File No: STD/1571

April 2016

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Polysiloxanes, methoxy vinyl

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (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 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.

This Public Report is 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:

Street Address:	Level 7, 260 Elizabeth Street, SURRY HILLS NSW 2010, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX:	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

Director
NICNAS

TABLE OF CONTENTS

SUMMARY 3
CONCLUSIONS AND REGULATORY OBLIGATIONS 3
ASSESSMENT DETAILS 5
1. APPLICANT AND NOTIFICATION DETAILS 5
2. IDENTITY OF CHEMICAL 5
3. COMPOSITION 5
4. PHYSICAL AND CHEMICAL PROPERTIES 5
5. INTRODUCTION AND USE INFORMATION 6
6. HUMAN HEALTH IMPLICATIONS 7
6.1. Exposure Assessment 7
6.1.1. Occupational Exposure 7
6.1.2. Public Exposure 7
6.2. Human Health Effects Assessment 7
6.3. Human Health Risk Characterisation 10
6.3.1. Occupational Health and Safety 10
6.3.2. Public Health 10
7. ENVIRONMENTAL IMPLICATIONS 11
7.1. Environmental Exposure & Fate Assessment 11
7.1.1. Environmental Exposure 11
7.1.2. Environmental Fate 11
7.1.3. Predicted Environmental Concentration (PEC) 11
7.2. Environmental Effects Assessment 11
7.2.1. Predicted No-Effect Concentration 12
7.3. Environmental Risk Assessment 12
APPENDIX A: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS 13
A.1. Environmental Fate 13
A.1.1. Ready biodegradability 13
A.2. Ecotoxicological Investigations 13
A.2.1. Acute toxicity to fish 13
A.2.2. Acute toxicity to aquatic invertebrates 14
A.2.3. Algal growth inhibition test 15
BIBLIOGRAPHY 16

SUMMARY

The following details will be published in the NICNAS *Chemical Gazette:*

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
STD/1571	Evonik Australia Pty Ltd	Polysiloxanes, methoxy vinyl	Yes	≤ 10 tonnes per annum	Cross-linking agent for cable and plastic industries

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified polymer is recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the following table.

Hazard classification	*Hazard statement*
Flammable Liquid, Category 4	H227 – Combustible liquid

Human health risk assessment
Provided that the recommended controls are being adhered to, under the conditions of the occupational settings described, the notified polymer is not considered to pose an unreasonable risk to the health of workers.

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

Environmental risk assessment
On the basis of the reported use pattern and limited aquatic exposure, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified polymer and methanol released during use:
  - Enclosed, automated processes, where possible
  - Local exhaust ventilation

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure to the notified polymer and methanol released during use:
  - Avoid contact with skin
  - Avoid breathing in vapours, mists or aerosols

- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer and methanol released during use:
  - Protective clothing
  - Impervious gloves
  - Protective goggles

- Respiratory protection, where vapours, mists or aerosols may be formed

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

- A copy of the (M)SDS should be easily accessible to employees.

- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Disposal

- Where reuse or recycling are not appropriate, dispose of the notified polymer in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by containment, physical 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 polymer 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(1) of the Act; if
- the notified polymer is intended to be used in products available to the public;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the polymer has changed from a cross-linking agent for cable and plastic industries, or is likely to change significantly;
- the amount of polymer being introduced has increased, or is likely to increase, significantly;
- the polymer has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the polymer 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.

(Material) Safety Data Sheet
The (M)SDS of the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

This notification has been conducted under the cooperative arrangement with Canada. The health and environmental hazard assessment components of the Canadian report were provided to NICNAS and, where appropriate, used in this assessment report. The other elements of the risk assessment and recommendations on safe use of the notified polymer were carried out by NICNAS.

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Evonik Australia Pty Ltd (ABN: 31 145 739 608)
Suite 33, 1 Ricketts Road
MOUNT WAVERLEY VIC 2149

NOTIFICATION CATEGORY
Standard (Reduced fee notification): Synthetic polymer with Mn < 1,000 Da (more than 1 tonne per year) – Previously assessed by a comparable agency

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: molecular and structural formulae, molecular weight, analytical data, polymer constituents, residual monomers, impurities, additives/adjuvants and identity of analogue

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed for all physical-chemical properties, and toxicological and ecotoxicological endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Canada (2003), China (2002), Korea (2003) and Taiwan (2010)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Dynasylan® 6490

CAS NUMBER
131298-48-1

CHEMICAL NAME
Polysiloxanes, methoxy vinyl

MOLECULAR WEIGHT (MW)
Mn < 1,000 Da

ANALYTICAL DATA
Reference GC-MS spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 99%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Colourless liquid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	< -70 °C	(M)SDS
Boiling Point	~220 °C at 101.3 kPa	(M)SDS
Density	~1,000 kg/m^3 at 20 °C	(M)SDS
Vapour Pressure	0.2 kPa at 20 °C	(M)SDS
Water Solubility	Immiscible	(M)SDS; expected to rapidly hydrolyse on contact with water
Hydrolysis as a Function of pH	$t_{½}$ < 10 min at pH 4, 9 $t_{½}$ < 2.4 h at pH 7	Measured analogue data*; expected to rapidly hydrolyse on contact with water, acids and bases to release methanol
Partition Coefficient (n-octanol/water)	Not determined	Expected to rapidly hydrolyse on contact with water
Adsorption/Desorption	Not determined	Expected to rapidly hydrolyse on contact with water
Dissociation Constant	Not determined	Expected to rapidly hydrolyse on contact with water
Flash Point	84 - 107 °C (closed cup)	(M)SDS
Flammability	Not determined	Combustible liquid based on flash point
Autoignition Temperature	Not determined	
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidative properties

* OECD SIDS (2010)

DISCUSSION OF PROPERTIES

Reactivity
The notified polymer reacts with moisture to release methanol and form a water insoluble polymeric mass.

Physical hazard classification
Based on the submitted physico-chemical data depicted in the above table, the notified polymer is recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the following table.

Hazard classification	*Hazard statement*
Flammable Liquid, Category 4	H227 – Combustible liquid

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will not be manufactured in Australia. The notified polymer will be imported neat as a liquid.

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

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

TRANSPORTATION AND PACKAGING
The notified polymer will be imported in 25 kg cans, 200 kg drums and 1,000 kg IBCs, and transported within Australia by road and rail.

USE
The notified polymer is a cross-linking agent for both inorganic materials and organic polymers. Major fields of applications are expected to be in the cable and plastics industries.

OPERATION DESCRIPTION
Typically, use of the notified polymer will involve automated and enclosed systems, although manual addition of the polymer to the reactor/mixer may occur. The use concentrations of the notified polymer will be 0.5 – 2%. Methanol will be released during the treatment process from reaction of the notified polymer with the substrate to be treated.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Process workers	1	100

EXPOSURE DETAILS
Dermal and ocular exposure to the notified polymer at up to 100% concentration may occur during weighing and formulation with other components before addition to the reactor/mixer. Dermal and ocular exposure to the notified polymer at up to 100% concentration may also occur when the polymer is manually added to the reactor/mixer. During the treatment process exposure to the notified polymer is not expected as it will be largely automated and enclosed. There is also potential for inhalation exposure to methanol released during the treatment process. Workers are expected to wear PPE and local exhaust ventilation is expected to be in place that should minimise exposure to the notified polymer and the methanol released.

6.1.2. Public Exposure
The notified polymer will be used in industrial settings only. Following use the notified polymer will become covalently bound to the application matrix and will not be available for further exposure. Therefore public exposure to the notified polymer is not expected.

6.2. Human Health Effects Assessment
The notifier stated in the application that no toxicological or ecotoxicological studies are available for the notified polymer and therefore proposed the monomer of the notified polymer as an analogue for the purposes of risk assessment. Due to higher molecular weight and complex polymer structure, the notified polymer is expected to have reduced bioavailability and toxicity compared to the analogue. The analogue is therefore expected to represent the worst-case and is considered acceptable to estimate the toxicity of the notified polymer.

An OECD SIDS dossier and initial assessment report on the analogue are available (OECD SIDS, 2010). The results from toxicological investigations conducted on the analogue are summarised in the following table.

Endpoint	*Result and Assessment Conclusion*	
Acute oral toxicity (rat)	study 1	LD50 = 7,120 mg/kg bw (male); low toxicity
		LD50 = 7,236 mg/kg bw (female); low toxicity
	study 2	LD50 = 7,954 mg/kg bw (male and female); low toxicity
	study 3	LD50 > 300 but < 2,000 mg/kg bw (female); harmful
Acute dermal toxicity (rabbit)	LD50 = 3,880 mg/kg bw (male); low toxicity	
	LD50 = 3,529 mg/kg bw (female); low toxicity	
Acute inhalation toxicity (rat)	LC50 = 16.8 mg/L/4 hour; harmful	
Eye irritation (rabbit)	non-irritating	
Skin sensitisation (Guinea pig)	evidence of sensitisation	
Repeat dose oral toxicity (rat)	LOAEL = 62.5 mg/kg bw/day	
Repeat dose inhalation toxicity (rat)	NOAEC = 0.06 mg/L	
Genotoxicity	evidence of clastogenicity	
Reproductive and developmental toxicity (rat)	oral	NOAEL = 1,000 mg/kg bw/day (male reproduction)
		NOAEL = 250 mg/kg bw/day(female reproduction)
		NOAEL = 1,000 mg/kg bw/day (developmental)
	inhalation	NOAEC = 0.15 mg/L (maternal toxicity)
		NOAEC = 0.60 mg/L (developmental)

Toxicokinetics
The notified polymer is of low molecular weight (458 Da) and therefore may have the potential to be absorbed through biomembranes. However, the notified polymer reacts with moisture to form a highly cross-linked, high molecular weight polymer which is not expected to be significantly absorbed by skin or mucous membranes.

Acute toxicity
The acute toxicity of the analogue has been studied by the oral, dermal and inhalation routes in rats (OECD SIDS, 2010).

Acute oral toxicity
For acute oral toxicity of the analogue, 3 independent studies were available.

In a study conducted in compliance with OECD TG 401, the oral LD50 for the analogue was determined as 7.34 mL/kg bw (equivalent to 7,120 mg/kg bw) for male rats and 7.46 mL/kg bw (equivalent to 7,236 mg/kg bw) for female rats. Sluggishness, red to brown discharge, lacrimation, piloerection, unkempt appearance, prostration, emaciation and unsteady gait were among the signs of toxicity observed. All animals (5/sex) dosed at the highest dose (16 mL/kg bw) died and 6 (3/5 males and 3/5 females) animals died at the next highest dose (8 mL/kg bw). One male also died at a dose of 2 mL/kg bw, although no deaths were observed in the 4.0 mL/kg bw dose group. Deaths occurred at 2.5 hours to 4 days. Survivors recovered by day 5. At necropsy, there were several instances of dark red kidney sections among the animals that died. Most survivors had no remarkable gross lesions; however, one female animal in the 8.0 mL/kg bw dose group was observed to have an enlarged kidney.

In another study conducted in compliance with OECD TG 401, the combined oral LD50 of the analogue in rats was determined as 8.20 mL/kg bw (equivalent to 7,954 mg/kg bw). The incidence of mortality was 0%, 10%, 20%, 50%, and 70% at dose levels of 3783, 4850, 6111, 7663, and 9700 mg/kg bw, respectively. Deaths occurred up to 96 hours after administration. Signs of toxicity included lethargy, diuresis and diarrhoea within 6 hours of administration followed by blood staining around mouth and nostrils at 24 hours.

In a third study conducted to OECD TG 423, the oral LD50 of the analogue in female rats was determined to be between 300 and 2,000 mg/kg bw. In the first trial 3 rats were administered the analogue in a single oral dose at 2,000 mg/kg bw, and groups of 3 rats were dosed at 300 mg/kg bw in the second and third trials. Signs of toxicity included diarrhoea, perianal soiling, and reddish urine. Two animals receiving 2,000 mg/kg bw died within 3 days of administration. All other rats survived until the scheduled necropsy. At necropsy, small thymi and spleens were noted in the animals that died. Histopathological examination showed atrophy of the cortex of the thymus and of the red and white pulp of the spleen.

Acute dermal toxicity
In a study conducted in compliance with OECD TG 402, the dermal LD50 for the analogue was determined as 4.00 mL/kg bw (equivalent to 3,880 mg/kg bw) for male rabbits and 3.36 mL/kg bw (equivalent to 3,259 mg/kg bw) for female rabbits. Deaths occurred at all doses tested (ca. 1940, 3880 and 7760 mg/kg bw) in both males and females, with most deaths occurring in 1 to 5 days. Survivors recovered at 2 to 3 days. Clinical signs including discomfort, sluggishness, unsteady gait, and prostration were observed. Skin reactions included erythema, ecchymosis and desquamation. At necropsy, red and mottled lungs and mottled livers were recorded in the animals that died during the study. No remarkable necropsy findings were noted in survivors.

Acute inhalation toxicity
In a study conducted in compliance with OECD TG 403, the inhalation LC50 in rats for the analogue was determined as 16.8 mg/L/4 hour. Mortalities were observed in all but two exposure groups (11.9 and 14.1 mg/L). Mortalities in males/females were reported to be 2/5, 5/5 and 5/5 at doses of 16.9, 21.5 and 32.5 mg/L, respectively. Clinical signs included perinasal, periocular, perioral and urogenital wetness, perioral and perinasal encrustation, unkempt fur, hypoactivity, blepharospasm, lacrimation, respiratory difficulties, ataxia, prostration, tremors, distended stomachs, and negative righting and pinch reflexes. Body weight gains for all exposure groups were depressed during post-exposure week 1. At necropsy, eye opacities and gas-filled stomachs were observed in rats which died from the 32.5 mg/L exposure group. There were no significant toxicological findings at necropsy in surviving animals. Based on the results, the analogue is classified as Acute Inhalation Toxicity Category 4 (H332 – Harmful if inhaled) under the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS).*

Based on the information available from the analogue, the notified polymer may have the potential to cause effects via the inhalation and oral routes. However, the notified polymer is expected to be of low toxicity via the dermal route.

Irritation and sensitisation
Information on eye irritation, respiratory irritation and skin sensitisation for the analogue were available (OECD SIDS, 2010). However, no valid skin irritation data was available.

In studies conducted to OECD TG 405, the analogue was determined to be non-irritating to the eyes of rabbits.

Although no direct study has been conducted to evaluate respiratory irritancy, data exist to support that the analogue is irritating to the respiratory tract. In the acute inhalation toxicity study, when rats were exposed for four hours to a vapour of the analogue, respiratory difficulties including blepharospasm, mouth breathing, audible respiration, and decreased respiration rate were observed.

Under the conditions of the guinea pig maximization test (OECD TG 406), the analogue did not elicit a delayed contact hypersensitivity response in guinea pigs. However, under the conditions of the Buehler test (OECD TG 406), the analogue was determined to be a skin sensitiser.

Based on the above information, the notified polymer may be irritating to the respiratory tract if inhaled and its potential for skin sensitisation cannot be ruled out.

Repeated dose toxicity
The repeated-dose toxicity of the analogue has been studied by the inhalation and oral routes in rats (OECD SIDS, 2010).

Groups of rats were exposed 6 hours/day, 5 days/week for 14 weeks to the vapour of the analogue at target concentrations of 0, 0.06, 0.6 and 2.4 mg/L. There were no mortalities observed in the study. Clinical signs in the 2.4 mg/L group included urogenital area wetness, alopecia and statistically significant decreases in body weights. Occasional decreases in body weights of the female rats in the 0.60 mg/L group were also observed. Urinalysis results indicated that rats of the 2.4 mg/L group had lower osmolality, lower electrolyte concentrations, and a decrease in estimated creatinine clearance. Microscopic lesions were observed in the urinary bladder and the kidney in the 2.4 mg/L group. Minimal cystitis in the bladder submucosa was observed at 14 weeks, and submucosal mastocytosis was observed at 18 weeks. Renal lesions included papillary necrosis, interstitial oedema, and/or papillary hyperplasia of the transitional epithelium. The No Observed Adverse Effect Concentration (NOAEC) was established as 0.06 mg/L, based on effects in the urinary bladder and kidneys.

In a combined repeated dose oral toxicity study with the reproduction/developmental toxicity screening test conducted to OECD TG 422, male (6/dose) and female (12/dose) rats were administered the analogue via gavage at 62.5, 250 and 1,000 mg/kg bw/day for up to 42 days. Three test animals (2 males and 1 female) at 1,000 mg/kg bw/day dose level died. Soiled hair, decrease in locomotor activity, reddish urine, hypothermia, perioral smudges, perianal soiling, diarrhoea, bradypnea, and/or piloerection were noted in the dying animals. Soiled hair and reddish urine were also noted in the surviving rats at 250 and 1,000 mg/kg bw/day dose levels. Effects primarily on the urinary bladder, intestine, kidney, and thymus in both sexes at all dose levels were observed. The No Observed Adverse Effect Level (NOAEL) was not established in this study. The Lowest Observed Adverse Effect Level (LOAEL) was 62.5 mg/kg bw/day, based on decreased relative thymus weight in females and histopathological changes in the urinary bladder of males.

Based on the above information on the analogue, upon repeated or prolonged exposure the notified polymer may have similar potential to cause adverse effects on certain organs including the urinary bladder and kidney.

Mutagenicity/Genotoxicity
In several genotoxicity studies, the analogue did not induce gene mutations in bacteria or mammalian cells *in vitro*, did not induce dose-related increase in sister chromatid exchange and did not induce micronuclei *in vivo*. However, in two chromosome aberration studies the analogue had positive clastogenic effects *in vitro*, especially in the presence of metabolic activation (OECD SIDS, 2010).

The potential for the notified polymer to cause clastogenicity effects cannot be ruled out.

Toxicity for reproduction
In the combined repeated dose oral toxicity study with the reproduction/developmental toxicity screening test conducted to OECD TG 422, a low number of oestrous cases were noted at the highest dose tested (1,000 mg/kg bw/day). No other adverse effects on reproductive parameters attributable to the analogue were noted. The NOAEL for reproductive performance was established in this study as 1,000 mg/kg bw/day for males and 250 mg/kg bw/day for females. There were no effects on developmental parameters, thus the NOAEL for developmental effects was established as 1,000 mg/kg bw/day.

In the 14-week repeated-dose inhalation toxicity study, an evaluation of the reproductive organs was also conducted. The study showed that the analogue did not show effects on the reproductive organs at all doses tested.

In a developmental toxicity study, pregnant rats were exposed 6 hours/day on gestational days 6 through 15 to the vapour of the analogue at concentrations of 0.15, 0.60 and 1.8 mg/L. The NOAEC for maternal toxicity was established in this study as 0.15 mg/L based on decreased body weight gain. The NOAEC for developmental effects was established as 0.60 mg/L based on evidence of slightly delayed skeletal ossification in foetuses in the high dose group.

Health hazard classification
As no toxicity data were available for the notified polymer itself, the notified polymer cannot be recommended for classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human Health Risk Characterisation
Based on the results from studies conducted on the analogue, the notified polymer may have potential to cause acute and repeated dose toxicity effects via the inhalation and oral routes. Its potential for respiratory irritation, skin sensitisation and clastogenicity cannot be ruled out. However, given the relatively low vapour pressure and high molecular weight of the notified polymer, inhalation exposure is only expected where vapours, mists or aerosols are formed. The notified polymer also releases methanol during end-use which is known to be toxic and flammable.

6.3.1. Occupational Health and Safety
Dermal and ocular exposure to the notified polymer at up to 100% concentration may occur during industrial applications only if manual handling of the polymer is required. During the treatment process exposure to the notified polymer is not expected as it will be largely automated and enclosed. However, there may be potential for inhalation exposure to methanol released during the treatment process from reaction of the notified polymer with the substrate to be treated. The notifier has stated that workers are expected to wear PPE and local exhaust ventilation will be in place. These control measures are expected to minimise exposure to the notified polymer and the methanol released.

Therefore, provided control measures are in place to minimise exposure to the notified polymer and methanol released during use, the risk to workers from use of the notified polymer is not considered to be unreasonable.

6.3.2. Public Health
The notified polymer will not be made available for public use. After the industry applications, the notified polymer will become covalently bound to the application matrix and will not be available for further exposure. Therefore public exposure to the notified polymer is not expected.

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

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer will be imported neat to act as a cross-linking agent between organic polymers and inorganic materials for the cable and plastics industry. There is unlikely to be any significant release to the environment from transport and storage, except in the case of accidental spills and leaks. In the event of spills, the product containing the notified polymer is expected to be collected with inert material, and disposed of to landfill in accordance with local government regulations.

The reformulation process will involve transfer of the notified polymer into blending vessels, followed by blending operations that will be highly automated and expected to occur within a fully enclosed environment. Therefore, significant release of the notified polymer from this process to the environment is not expected. Wastes containing the notified polymer generated during reformulation include spilt materials and empty import containers, and are expected to be collected and disposed of to landfill in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE

Upon application as a cross-linker, the notified polymer will react rapidly and become part of a cured inert matrix. No significant release of the notified polymer to the aquatic compartment is expected from use. Accidental spills and leaks are expected to be collected for disposal to landfill in accordance with local government regulations.

RELEASE OF CHEMICAL FROM DISPOSAL

The notified polymer will act as a cross-linking agent between organic polymers and inorganic materials in an industrial setting, and will share the fate of the articles to which it is bound. At the end of their useful lives, articles containing the notified polymer are expected to be disposed of to landfill, or undergo thermal decomposition during substrate reclamation. Residues of the notified polymer in empty import containers are expected to be disposed of to landfill. Therefore, no significant aquatic release of the notified polymer is expected from disposal.

7.1.2. Environmental Fate

No environmental fate studies were submitted for the notified polymer. However, a ready biodegradability report is available for a suitable analogue chemical. Based on the biodegradability of the analogue, the notified polymer is not expected to be readily biodegradable (64-123% in 28 days, failing the 10-day window), but is expected to be ultimately biodegradable. This is supported by the results from another ready biodegradability study on the analogue (tested according to OECD TG 301 F) which showed 51% degradability in 28 days (OECD SIDS, 2010). For details of the environmental fate study, please refer to Appendix A.

The majority of the notified polymer will be bound within an inert matrix, and will not be mobile or bioavailable once cured. The notified polymer will share the fate of the articles to which it is adhered, and will most likely entail disposal to landfill or undergo thermal decomposition during substrate reclamation. Therefore, in landfill and in recycling, the notified polymer is expected to eventually degrade through biotic and abiotic processes to form water and oxides of carbon and silicon.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has not been calculated for the notified polymer, as no significant aquatic release is expected from the proposed use pattern.

7.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on the analogue of the notified polymer are summarised in the table below. Details of these studies can be found in Appendix A.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	96 h LC50 > 100 mg/L	Not harmful to fish
Daphnia Toxicity	48 h EC50 = 168.7 mg/L	Not harmful to *Daphnia*

Endpoint	*Result*	*Assessment Conclusion*
Algal Toxicity	72 h E_rC50 > 957 mg/L	Not harmful to algae
Inhibition of Bacterial Respiration*	3 h IC50 > 1000 mg/L	Not inhibitory to microbial respiration

* OECD SIDS (2010)

Based on the above ecotoxicological endpoints for the analogue, and therefore the notified polymer, it is not expected to be harmful to aquatic life. Therefore, the notified polymer is not formally classified under the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* (United Nations, 2009) for acute and chronic toxicities.

7.2.1. Predicted No-Effect Concentration

The predicted no-effects concentration (PNEC) has not been calculated, as the notified polymer is not expected to be harmful to aquatic life, and no significant release is expected from the proposed use pattern.

7.3. Environmental Risk Assessment

A Risk Quotient (RQ = PEC/PNEC) has not been calculated, as no significant release of the notified polymer to the environment is expected from the proposed use pattern. The majority of the notified polymer will be disposed of to landfill as a cured inert matrix and will not be bioavailable or mobile in this form. On the basis of the assessed use pattern as an industrial cross-linking agent for cables and plastic products and the expected limited aquatic release, the notified polymer is not expected to pose an unreasonable risk to the environment.

APPENDIX A: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

A.1. Environmental Fate

A.1.1. Ready biodegradability

TEST SUBSTANCE	Analogue
METHOD	OECD TG 301 B Ready Biodegradability: CO2 Evolution Test.
Inoculum	Activated sludge from a domestic wastewater treatment plant.
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Theoretical Carbon Dioxide ($ThCO_2$)
Remarks - Method	No significant deviation in protocol was reported. The test was conducted at two concentrations of the test substance, 10.1 mg/L and 19.93 mg/L.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
6	31-35	6	70
11	37-45	11	73
20	49-70	20	78
28	64-123	28	93

Remarks - Results	All validity criteria for the test were satisfied. The percentage degradation of the reference compound surpassed the threshold level of 60% by 6 days (70%). Therefore, the test indicates the suitability of the inoculum. The degree of degradation of a 10.1 mg/L concentration of the test substance after 28 days was 64%, and the degradation at 19.93 mg/L of the test substance was 123% after 28 days; a degradation plateau was not achieved at 10.1 mg/L of the test substance. For both test concentrations, the 10-day window was not achieved. Therefore, the test substance is not considered to be readily biodegradable according to the OECD (301 B) guideline, although the test substance demonstrated ultimate biodegradability. However, these data should be treated with caution given the large discrepancy between the results for the two test concentrations.
CONCLUSION	The analogue, and hence the notified polymer, is not readily biodegradable.
TEST FACILITY	Hüls AG (1993c)

A.2. Ecotoxicological Investigations

A.2.1. Acute toxicity to fish

TEST SUBSTANCE	Analogue
METHOD	EC Regulation 92/69/EEC Method C.1 Acute Toxicity for Fish – Semi-static
Species	*Brachydanio rerio* (zebrafish)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	190 mg $CaCO_3$/L
Analytical Monitoring	Not specified
Remarks – Method	No significant deviation in protocol was reported.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality (%)*				
Nominal	*Actual*		*0 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control	Control	10	0	0	0	0	0
100	103	10	0	0	0	0	0

LC50	> 100 mg/L at 96 hours.
NOEC	≥ 100 mg/L at 96 hours.
Remarks – Results	All validity criteria for the test were satisfied. The frequency of renewal of the test solutions was not specified. The actual concentrations of the test substance were measured 24 hours during the 96 h test period. The 96 h LC50 and NOEC for fish were determined to be > 100 mg/L and 100 mg/L, respectively, based on the nominal concentration.
CONCLUSION	Under the study conditions the analogue, and hence the notified polymer, is not considered to be harmful to fish.
TEST FACILITY	Hüls AG (1994)

A.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Analogue
METHOD	EC Regulation 84/449/EEC Method C.2 Acute Toxicity for *Daphnia* – Static
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	None
Remarks - Method	No significant deviation in protocol was reported. The definitive test was conducted at the nominal concentrations of 57, 80, 115, 160, 229, 321, and 458 mg/L of the test substance. A total of 20 daphnids (5 daphnids/replicate across 4 replicates) were used.

RESULTS

Nominal Concentration mg/L	*Number of D. magna*	*Cumulative Immobilised (%)*	
		24 h	*48 h*
Control	20	0	0
57	20	5	25
80	20	5	25
115	20	5	35
160	20	0	35
229	20	25	45
321	20	55	75
458	20	90	100

EC50	168.7 mg/L (95% CI 126.9-224.2 mg/L) at 48 hours
NOEC	< 57 mg/L at 48 hours
Remarks - Results	All validity criteria for the test were satisfied. The test solutions were not renewed during the 48 h test period. The 48 h EC50 and NOEC for daphnids were determined to be 168.7 mg/L and < 57 mg/L, respectively, based on the nominal concentration.
CONCLUSION	Under the study conditions the analogue, and hence the notified polymer, is not considered to be harmful to aquatic invertebrates.
TEST FACILITY	Hüls AG (1993b)

A.2.3. Algal growth inhibition test

TEST SUBSTANCE	Analogue
METHOD	OECD TG 201 Freshwater Alga and Cyanobacteria, Growth Inhibition Test
Species	*Scenedesmus subspicatus* 86.81 SAG (green alga)
Exposure Period	72 hours
Concentration Range	Nominal: 64-957 mg/L Actual: Not determined
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	None
Remarks - Method	No significant deviation in protocol was reported.

RESULTS

Biomass		*Growth*	
E_bC50 mg/L at 72 h	*NOEC mg/L*	*E_rC50 mg/L at 72 h*	*NOEC mg/L*
> 957	957	> 957	957

Remarks - Results	All validity criteria for the test were satisfied. The 72 h E_bC50, E_rC50 and NOEC were all determined to be > 957 mg/L and 957 mg/L, based on the nominal concentration.
CONCLUSION	Under the study conditions the analogue, and hence the notified polymer, is not considered to be harmful to algae.
TEST FACILITY	Hüls AG (1993a)

BIBLIOGRAPHY

Hüls AG (1993a) Determination of the Effects of [Analogue] on the Growth of *Scenedesmus subspicatus* 86.81 SAG (Study No. AW-312; 09 August 1993). Marl, Germany, Hüls Aktiengesellschaft (Unpublished report submitted by the notifier).

Hüls AG (1993b) Determination of the Effects of [Analogue] on the Swimming Behavior of *Daphnia magna* (Study No. DK-561; 09 August 1993). Marl, Germany, Hüls Aktiengesellschaft (Unpublished report submitted by the notifier).

Hüls AG (1993c) Determination of the Biodegradability of [Analogue] in the Modified OECD Sturm Test (Study No. ST-70/93; 20 August 1993). Marl, Germany, Hüls Aktiengesellschaft (Unpublished report submitted by the notifier).

Hüls AG (1994) Determination of the Acute Effects of [Analogue] on Fish (Study No. FK-1252; 07 January 1994). Marl, Germany, Hüls Aktiengesellschaft (Unpublished report submitted by the notifier).

NOHSC (2004) Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

OECD SIDS (2010) OECD Existing Chemicals Database: [Analogue] (Published in August 2010).

United Nations (2009) Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 3rd revised edition. United Nations Economic Commission for Europe (UN/ECE), <http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html>.