toluene (~2%), and ethylbenzene (~ 10%); 2) the Component 1; and/or 3) the accepted analogue.

Melting Point 25 – 35ºC

Remarks Data for the analogue from confidential reference 2

Boiling Point 100 – 200°C

Remarks Cited in the MSDS for Additol XL 270. The boiling point for the analogue is > 200ºC from confidential reference 2.

Density ~911 kg/m^3 at 20 °C (for Additol XL 270)

METHOD DIN EN ISO 2811-2 - Determination of Density Part 2: Immersed body (plummet) method which bases on Archimedes' principal. A beaker was filled with the sample of Additol XL 270 and placed on an analytical balance. A body with known volume of 3334 mL was clamped to a stand and then immersed in the sample. The density of the sample was obtained by dividing the gain in weight due to the immersion of the body by the volume of 3334 mL. The test was carried out at sample temperature of 20°C.

Remarks Only summary report was provided.
The Density for the analogue is ~850 kg/m^3 at 75 °C from confidential reference 2.

TEST FACILITY Cytec Surface Specialities (2007)

Water Solubility 3.07 g/L @ 23°C (pH 4)

METHOD The notified chemical (5 g) was added to 500 mL of an aqueous buffer solution at pH 4, 6 and 9, and also to pure demineralised water. After thorough stirring for about 24 hours, the solution was filtered. An aliquot portion was taken from the filtrate and the majority of the water was removed using a rotary evaporator. After the volume was significantly reduced, the flask was placed in a 120°C oven until constant weight was achieved. The residue content was then determined. Only the pH 4 buffer solution yielded a fairly good separation of notified chemical. All other treatments formed a hazy, opaque solution, probably induced by dispersed notified chemical.

Data provided for Component 1 and the analogue showing a much lower solubility was not directly applicable as they were for neutral rather than anionic species.

Remarks

TEST FACILITY Cytec Specialty Chemicals Analytical Laboratories (2008)

Partition Coefficient (n-octanol/water) Not determined. $\log P_{ow}$ = 1.0 – 2.5 (estimated based on Component 1 at pH 2)

METHOD OECD Test Method 117 – Component 1

TEST FACILITY Confidential reference 1

Flash Point 26°C (for Additol XL 270)

METHOD DIN EN ISO 1523 (Closed cup equilibrium method)

Remarks Only summary report was provided. This flash point probably reflects the solvent components of Additol XL 270.

TEST FACILITY Cytec Surface Specialities (2007)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

No toxicity data are available for the notified chemical. Information on the two major components of the notified chemical and one analogue was provided and considered to be acceptable.

The results from toxicological investigations conducted on Component 1 and the analogue are described below. A review of toxicological literature on Component 2 is available and is summarised following the data on Component 1 and the analogue.

B.1a. Acute toxicity – oral

TEST SUBSTANCE	Component 1
METHOD	Testing was conducted according to OECD Test Method 401, "Acute Oral Toxicity."
Species/Strain	Rat / Wistar
Vehicle	Not stated
Remarks – Method	Wistar rats (n = 5/sex) received a single oral dose of 5000 mg/kg of Component 1 and were observed for 14 days.
RESULTS	
LD50	> 5000 mg/kg bw
Remarks – Results	No effects on mortality, clinical signs or body weight were reported. Gross necropsy revealed no treatment-related effects.
CONCLUSION	Component 1 is of low toxicity via the oral route.
TEST FACILITY	Confidential reference 1

B.1b. Acute toxicity – oral

TEST SUBSTANCE	Component 1
METHOD	Testing was conducted according to OECD Test Method 401, "Acute Oral Toxicity."
Species/Strain	Rat/Sprague-Dawley
Vehicle	Not stated
Remarks – Method	Sprague-Dawley rats (n = 5/sex) received a single oral dose of 2000 mg/kg of Component 1 and were observed for 14 days.
RESULTS	
LD50	> 2000 mg/kg bw
Remarks – Results	No mortalities occurred and no changes in clinical signs, body weight or gross pathology were reported.
CONCLUSION	Component 1 is of low toxicity via the oral route.
TEST FACILITY	Confidential reference 1

B.1c. Acute toxicity – oral

TEST SUBSTANCE	Analogue (2 studies with limited information)
METHOD	Study 1 – Regulation of the enforcement of the Federal Hazardous Substances Act (Title 16, CFR 1500.40, 1500. 41, 1500. 42) Study 2 - Not specified
Species/Strain	Rat in both studies
Vehicle	Not stated
Remarks – Method	No other information is available.
RESULTS	

LD50	Study 1 – LD50 > 21.5 ml/kg Study 2 – LD50 > 2000 mg/kg bw
Remarks – Results	No information on signs of toxicity and effects in organs.
CONCLUSION	The analogue is of low toxicity via the oral route based on the limited information.
TEST FACILITY	Confidential reference 2

B.2. Irritation – skin

TEST SUBSTANCE	Analogue (2 studies with limited information)
METHOD	Study 1 – not specified Study 2 – Regulation for the Enforcement of the Federal Hazardous Substances Act (Title 16, CFR 1500.40, 1500.41, 1500.42)
Species/Strain	Rabbit in both studies
Remarks – Method	No other information is available.
RESULTS	Study 1 – non-irritating Study 2 – non-irritating (Primary irritation index was 1.0)
CONCLUSION	The analogue is non-irritating to skin based on the limited information.
TEST FACILITY	Confidential reference 2

B.3. Irritation – eye

TEST SUBSTANCE	Analogue (2 studies with limited information)
METHOD	
Species/Strain	Rabbit in both studies
Remarks – Method	No other information is available.
RESULTS	Study 1 – Non-irritating Study 2 – Non-irritating (very slight erythema in four rabbits)
CONCLUSION	The analogue is non-irritating to the eye based on the limited information.
TEST FACILITY	Confidential reference 2

B.4. Skin sensitisation

TEST SUBSTANCE	Analogue (limited information)
METHOD	Not specified
Species/Strain	Humans
Remarks – Method	No other information is available.
RESULTS	Non-sensitising
CONCLUSION	There is no evidence of reactions indicative of skin sensitisation to the analogue under the conditions of the test (limited information available).
TEST FACILITY	Confidential reference 2

B.5. Repeat dose toxicity

TEST SUBSTANCE	Component 1
METHOD	Testing was conducted according to OECD Test Method 408, "Subchronic Oral Toxicity – Rodent: 90-Day."
Species/Strain	Rat/Sprague-Dawley
Route of Administration	Oral – diet
Exposure Information	Total exposure days: 13 weeks
Vehicle	Not stated
Remarks – Method	Test concentrations were 0, 0.1, 1, or 5%. No significant protocol deviations.

RESULTS

Mortality and Time to Death

No deaths occurred.

Clinical Observations

No treatment-related effects on clinical signs, body weight, body weight gain, or water intake were noted. A transient, statistically significant decrease in food consumption occurred in the 5% males and females during the first four weeks of study.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Slight changes in hemoglobin (increased in 5% males) and prothrombin time (increased in 1% females and 5% males and females) were considered to not be toxicologically significant. Treatment-related clinical chemistry changes included increased alkaline phosphatase (1 and 5% males and females) and alanine amino transferase (5% males and females), and decreases in total cholesterol and triglycerides (1 and 5% males and females), total serum protein and albumin (5% males and females), and beta-globulin fraction (1 and 5% males).

Effects in Organs

At necropsy, the mesenteric lymph nodes were slightly to moderately enlarged in all treatment groups. Uterine fluid distension occurred with increased incidence at 5%. Absolute and relative spleen (males at 1 and 5%) and liver (males and/or females at 1 and 5%) weights were statistically significantly decreased. In addition, absolute kidney weight was significantly decreased in females at 5% and absolute and relative liver weights were significantly decreased in females at 0.1%. The relevance of these decreases in organ weights is not known, since they did not correlate to any microscopic changes. Histopathology revealed treatment-related findings in the following organs: mesenteric lymph nodes (aggregation of macrophages in both sexes at 0.1% and higher); spleen (macrophages with brown pigment in both sexes at 1 and 5% and in the females at 0.1%); liver (bile duct proliferation and bile duct sclerosis in males at 5%); adrenals (cortical vacuolation in females at 1 and 5%); and thyroids (follicular epithelial hypertrophy in females at 5%).

CONCLUSION

Although a no-effect level was not identified in this study, 0.1% (approximately 100 mg/kg bw/day) can be considered a no observed adverse effect level (NOAEL) based on minimal increases in clinical chemistry parameters and histopathological findings at the higher doses.

TEST FACILITY	Confidential reference 1

B.6. Genotoxicity – bacteria

TEST SUBSTANCE	Component 1
METHOD	OECD TG 471 Bacterial Reverse Mutation Test.
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100, TA102
Metabolic Activation System	S9
Concentration Range	a) With metabolic activation: 33 - 5000 µg/plate b) Without metabolic activation: 33 - 5000 µg/plate
Vehicle	Not stated
RESULTS	No substantial increase in revertant colony numbers of any of the five

	tester strains was observed following treatment with Component 1 at any concentration level either in the presence or absence of metabolic activation (S9 mix). Thus, Component 1 was not considered to be mutagenic.
CONCLUSION	Component 1 was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Confidential reference 1

B.7a. Genotoxicity – in vitro

TEST SUBSTANCE	Component 1
METHOD	OECD TG 476 In vitro Mammalian Cell Gene Mutation Test.
Cell Type/Cell Line	Mouse lymphoma L5178Y cells
Metabolic Activation System	S9
Concentration Range	a) With metabolic activation: 25 - 300 µg/plate b) Without metabolic activation: 25 - 300 µg/plate
Remarks – Method	No significant protocol deviations.
RESULTS	In Test 1 (without S9), toxicity was observed at 300 mg/mL and in Test 2 (without S9) toxicity was observed at 275 and 300 mg/mL. These concentrations were excluded from the mutation analyses. A statistically significant increase in mutant frequency was observed in Test 2 at 250 mg/mL. However, because the increase was small, it was not considered biologically significant; no increase occurred in Test 1. Tests 1 and 2 (with S9 mix) produced reduced survival at 300 mg/mL and 250 mg/mL and above, respectively. These concentrations were excluded from the mutation analyses. No increase in mutant frequency was observed. Component 1 did not demonstrate mutagenic potential in this assay.
CONCLUSION	Component 1 was not clastogenic to mouse lymphoma L5178Y cells treated in vitro under the conditions of the test.
TEST FACILITY	Confidential reference 1

B7b. Genotoxicity – in vitro

TEST SUBSTANCE	Component 1
METHOD	OECD TG 473 In vitro Mammalian Chromosomal Aberration Test.
Cell Type/Cell Line	Human lymphocytes
Metabolic Activation System	S9
Concentration Range	a) With metabolic activation: 75 - 300 µg/plate b) Without metabolic activation: 75 - 300 µg/plate
Remarks – Method	No significant protocol deviations.
RESULTS	No significant increase in the proportion of aberrant cells was observed in either the first or second assay with or without metabolic activation. Component 1 demonstrated no clastogenic activity in this assay.
CONCLUSION	Component 1 was not clastogenic to human lymphocytes treated in vitro under the conditions of the test.
TEST FACILITY	Confidential reference 1

B.8. Toxicity to reproduction – one generation study

TEST SUBSTANCE	Component 1
METHOD	OECD 421 Reproduction/Developmental Toxicity Screening Test
Species/Strain	Rat/Sprague-Dawley
Route of Administration	Oral, diet
Exposure Information	Exposure period - female: 2 weeks prior to mating, then through mating until termination after Day 4 of lactation Exposure period - male: 2 weeks prior to mating until termination
Number of Test Animals	40/sex
Remarks – Method	Test concentrations were 0, 200, 2000 and 20 000 ppm. No significant protocol deviations.

RESULTS

Mortality and Time to Death

Paternal toxicity was exhibited at 20000 ppm as a slight decrease in weight gain and an increase in piloerection. There were no obvious maternal effects at this level.

Effects on Parental (P) animals:

There were no obvious parental effects at 200 or 2000 ppm, nor were there any effects of treatment on the reproductive parameters at any dose level applied. The testes and epididymides weights were essentially similar in all groups.

Effects on 1st Filial Generation (F1)

The mean number of implants per pregnancy was higher in all the treated groups compared to controls. However, historical data shows that the findings in the treated groups were within background ranges for animals of this age and strain. Rather, it was considered most likely that the control value was at the lower end of the background range. There were no obvious effects of treatment on litter size, litter survival, or pup weights at any dose level and no abnormalities noted among pups.

CONCLUSION

Under the conditions of this study, the parental No Observed Effect Level (NOEL) was considered to be 2000 ppm (approximately 180 mg/kg bw/day) and for reproductive parameters the NOEL was considered to be 20 000 ppm (approximately 1858 mg/kg bw/day).

TEST FACILITY	Confidential reference 1

Summary of toxicity data on Component 2 (Confidential reference 3)

Acute toxicity

Oral LD50 ranged from 1750 to 3918 mg/kg (mouse) to 865 to 6000 mg/kg (rat). Dermal LD50s were derived only for rabbits and ranged from 1215 to 3135 mg/kg. Inhalation studies resulted in LC50 values in the mouse of 884 ppm. The upper range for the rat was reported at 6.5 mg/L.

Signs of toxicity from inhalation exposures included irritation to the mucous membranes of the eyes and upper respiratory tract and incoordination; blepharospasms and lacrimation; excessive salivation; ocular, oral, and nasal discharge and encrustation; respiratory difficulties; decreased motor activity; coordination loss, and swelling and bleeding of extremities from excessive preening (high-dose only); and a substantial body-weight loss. Discolored lungs, liver, kidneys, and spleen were observed in rats that died and in two high-dose survivors.

Irritation effects

Moderate to severe erythema and edema with ecchymoses, necrosis, and ulceration occurred after application of Component 2 for 24 hours, and progressed to local desquamation, alopecia, and scarring. Component 2 has been classified as corrosive (occlusive or semi-occlusive dressings).

Application of 0.75 mg Component 2 to the eyes of rabbits produced severe irritation. Moderate to severe corneal injury, iritis, and severe conjunctival irritation (with necrosis) was observed in all rabbits treated with 0.005 mL (4 mg) Component 2.

Skin sensitisation

Component 2 has been classified as a potential skin sensitiser, although this classification has not been supported by human experiences with Component 2 under normal handling procedures. When evaluated in the guinea pig maximation test, Component 2 showed no clear evidence of skin sensitisation.

Repeated dose toxicity
All high-dose (586 ppm) F344 rats died between days 4 through 8, and 4 of 15 mid-dose (288 ppm) males died on days 8 through 12 after inhalation exposure to Component 2 (6 hours/day, 5 days/week, 9 exposures in 11 days). Signs of toxicity included respiratory distress, ocular and nasal irritation, and corneal opacity.

Male and female F344 rats exposed to Component 2 (8 to 76 ppm, 6 hours/day, 5 days/week, 13 weeks) produced corneal opacity in mid- and high-dose rats; an increase in audible respiration was demonstrated in the high-dose group. Histopathologic changes in nasal tissue were observed, including rhinitis, squamous metaplasia, degeneration of respiratory epithelium, atrophy of olfactory epithelium, and microcysts in respiratory epithelium. Nasal lesions were limited to the anterior nasal cavity.

A 4-month continuous inhalation exposure of rats to high concentrations of Component 2 (2.76 mg/m^3) resulted in a disturbance in the "dynamic equilibrium between processes of inhibition and excitation" with "prevalence for excitation."

Chronic exposures of mice to emissions from freshly foamed polyurethane insulation (6.7 mg/m^3 Component 2) produced disturbances in blood composition including increased leukocyte count and decrease in erythrocytes and hemoglobin content.

Male and female New Zealand White rabbits treated dermally with Component 2 up to 1800 mg/kg bw/day developed severe skin irritation. Microscopic examination revealed no treatment related effects in regions other than treated skin.

A 90-day feeding study resulted in a NOAEL and LOAEL of 180 and 890 mg/kg bw/day, respectively, based on increased liver and kidney weights. No further details were reported.

Genotoxicity
Component 2 failed to demonstrate genotoxicity in the *Salmonella typhimurium* assay, *Drosophila melanogaster* sex-linked recessive lethal assay, sister chromatid exchange assays, or hypoxanthineguanine phosphoribosyl transferase forward gene mutation tests (HGPT). No significant increases in the incidence of micronucleated polychromatic erythrocytes were observed in Swiss-Webster mice at dose levels ranging from 270 to 860 mg/kg bw.

Carcinogenicity
There was no statistically significant increase, or morphological difference, in the incidence of neoplasms in any organ in female C3H/HeN mice given drinking water with 900 µg/mL Component 2 for 105 weeks, or in female C3H/HeJ(+) mice given 1300 µg/mL Component 2 for 123 weeks.

Reproductive and teratological Effects
No histopathological changes in the gonads were observed after repeated exposure to Component 2 in a 90-day inhalation study in rats.

Component 2 induced maternal toxicity as demonstrated by changes in body weight gain in the mid- and high-dose (30 and 100 ppm) groups and ocular changes in the mid- and low dose groups (30 and 10 ppm). Sporadic, inconsistent alterations in gestational parameters included significant decreases in viable implants per litter, percentage live fetuses/litter, and litter size in rats exposed to 10 ppm. A significant decrease in the percentage of male fetuses in rats exposed to 30 ppm was reported. Inhaled Component 2 induced an inconsistent pattern of skeletal variations reported as poorly ossified cervical centrum, bilobed thoracic centrum, bilobed sternebrae, unossified proximal phalanges of the forelimb, and increased incidences of split cervical centra, and bilobed thoracic centrum. A NOAEL of 100 ppm or greater was established for embryofetal toxicity and teratogenicity. A NOAEL for maternal toxicity was estimated at 10 ppm.

Pups derived from pregnant rats dosed with Component 2 (gestation day 12 through postnatal day 10) demonstrated diminished behavioral decrements (motor activity in the pups; striatal dopamine release in adults) induced by postnatal hypoxia.

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

Data have been provided for two major components and one analogue of the notified chemical. Component 1 and the analogue are neutral substances closely related to the anionic notified chemical. As these would become ionised in the aquatic environment, in theory, the data (particularly for fate) should be applicable though there may be kinetic considerations due to much lower water solubility. Component 2 is the parent base of the notified chemical, which again should be cationic in the pH range of 4-9.

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Component 1
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test.
Inoculum	Inoculum: Activated sludge microorganisms were obtained from a municipal sewage treatment plant at Wateschap de Aa, Schijndel, the Netherlands.
Exposure Period	28 days
Positive Control	Sodium benzoate
Remarks – Method	The test concentrations used were 10 and 20 mg/L. Analysis: Samples from the CO_2 absorbers were analysed using a Heraeus CHN-analyzer.
RESULTS	
Remarks – Results	6.6% at 10 mg/L and 6.3% at 20 mg/L at 28 days (test substance); 71% at 28 days (sodium benzoate). After 28 days the test substance at both low and high concentrations was degraded approximately 6% and sodium benzoate was degraded 71%.
CONCLUSION	Component 1 cannot be classed as ready biodegradable.
TEST FACILITY	Confidential reference 1

C.1.2. Ready biodegradability

Test Substance	Analogue
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test. Directive 84/449/EEC, C5, CO_2 Evolution Test (modified Sturm)1984
Inoculum	Activated sludge, domestic
Exposure Period	28 days
Remarks – Method	Test concentrations used: 10 mg/L and 20 mg/L
RESULTS	
Remarks – Results	Degradation: 88% and 62% for 10 mg/L and 20 mg/L, respectively, after 28 days.
CONCLUSION	Although the analogue did not meet the criteria for readily biodegradability the substance was considered to biodegrade under the test conditions.
TEST FACILITY	Confidential reference 2

C.1.3. Ready biodegradability - Summary of data for Component 2 (Confidential reference 3)

Test type	*Method*	*Inoculum*	*Concentration*	*Degradation*
Aerobic	Directive 87/302/EEC, Part C, "Biodegradation: Zahn-Wellens test"	Activated sludge	1000 mg/L related to COD	90% after 13 days
Aerobic	OECD Guideline 302B "Inherent biodegradability: Modified Zahn-Wellens Test"	Activated sludge, non-adapted	1000 mg/L related to COD	Lag phase of 3 days > 90% after 13 days
Aerobic	Japanese MITI – BOD, 100 mg/L in 30 g/L activated sludge	Activated sludge	100 mg/L related to test substance	30-100% after 14 days
Aerobic	Japanese MITI, 100 mg/L in 30 g/L sewage	Domestic sewage	100 mg/L related to test substance	60.5 % after 14 days
Aerobic	Dilution bottle BOD test.	Domestic sewage, non-adapted		5 days = 4% 10 days = 67% 20 days = 85%
Aerobic	Not specified	Industrial sewage	100 mg/L related to test substance	79.9% after 14 days

COD = Chemical Oxygen Demand; BOD = Biochemical Oxygen Demand; ThOD = Theoretical Oxygen Demand

C.1.4. Bioaccumulation

CONCLUSION A bioaccumulation study was not performed for the notified chemical. However, data on the major components and an accepted analogue have shown that these may be readily biodegradable. Any bioaccumulation potential is further mitigated by lack of aquatic exposure under the proposed use pattern.

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE Component 1

METHOD
- Species: Fathead minnows (*Pimephales promelas)*
- Exposure Period: 96 hours
- Water Hardness: Not specified
- Remarks – Method: Followed procedures in OECD (2000) Series on Testing and Assessment, No. 23, "*Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures*".

RESULTS
- LLR50 (Lethal Loading Rate): > 1000 mg/L at 96 hours
- $NOEL_r$ (No Observed Effect Loading Rate): 1000 mg/L
- Remarks – Results: The 96 h LL50 was > 1000 mg/L the highest loading rate tested. The No Observed Effect Loading Rate (NOELr) was 1000 mg/L.

CONCLUSION Component 1 is not classifiable using the GHS classification scheme.

TEST FACILITY Confidential reference 1

C.2.2. Acute toxicity to fish

Test Substance Analogue

METHOD Not specified
- Species: *Cyprinus auratus*

Exposure Period	96 hours
Method - Remark	No other details are reported.
RESULTS	
NOEC	≥ 1000 mg/L at 96 hours
Remarks – Results	Due to insoluble nature of product, the water accommodated fraction (WAF) was used for the tests.
CONCLUSION	The analogue is not classifiable using the GHS classification scheme.
TEST FACILITY	Confidential reference 2

C.2.3. Acute toxicity to fish

Test Substance	Analogue
METHOD	Not specified
Species	*Cyprinus carpio* (Fish, fresh water)
Exposure Period	48 hours
Method - Remark	No other details are reported.
RESULTS	
LC0	10 mg/L
LC50	13.4 mg/L
LC100	32 mg/L
CONCLUSION	The test substance is harmful to *Cyprinus carpio* using the GHS classification scheme.
TEST FACILITY	Confidential reference 2

C.2.4. Acute toxicity to fish - Summary of data for Component 2 (Confidential reference 3)

Test type	*Species*	*Method*	*Results*
Static	*Cyprinus carpio* (Fish, fresh water)	Exposure: 96 h	LC0: 107-167 mg/L Not classifiable using the GHS classification scheme. No analyses of test water.
Static	*Cyprinus carpio* (Fish, fresh water)	Exposure: 96 h	LC0: 88-131 mg/L Not classifiable using the GHS classification scheme. No analyses of test water.
Static	*Leuciscus idus* (Fish, fresh water)	Exposure: 96 h	NOEC: 100 mg/L LC0: 100 mg/L LC50: 100 – 200 mg/L Not classifiable using the GHS classification scheme.
Static	*Pimephales promelas* (Fish, fresh water)	Exposure: 96 h	LC50 = 81 mg/L Harmful to fathead minnows using the GHS classification scheme.

C.2.5. Acute toxicity to aquatic invertebrates

Test Substance Component 1

METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – Static conditions.
Species	*Daphnia magna*
Exposure Period	48 hours
Water Hardness	Not specified
Remarks – Method	Followed procedures in OECD (2000) Series on Testing and Assessment, No. 23, "*Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures*".

RESULTS	
LLR50 (lethal loading rate)	> 1000 mg/L at 48 hours
$NOEL_r$ (No Observed Effect Loading Rate)	1000 mg/L at 48 hours
Remarks – Results	The 48 h LLR50 was > 1000 mg/L the highest loading rate tested. The No Observed Effect Loading Rate (NOELr) was 1000 mg/L.
CONCLUSION	Component 1 is not classifiable using the GHS classification scheme.
TEST FACILITY	Confidential reference 1

C.2.6. Acute toxicity to aquatic invertebrates

Test Substance	Analogue
METHOD	Not specified
Species	*Daphnia magna*
Exposure Period	48 hours
Water Hardness	Not specified
Method - Remark	No other details are reported.
RESULTS	
NOEC	≥ 1000 mg/L at 48 hours
Remarks – Results	Due to insoluble nature of product, the water accommodated fraction (WAF) was used for the tests.
CONCLUSION	The NOEC for the analogue to *Daphnia magna* is ≥1000 mg/L and is therefore not classifiable using the GHS classification scheme.
TEST FACILITY	Confidential reference 2

C.2.7. Acute toxicity to aquatic invertebrates - Summary of data for Component 2 (Confidential reference 3)

Species	*Method*	*Exposure*	*Results*
Daphnia magna	Directive 84/449/EEC, C2 "Acute toxicity for Daphnia"	48 h	EC0: 62.5 mg/L EC50: 98.77 mg/L EC100: 250 mg/L Harmful using the GHS classification scheme.
Daphnia magna	Directive 84/449/EEC, C2 "Acute toxicity for Daphnia"	24 h	EC0: 62.5 mg/L EC50: 105.42 mg/L EC100: 250 mg/L Not classifiable using the GHS classification scheme.
Daphnia magna	Directive 84/449/EEC, C2 "Acute toxicity for Daphnia"	48 h	EC0: 62.5 mg/L EC50: 98.37 mg/L EC100: 250 mg/L Harmful using the GHS classification scheme.

C.2.8. Algal growth inhibition test

Test Substance	Component 1
METHOD	OECD TG 201 Alga, Growth Inhibition Test.
Species	Green alga (*Selenastrum capriconutum)*
Exposure Period	72 hours
Concentration Range Nominal	0, 1, 10, 100 and 1000 mg/L
Water Hardness	Not specified
Remarks – Method	Followed procedures in OECD (2000) Series on Testing and Assessment, No. 23, "*Guidance Document on Aquatic Toxicity Testing of Difficult*

Substances and Mixtures".

RESULTS	
Remarks – Results	The 72 h EL50 for area under growth curve (AUC) and Average Specific Growth Rate (0-72h) was > 1000 mg/L. The No Observed Effect Loading Rate (NOELr) for Average Specific Growth Rate and AUC was 1000 mg/L.
CONCLUSION	Component 1 is not considered to be toxic to alga.
TEST FACILITY	Confidential reference 1

C.2.9. Algal growth inhibition test

Test Substance	Analogue
METHOD	Not specified
Species	Other algae
Exposure Period	72 hours
Method - Remark	No other details are reported.
Remarks – Results	NOEC ≥ 1000 mg/L Due to insoluble nature of product, the water accommodated fraction (WAF) was used for the tests.
CONCLUSION	The analogue is not classifiable using the GHS classification scheme.
TEST FACILITY	Confidential reference 2

C.2.10. Algal growth inhibition test - Summary of data for Component 2 (Confidential reference 3)

Species	*Method*	*Exposure*	*Results*
*Scenedesmus sp (*Algae)	Not specified	72 hours	EC20: 18 mg/L EC50: 35 mg/L In contrast to the non-neutralised test (100 mg/L – 94% inhibition), the neutralised test showed a reduction in toxicity (100 mg/L – 74% inhibition) Harmful using the GHS classification scheme.

C.2.11. Inhibition of microbial activity - Summary of data for Component 2
(Confidential reference 3)

Species	*Method*	*Exposure*	*Results*
Pseudomonas putida (bacteria)	Not specified	Not specified	E10: > 8000 mg/L Not classifiable using the GHS classification scheme.

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