

Existing Chemical Secondary
Notification Assessment Report
ECSNA/2



Australian Government

Department of Health

National Industrial Chemicals

Notification and Assessment Scheme

Polymer in FDP-S948B-09

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

GPO Box 58, Sydney NSW 2001 AUSTRALIA

www.nicnas.gov.au

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Preface

The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) carried out this assessment. This scheme was established by the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act), to aid in the protection of the Australian people and the environment. The scheme achieves this by assessing the risks of industrial chemicals, providing information and making recommendations to promote their safe use. Staff employed by the Australian Government Department of Health carry out NICNAS assessments in conjunction with the Australian Government Department of the Environment and Energy.

This assessment 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 2010, Australia

Postal address: GPO Box 58, Sydney NSW 2001, Australia

Telephone: + 61 2 8577 8800

Fax: + 61 2 8577 8888

Email: info@nicnas.gov.au

Website: www.nicnas.gov.au

Director
NICNAS

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Overview

Background

NICNAS assessed the Polymer in FDP-S948B-09 under the limited notification category. At application, a notifier submitted an assessment of the polymer by a notification and assessment scheme in an Organisation for Economic Cooperation and Development (OECD) country (Canada). Canadian authorities provided health and environment hazard assessments of the Canadian report to NICNAS. Where appropriate, NICNAS used them in the assessment report. NICNAS carried out the other elements of the risk assessment and made recommendations on safe use of the notified polymer.

In 2017, NICNAS was informed of an intended new use for the polymer with a similar number-average molecular weight (NAMW) and weight-average molecular weight (WAMW) that warranted a secondary notification. This secondary notification assessment assesses the risks posed to the public, workers and the environment from the new use of the polymer.

Exempt Information (Section 75 of the Act)

The applicant has claimed as exempt from publication the following details and data items:

- exact product composition
- molecular formula
- other names
- structural formula
- molecular weight
- spectral data
- details of use
- manufacture/import volume

Additional third party provided data items exempt from publication are:

- chemical name
- CAS number
- structural formulae
- analytical data
- degree of purity
- polymer constituents
- residual monomers
- impurities
- additives/adjuvants
- site of manufacture/reformulation
- identity of manufacturer/recipients
- identity of impurities not declared in the Safety Data Sheet
- details of manufacturing methods

Importation/manufacturing volume and uses

The notified polymer is not manufactured in Australia and is imported at a concentration of 10-30% as part of the product FDP-S948B-09. The product is a hardener for an epoxy resin system used in on-shore oil/gas well operations, primarily in coal seam gas (CSG) extraction. The polymer was originally notified for the new chemical assessment as being imported at <30% concentration in a product used in the construction sector.

The maximum import volume of the polymer is up to two tonnes per annum, compared to an initial annual introduction of up to one tonne as originally assessed. The product FDP-S948B-09, containing the notified polymer, will be used in a trial in Australia to assess the local technical performance and the product's market viability. If the trial is successful, and the applicant decides to bring the product to market, an increase in import volume is expected.

Human health effects

The applicant submitted no new human health toxicity data for the secondary notification of Polymer in FDP-S948B-09. Therefore, the health effects of the notified polymer were not reassessed in this secondary notification assessment and they remain unchanged from the original assessment.

Based on the physico-chemical properties and given the low molecular weight, percutaneous absorption and absorption across the GI tract of the notified polymer is possible.

Human health toxicity data showed that the polymer has low acute toxicity via the oral and dermal routes based on studies in rats. It was a slight skin irritant and a severe eye irritant in rabbits. The polymer is also a skin sensitiser based on the results of a guinea pig maximisation test and two Local Lymph Node Assays in mice. No repeat dose toxicity studies were provided.

Occupational exposure and health risks

Based on information assessed in the original new chemical report, the notified polymer is a slight skin irritant, a severe eye irritant and a skin sensitiser.

The product containing the notified polymer will be shipped in intermediate bulk container (IBC) totes and large drums, and will be transported by truck to on-shore drilling sites for trial.

During use (i.e. mixing and pumping of resin into the well) incidental dermal, ocular, and inhalation exposure of workers to the notified polymer at concentrations up to 30% may occur. There is a risk of skin and eye irritation and skin sensitisation in these workers if exposure occurs. However, manual handling is expected to be of low frequency and workers will wear appropriate personal protective equipment (PPE) while handling the product. The operations using the product are expected to be performed in ventilated areas and most handling of the product will occur outdoors. It is anticipated that these control measures already in place to minimise exposure will be sufficient to mitigate these health risks for workers. After preparation the product will be used in a closed system and exposure to the notified polymer is expected to be limited.

Overall, given the minimal manual handling and PPE used by workers, the health risk to workers during the proposed use of the polymer is expected to be low.

Public exposure and health risks

The notified polymer is intended only for use in industry, and as such direct public exposure to the notified chemical is not expected. The polymer will be introduced into the oil/gas well as part of a specific treatment application, and will harden and remain down hole. Only small quantities of residual polymer at high dilution are expected to come up from the well and, together with any remaining fluid and washings from the mixing equipment, will be disposed of by the operators according to local regulations. Overall, given the use pattern, the health risk to the public is considered to be negligible.

Environmental effects

The applicant provided a biodegradability study and new marine ecotoxicity studies for a mixture containing 40-70% of the notified polymer for this assessment. The data indicate that the polymer is not readily biodegradable in seawater, is toxic to marine invertebrates and algae and not toxic to marine fish under the conditions of the studies. All studies were considered relevant to this assessment based on the reported salinity levels of the region in which the CSG trial sites are located.

Environmental exposure and risks

The proposed new use of the notified polymer is primarily in coal seam gas (CSG) operations as a component of an epoxy resin system. On the basis of the assessed use pattern and the currently available information, the notified polymer is not considered to pose an unreasonable risk to the environment provided the control measures described in the Recommendations section are implemented.

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Recommendations

This section provides the recommendations arising from the secondary notification assessment of the notified polymer, and incorporates the applicable recommendations from the new chemical assessment report. The hazard classifications presented below are according to the GHS (United Nations, 2009). Recommendations based on the assessment of new data are marked **ND**.

Recommendations are directed principally at importers.

Recommendations to importers and state and territory governments

Based on the assessment findings, the notified polymer is classified according to the GHS (United Nations, 2009) as below:

- Serious Eye Damage/Eye Irritation (Category 1): H318 – Causes serious eye damage
- Skin sensitiser (Category 1): H317 – May cause an allergic skin reaction
- Acute Aquatic Toxicity (Category 1): H400 – Very toxic to aquatic life (**ND**)
- Chronic Aquatic Toxicity (Category 1): H410 – Very toxic to aquatic life with long lasting effects (**ND**)

Hazard communication

Labels

The classification recommended above contains an environmental hazard classification. At the time of this assessment, labelling to include the environmental hazard classification under the GHS is not mandated in Australia and it carries no legal status. However importers could consider including it in the labels as best practice.

Safety Data Sheets (SDSs)

Employees must have easy access to SDSs for hazardous substances at their workplace under:

- the *Model Work Health and Safety Regulations* (Safe Work Australia, 2016a)
- Commonwealth, state and territory regulations introduced in accordance with these model regulations

SDSs provide information to those who use the hazardous substance.

Importers of the notified polymer should:

- update their SDS to reflect the updated environmental hazard information in this assessment
- review their SDS for compliance with the *Preparation of safety data sheets for hazardous chemicals - Code of practice* (Safe Work Australia, 2016b)
- ensure that employees exposed to the polymer have easy access to a copy of the SDS

Control measures

Occupational controls

A person conducting a business or undertaking (PCBU) at a workplace should implement the following engineering controls to minimise occupational exposure to the notified polymer during reformulation processes:

- enclosed, automated processes, where possible
- adequate general and local exhaust ventilation if handling occurs in confined workplaces

A PCBU at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer:

- avoid skin and eye contact
- avoid contact with uncured product
- do not inhale vapours/mists

A PCBU at a workplace should ensure that workers use the following PPE to minimise occupational exposure to the notified polymer when handling is required for blending, hose disconnection and cleaning:

- safety goggles
- impervious gloves
- protective coveralls
- respiratory protection if vapours/mists are generated

Guidance in the selection of PPE can be obtained from Australian, Australian/New Zealand or other approved standards.

If products and mixtures containing the notified polymer are also classified as hazardous to health in accordance with the GHS (United Nations, 2009) as adopted for industrial chemicals in Australia, then PCBUs must adopt workplace practices and control procedures. They must be consistent with provisions of state and territory hazardous substances legislation for handling these products and mixtures.

Health surveillance

As the notified polymer is a potential skin sensitiser, employers should monitor the health of any worker identified in the workplace risk assessment as having a significant risk of sensitisation. Employers should review the publication *Health Monitoring for Exposure to Hazardous Chemicals – Guide for Medical Practitioners* (Safe Work Australia, 2013).

Environment

Based on the assessed use pattern and currently available information the notified polymer is not considered to pose an unreasonable risk to the environment provided the control measures described below are implemented.

Disposal

Where reuse or recycling are not appropriate, users of the notified polymer should dispose of it in accordance with the relevant Commonwealth, state, territory and local government legislation. They should not directly dispose of it to surface and ground waters (**ND**).

To minimise exposure of the environment to the notified polymer, users of the notified polymer (or products containing the notified polymer) should employ best practice on-site treatment to maximise removal of the notified polymer from waste streams (**ND**).

Storage

Users of the notified polymer should securely close containers and store them according to container label instructions.

Emergency procedures

Users should capture any spills or overflow on-site. They should handle spills or accidental release of the notified polymer by physical containment, collection and subsequent safe disposal. They should

implement local work methods on-site that provide guidance on the appropriate course of action to be taken in the event of spill and ensure the protection of persons and the environment. They must report any spill in accordance with standard Health, Safety and Environment (HSE) incident reporting/recording.

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Regulatory Obligations

Secondary Notification

This risk assessment is based on the information available at the time of the secondary notification. The Director may call for the reassessment of the polymer under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) an introducer (importer/manufacturer) of the notified polymer, has post-assessment regulatory obligations to notify NICNAS when any of these circumstances change.

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

- details of the operation description are altered such that exposure to workers or the environment may be increased

or

(2) Under Section 64(2) of the Act; if

- the function or use of the polymer has changed from CSG applications in the Surat Basin, Queensland, or is likely to change significantly
- the amount of polymer being introduced has increased, or is likely to increase, significantly
- if 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.

Abbreviations and acronyms

Abbreviation / Acronym	Meaning
Act, the	Commonwealth Industrial Chemicals (Notification and Assessment) Act 1989
AICS	Australian Inventory of Chemical Substances
bw	body weight
CAS RN	Chemical Abstracts Service Registry Number
CHARM	Chemical Hazard and Risk Management
CI	confidence interval
COD	chemical oxygen demand
CSG	coal seam gas
d	day
Da	Daltons (units of molecular weight)
DPM	disintegrations per minute
EC3	estimated concentration needed to produce a three-fold increase in lymphocyte proliferation
EC50	median effective concentration or half maximal effective concentration
E _b C50	the concentration which results in a 50 percent reduction in biomass
E _r C50	the concentration which results in a 50 percent reduction in growth rate
g	gram
GHS	Globally Harmonized System of Classification and Labelling of Chemicals (United Nations)
GPC	gel permeation chromatography
hazard	inherent property of an agent or situation having the potential to cause adverse effects when an organism, system or (sub)population is exposed to that agent; intrinsic property of a substance to cause harm
HPLC	high performance liquid chromatography
IBC	intermediate bulk container
ISO	International Organisation for Standardisation
Kow (or Pow)	octanol-water partition coefficient (see also Pow)
kg	kilogram
kPa	kilopascals
L	litre
LC50	median lethal concentration
LD50	median lethal dose

Abbreviation / Acronym	Meaning
LLNA	local lymph node assay
LOAEL	lowest observed adverse effect level
m ³	cubic metre
µg	microgram
mg	milligram
mg/kg bw	milligram per kilogram bodyweight
mL	millilitre
(M)SDS	(Material) Safety Data Sheet (also see SDS)
MW	molecular weight
NAMW	number-average molecular weight
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
n.d.	not determined
NOEC	no observed effect concentration
OECD	Organisation for Economic Co-operation and Development
OSPAR	Oslo/Paris convention (for the Protection of the Marine Environment of the North-East Atlantic)
Pa	pascal
PCBU	person conducting a business or undertaking
PEC	predicted environmental concentration
Pow (or Kow)	octanol-water partition coefficient (see also Kow)
PNEC	predicted no effect concentration
PPE	personal protective equipment
risk	probability or likelihood of harm and the likely extent of the harm; the probability of an adverse effect in an organism, system or (sub)population caused under specified circumstances by exposure to an agent
SDS	Safety Data Sheet (also see MSDS)
sp.	species
SI	Stimulation Index
TG	test guideline
UV	ultraviolet
WAMW	weight-average molecular weight
v/v	volume to volume
wt	weight
w/w	weight to weight

1. Introduction

1.1 Background

NICNAS assessed Polymer in FDP-S948B-09 as a new chemical under Section 32 of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) under the limited notification category. At application, the notifier submitted an assessment of the polymer by a notification and assessment scheme in an OECD country (Canada). The health and environmental hazard assessments of the Canadian reports were provided to NICNAS and, where appropriate, used in the new chemical assessment report. The risk assessment and recommendations on safe use of the notified polymer were carried out by NICNAS.

In 2017, Halliburton Australia Pty Ltd (the applicant) advised NICNAS of its intention to import the notified polymer with a similar number-average molecular weight (NAMW) and weight-average molecular weight (WAMW). The polymer was to be used as a component of an epoxy resin system to be trialed in on-shore oil/gas well operations, primarily in coal seam gas (CSG) extraction. This new use may result in a potential release of the polymer into the aquatic environment. The original assessment of the notified polymer by NICNAS was for use as a curing agent in a product used in the construction sector.

Furthermore, introduction volumes are proposed to significantly exceed those previously assessed. Therefore, a reassessment of environmental and human health risks for the polymer is required. This secondary notification assessment focuses on the new data the applicant provided.

This report summarises data submitted for the original assessment on toxicity. The reference details of the studies the original notifier provided for assessment of the polymer as a new chemical are not provided due to commercial confidentiality.

1.2 Declaration

NICNAS published a notice in the Chemical Gazette of February 2018, requiring a secondary notification of Polymer in FDP-S948B-09, in accordance with Section 65(2) of the Act. The declaration required the provision of any information relevant to the assessment of the notified chemical that the new chemical assessment did not cover and included the following:

- 1) Properties and uses:
 - a. Annual import volumes of the polymer
 - b. The concentration of the polymer in the imported formulated product
 - c. The geographical locations where the polymer will be used for CSG operations in Australia
 - d. Description of the use of the polymer in CSG operations and the concentration and volume of the polymer used during an application
 - e. Description of transportation, packaging and storage of the imported formulated product
 - f. Description of the operations involving the polymer including the concentration and volume of the polymer used during each operation
 - g. Description of the handling of the polymer during use, including:
 - i. Description of work done for each category of worker (transportation, storage, use in CSG operation)
 - ii. For each category of worker handling the product containing the polymer, the

number of workers involved in each category, frequency and duration of each activity (e.g. hours per day and days per year)

iii. Measures to prevent worker exposure

h. Description of the capture, storage, treatment and disposal of waste fluids containing the polymer produced from operations, including:

i. Expected volumes of waste fluids containing the polymer produced during use

ii. The concentration of the polymer in these waste fluids

i. Description of management measures in place for surface spills and leaks during transport, storage and use of the products containing the polymer, including:

i. Expected volumes of waste fluids containing the polymer produced during use

2) Human health and environmental data:

a. Any toxicology data for the polymer, or a suitable analogue

b. Any ecotoxicology data for the polymer, or a suitable analogue

c. Any environmental fate studies for the polymer, or a suitable analogue

1.3 Objectives

The objectives of this assessment are to review the new data made available since the publication of the new chemical assessment report and, where appropriate, to revise the original assessment to:

- re-assess the human health hazards associated with the notified polymer
- re-assess the environmental hazards associated with the notified polymer
- re-assess the risks of adverse effects resulting from exposure to workers, the public and the environment from the use of the notified polymer
- based on the above, make appropriate recommendations to control exposures and reduce potential risks for workers, the public and the environment, as required.

1.4 Peer review

During all stages of preparation, this report has been subject to internal peer review by NICNAS.

1.5 Applicant

Following the secondary notification declaration of Polymer in FDP-S948B-09, the company specified in the declaration, Halliburton Australia Pty Ltd, applied for reassessment of this polymer. In accordance with the Act, NICNAS provided the applicant with a draft copy of the report for comment during the corrections/variations phase of the assessment. The applicant details are as follows:

Halliburton Australia Pty Ltd
Level 10, 147 Pirie Street
Adelaide, SA 5000

1.6 Exempt information

The applicant claimed the following details as exempt from publication under Section 75 of the Act:

- exact product composition
- molecular formula

- other names
- structural formula
- molecular weight
- spectral data
- details of use
- manufacture/import volume

Additional third party provided data items exempt from publication are:

- chemical name
- CAS number
- structural formulae
- analytical data
- degree of purity
- polymer constituents
- residual monomers
- impurities
- additives/adjuvants
- site of manufacture/reformulation
- identity of manufacturer/recipients
- identity of impurities not declared in the Safety Data Sheet
- details of manufacturing methods

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2. Chemical identity, physical and chemical properties

The chemical identity, physical and chemical data assessed by NICNAS in the new chemical assessment report are reproduced in this report. New data the applicant submitted for this secondary notification assessment are indicated as **ND**.

2.1 Chemical identity

Chemical identity

Marketing name: Polymer in FDP-S948B-09 (**ND**)

Analytical data: The notifier provided reference GPC and UV spectra for the new chemical assessment.

2.2 Composition

Composition

Degree of purity: >90%

Loss of monomers, other reactants, additives and impurities: The polymer is stable under normal conditions of use

Degradation products: The polymer is not expected to degrade under normal conditions of use. In the event of degradation, the typical decomposition products are expected to be oxides of nitrogen and carbon.

2.3 Physical and chemical properties

The physical and chemical data for the notified polymer in the new chemical assessment report are shown in Table 2.1. The new data the applicant submitted for Polymer in FDP-S948B-09 are indicated as **ND**, and a robust summary of this data is in Appendix A.

Table 2.1 - Summary of physical and chemical properties

Unless otherwise stated, values are sourced from the MSDS for the product containing < 70% notified polymer.

Property	Value	Data Source/Justification
Appearance at 20°C and 101.3 kPa	Amber liquid	
Boiling Point	100°C at 101.3 kPa	
Density	1090 kg/m ³ at 21°C	
Vapour Pressure	< 0.67 kPa at 21°C	

Water Solubility	> 500 g/L at 20°C	Measured, OECD TG 105
Hydrolysis as a Function of pH	Not determined	Hydrolysis is not expected as the polymer contains no environmentally hydrolysable groups.
Partition Coefficient (n-octanol/water)	Log K _{OW} = 1.67 Log Pow = 1.5 (weighted average) (ND)	Predicted. The polymer is expected to have a low log K _{OW} based on the high water solubility. OECD TG 117. HPLC determined value for the product containing 40-70% notified polymer (Opus Plus, 2010a)
Adsorption/Desorption	Not determined	Due to low MW and high water solubility, the notified polymer is not expected to adsorb significantly to organic carbon through hydrophobic interactions. It may partition to the solid phase based on electrostatic interactions.
Dissociation Constant	Not determined	As a salt the polymer will be ionised in the environmental pH range of 4-9.
Particle Size	Not relevant	Liquid
Flash Point	> 100°C (pressure unknown)	Closed cup
Explosive Properties	Not explosive	Based on structure and the lack of structural alerts.

3. Importation and use

Importation

The applicant will import the notified polymer by sea as a component of the product, FDP-S948B-09, at 10-30% concentration as a liquid. It will not be manufactured, processed or reformulated in Australia. The product containing the notified chemical at 10-30% concentration in intermediate bulk will be imported in container (IBC) totes and drums. The product will be transported from the wharf by truck to on-shore drilling sites for storage prior to trial use.

The maximum introduction volume of the notified chemical over the next two years will be up to two tonnes per annum as compared to an annual introduction of one tonne per annum as originally assessed. The product FDP-S948B-09, containing the notified polymer, will be used in a trial in Australia to assess the technical performance and the market viability of the product. An increase in import volume is expected pending success of the trial and a decision by the applicant to market the product in Australia.

The notified polymer was originally assessed for introduction to Australia as a curing agent in a product used in the construction sector. The annual introduction volume of the notified chemical in these products was less than one tonne and no manufacture or reformulation occurred in Australia.

Use

The product FDP-S948B-09, containing the notified polymer at 10-30% concentration, is the hardener component in an epoxy resin system. The applicant will use the product in on-shore oil/gas well operations, primarily (approximately 90%) in on-shore CSG operations. The resin permanently consolidates and binds fine particles, the proppant, and the geologic formation together in oil/gas wells that have been hydraulically fractured. After mixing with other components on site and just before use, the notified polymer is present in the total resin system at a concentration of <15%.

4. Exposure

New information on the use of the chemical reported for the secondary notification assessment has significantly altered the occupational and environmental exposure that was originally assessed. Therefore, the public, occupational and environmental exposure sections below are based on the new scenarios resulting from the proposed changes to the use of the notified polymer.

4.1 Occupational exposure

4.1.1 Operational description

The applicant will import the FDP-S948B-09 product containing the notified polymer by ship for trial use, primarily in CSG applications at approximately 20 wells in the Surat Basin in Queensland. The product, in 1250 L (330 gallon) intermediate bulk container (IBC) totes and 208 L (55 gallon) drums, will be temporarily stored at a warehouse at the entry port before transfer by truck to the trial sites and stored on a chemical trailer until use.

The product, containing the notified polymer at 10-30% concentration, will be used as the hardener component in an epoxy resin system. During on-site trials the notified polymer will be transferred via hoses and pumps to the batch mixing unit where it will be mixed with the other resin components in a closed system to a final concentration of <15%. After dilution in brine solution, the epoxy resin system containing the notified polymer at <1% v/v will be pumped downhole and will remain intact for 72 hours.

The applicant has estimated that at least 90% of the notified polymer will be trapped and hardened within the resin mixture after 72 hours curing and 10% of the notified polymer may return to the surface at a concentration of <0.1% in flowback fluid. Approximately two wellbore volumes of fluid will be circulated down hole to flush out the well, and this fluid containing less than 0.01% (v/v) of the residue of the notified polymer will be captured.

Table 4.1 - Number and category of workers*

Category of worker	Number	Exposure duration (hours/day)	Exposure frequency (days/year)
Logistics personnel (transport and storage)	1-2	<1	10
Blender operators	2	4	20
Chemical personnel	1	4	20

* Values are for the use of the FDP-S948B-09 product during commercial evaluation trial only, assuming approximately 20 wells with an exposure frequency of 1 day/well/year (0.5 day/well/year for logistics personnel).

4.1.2 Estimates of occupational exposure

Logistics (transportation and storage)

Transport and storage workers may come into contact with the notified polymer at up to 30% concentration in the event of accidental rupture of containers. Workers involved in storage will normally wear clothing that covers the body, safety glasses and gloves. In the event of a significant spill, clean-up workers will wear full PPE such as protective clothing, safety boots, gloves and safety goggles.

Mixing/Blending

Blending will occur on site in a closed system and significant release of the polymer is not expected during blending processes. Blender operators transfer the product, containing the polymer at up to 30% concentration, from the imported containers into closed blending tanks. The transfer operation involves opening the containers and connecting pumping equipment and transfer lines to the blending tank. High-speed dispersion and mixing are used to blend the hardener component with other components to form the epoxy resin system. Exposure (dermal, ocular) of workers to the polymer that may occur during these operations is minimised by the use of PPE such as coveralls, impervious gloves and safety glasses/goggles/face shield. While generation of mists/aerosols is possible during mixing, the applicant reported that the outdoor nature of the operations and the use of PPE by workers would minimise potential inhalation exposure.

Well injection

Exposure (dermal and ocular) of blender operators and chemical personnel to the notified polymer at a concentration of <1% is possible via inadvertent leaks during the pumping of the resin into the well. Similarly, exposure by these routes may also occur from contact with produced water and flush water containing residual polymer at <0.1%. Exposure to the dilute polymer is minimised as workers are trained in the proper handling of down-well chemicals and by the use of PPE such as coveralls, impervious gloves and safety glasses/goggles/face shield. While generation of mists/aerosols may result in inhalational exposure during injection operations, the outdoor nature of the operations and PPE the applicant reported that workers use would minimise potential exposure.

Transfer of flowback fluids after injection

Water from coal seam gas wells containing residual fracturing fluid with the notified polymer is transported via pipes to the retention pond. Dermal and ocular exposure may occur from spills during manipulation of transfer pipes containing the flowback water with the residual polymer.

Cleaning and maintenance

Dermal and ocular exposure of workers to the polymer may occur during cleaning and maintenance. The operators will clean the residual fluid from the mixing equipment using a solvent with the washings collected and isolated in a drum. After collection, a third party hazardous waste disposal company will dispose of the waste. They will treat all of the notified polymer in accordance with relevant Commonwealth, state, territory and local government legislation. Workers may experience dermal and accidental ocular exposure to flowback fluids containing the notified polymer while transferring the fluids to waste disposal facilities. However, overall exposure to the notified polymer is expected to be limited due to the low concentration (<0.1%) and use of PPE.

4.2 Public exposure

The notified polymer is intended only for use in industry, and as such direct public exposure is not expected. Spills or accidental releases of the product are expected to be physically contained, collected and be subsequently disposed of in accordance with the relevant requirements.

Workers will introduce the polymer into oil/gas wells as part of a specific treatment application and most will react, harden and remain immobile within the target geologic formation. The polymer is therefore not expected to migrate beyond the target formation and reach ground water given adequate well closure and plugging, and the controlled fracture propagation that will be applied. As a result, direct migration of the polymer to surface and ground water, and potential public exposure to contaminated water via these pathways, is not expected.

Approximately 10% of the unreacted notified polymer may return to the surface in flowback water and is expected to partition to the solids in the recovered fluids based on its high cationic charge density. The fluids containing the solids and residues of the notified polymer at a maximum concentration of 0.1% will be captured in retention ponds before treatment and/or disposal in accordance with the relevant Commonwealth, state, territory and local government regulations. Therefore, significant release of the notified polymer to the aquatic environment, and consequent public exposure, is not expected.

4.3 Environmental exposure

4.3.1 Releases

Release of chemical at site

Chemical storage of the hardening product containing the polymer and its incorporation into the epoxy resin system do not necessarily occur inside a bunded area with a non-permeable surface. However, the primary containment systems and the operational design are assumed to be adequate to prevent release to the environment as per the operator's development permit.

A potential release of the notified polymer to the environment may result from accidental spills during storage, transportation or handling. Spills or accidental releases of the product are expected to be physically contained, collected and be subsequently disposed of in accordance with the relevant Commonwealth, state, territory and local government regulations.

Release of chemical from use

The product containing the notified polymer will be the hardener in an epoxy resin system used in approximately 20 oil and gas wells. During on-site trials the notified polymer will be transferred via hoses and pumps to the batch mixing unit where it will be mixed with the other epoxy resin system components. This blending will occur on site in a closed system and significant release of the polymer is not expected during blending processes. The epoxy resin system containing the notified polymer diluted with brine at approximately <1% by mass will be pumped downhole where it will remain intact for 72 hours. The applicant has estimated that at least 90% of the notified chemical will be trapped and hardened within the resin mixture after 72 hours and 10% of the notified chemical may return to the surface along in the flowback water. This solution containing <0.1% by mass of the notified polymer may return to the surface when the well is flushed at the end of the resin curing period. Furthermore, two wellbore volumes of fluid will be circulated out of the well, and the estimated concentration of the notified polymer will be less than 0.01% by mass in the wellbore.

All fluids containing the residue of the notified polymer and subsequently produced from the well will be captured in retention ponds, treated and/or disposed of in accordance with the relevant Commonwealth, state, territory and local government regulations. The fluids containing the residues of the notified polymer will not be used for irrigation and dust suppression purposes. The notified polymer is not expected to migrate beyond the target formation and reach ground water given adequate well closure and plugging and controlled fracture propagation. Therefore, release of the notified chemical to surface and ground water is not expected.

Wastes containing the notified polymer (equipment solvent-based washings, residues in empty import containers and spilt materials) are required to be captured on site, treated and/or disposed of by a licensed waste management company.

Release of polymer from disposal

Release from residues in storage and shipping containers is expected to be minimal. Empty containers are expected to be cleaned with solvent and disposed of by a licensed hazardous waste management company. In the event of a retention pond leak/overflow, the event will be reported and managed in accordance with the relevant Commonwealth, state, territory and local government regulations.

4.3.2 Fate

The notified polymer will be used as a component of an epoxy resin system that consolidates and binds fine particles and ultimately hardens in the target formation in CSG applications. Approximately 90% of the polymer will remain within the target formation, and approximately 10% will be returned in flowback water. The submitted study (Opus Plus, 2010b) indicates that the hardening product containing 40-70% of the notified polymer was not readily biodegradable in seawater (5% in 28 days). Therefore, the polymer is not expected to undergo rapid degradation during the hardening process (~72 hr). Once the epoxy resin is hardened within the geologic formation, the polymer is not expected to be either mobile or bioavailable. The applicant has indicated that the cured resin is thermally stable at < 205°C and is not expected to decompose under typical conditions of CSG settings.

Approximately 10% of the unreacted polymer may return to the surface and is expected to partition to the solids in the recovered fluids based on its cationic properties. The flowback water containing the residues of the polymer will be treated and/or disposed of in accordance with the relevant Commonwealth, state, territory and local government regulations. Therefore, significant release of the polymer to the aquatic environment is not expected.

4.3.3 Predicted environmental concentration (PEC)

The polymer is not expected to be present in significant concentrations in the aquatic environment because of low potential for direct release to surface and ground waters. This expectation arises because the majority (90%) of the polymer will be unavailable due to curing in the resin system, and because the residual polymer in the flowback water must be used and disposed of in accordance with the relevant Commonwealth, state, territory and local government regulations. Therefore, the predicted environmental concentration (PEC) has not been calculated.

5. Hazard assessment

5.1 Physicochemical and human health hazard assessment

This section has a summary of all the data relevant to the physicochemical and human health hazard assessment of the notified polymer. The robust summaries of the toxicological data available for the assessment of the notified chemical as a new chemical are reproduced from the new chemical assessment report in Appendix A.

5.1.1 Physicochemical effects assessment

The applicant submitted no new physicochemical data for the secondary notification assessment.

5.1.2 Human health effects assessment

The applicant submitted no new human health studies for the secondary notification assessment. The results from toxicological investigations conducted on a product containing 60-70% notified polymer (unless otherwise indicated) at the time of the new chemical assessment are summarised in Table 5.1 and text below.

Table 5.1 - Summary of toxicological data

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Rat, acute oral	LD50 > 2000 mg/kg bw
Rat, acute dermal	LD50 > 2000 mg/kg bw
Rabbit, skin irritation	Slightly irritating
Rabbit, eye irritation	Severely irritating
Guinea pig, skin sensitisation – adjuvant test	Evidence of sensitisation
Mouse, skin sensitisation – Local lymph node assay	Evidence of sensitisation
Mouse, skin sensitisation – Local lymph node assay ^a	Evidence of sensitisation

LD50 = median lethal dose

^a *Toxicological investigation was conducted using 10-15% notified polymer. Details are in Appendix C.*

Toxicokinetics

No toxicokinetic data were submitted for the notified polymer in the new chemical assessment. However, based on the physicochemical properties, percutaneous absorption of the notified polymer is likely. Given the low molecular weight (< 1000 Da) absorption across the GI tract is possible by passive diffusion through the aqueous pores or micellular solubilisation.

Acute toxicity

An acute oral toxicity study on the test substance was performed in Sprague-Dawley rats (5/dose/sex). The test substance (in arachis oil) was administered once by oral gavage at a dose of 2000 mg/kg bw. One animal died within five hours of treatment. Clinical signs in surviving animals included hunched posture, laboured respiration, decreased respiratory rate, lethargy and ataxia, with all recovering within two days of dosing.

All surviving animals gained weight during the 14 day observation period and there were no gross abnormalities noted at necropsy. However, the decedent animal was found to have discoloured lungs,

liver and kidneys with haemorrhage and sloughing of the epithelium of the gastrointestinal mucosa and the non-glandular region of the stomach.

An acute dermal toxicity study was performed on the test substance in Sprague Dawley rats. The test substance was applied to the shaved intact skin of the animals (5 animals/sex) at a dose of 2000 mg/kg bw under a semi-occlusive dressing for a period of 24 hours. There were no mortalities and no signs of systemic toxicity during the 14 day-observation period. Very slight to well-defined erythema in addition to crust formation and desquamation of the application site were observed, which resolved during the first 10 days. No treatment-related gross pathological abnormalities were noted at necropsy.

The notified polymer has low acute oral and dermal toxicity in rats.

Skin irritation

A dermal irritation study was performed on the notified polymer in male New Zealand White rabbits. The test substance (0.5 mL) was applied to the intact, shaved skin of 3 animals under a semi-occlusive dressing for a period of 4 hours. At 1 hour, very slight erythema was observed in each rabbit with very slight erythema noted at the 24 hour observation for one animal. No oedema was observed in any of the animals at any of the observation time points and all evidence of skin irritation had resolved by 48 hours. The test substance caused very slight skin irritation with a primary irritation index (PII) of 0.33 between 1 and 72 hours.

Eye irritation

An eye irritation study was performed in a single female New Zealand White rabbit. The test substance (0.1 mL) was administered into the lower conjunctival sac. Sloughing of the cornea, corneal opacity, marked conjunctival redness, chemosis and discharge in addition to iridial inflammation were observed and the rabbit was euthanised on ethical grounds. The test substance is considered to be a severe to very severe eye irritant.

Sensitisation

A guinea pig maximisation test was performed to estimate the potential of the test substance to induce skin sensitisation. The treatment group (20 males) received three pairs of 0.1 mL intradermal induction injections. They were:

- Freund's Complete Adjuvant (FCA) 1:1 in water
- 0.5% test substance in water
- 0.5% test substance in a 1:1 mixture of FCA and water

Topical inductions were done on day 7; 50% test substance in water was applied and covered by an occlusive dressing for 48 hours. The negative control group (10 males) received the same treatment without the test substance. At 14 days after topical induction, all animals were challenged with the undiluted test substance to the right flank and 75% test substance to the left flank. Of the treatment group animals, 19/20 had erythematous dermal reactions indicative of skin sensitisation on both the undiluted and 75% test substance sites, 24 and 48 hours after challenge. The negative control group did not show any evidence of skin sensitisation. This study indicates that the notified chemical is a skin sensitiser.

The potential for skin sensitisation was also evaluated using a local lymph node assay (LLNA). For three consecutive days, the test substance (in ethanol) was topically applied to the dorsal surface of the ears of CBA/J mice at 0, 6.25, 25 and 50% concentration, together with a 25% positive control. No mortality occurred and no clinical signs of systemic toxicity were observed. A positive lymphoproliferative response, consisting of a relative Stimulation Index (SI) >3 was observed at a concentration of 50%. The EC3 (the estimated test substance concentration that will give a SI = 3) was approximately 25%, suggesting the test substance is a weak skin sensitiser. Assuming the notified

polymer is solely responsible for the sensitising activity of the test substance, after adjustment for the purity, the EC3 of the notified polymer is calculated as approximately 16%.

Based on an OECD Guideline LLNA (see Appendix C) for Part A of a coating (containing the notified polymer at 10-15%), Part B of a coating (containing no notified polymer) and a mixture of Part A and Part B (containing the notified polymer at 1-5%), the notified polymer in Part A is expected to be a skin sensitiser. However, upon mixing with Part B, 1-5% notified polymer in the mixture was not sensitising which is consistent with a curing reaction between Part A and Part B.

Overall, it is concluded that the notified polymer is a skin sensitiser.

5.1.3 Hazard classification

The new chemical assessment report concluded that the notified polymer, according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999):

- causes serious damage to eyes and recommended a hazard classification of R41
- may cause sensitisation by skin contact and recommended a hazard classification of R43

Based on the available information, the notified chemical is recommended to be classified according to the GHS (United Nations, 2009), as adopted for industrial chemicals in Australia. The recommended hazard classification is shown in Table 5.2.

Table 5.2 – Recommended human health hazard classification

Hazard classification	Hazard statement
Serious eye damage/eye irritation (Category 1)	H318 – Causes serious eye damage
Skin sensitisation (Category 1)	H317 - May cause an allergic skin reaction

5.2 Environmental hazard assessment

This section has a summary of the data relevant to the environmental hazard assessment of the notified polymer, including new data.

5.2.1 Environmental effects assessment

The following tables have summary data for the freshwater ecotoxicological study submitted for the new chemicals assessment and for marine studies the applicant submitted for the secondary notification assessment (designated as **ND**).

The robust summaries of the data available for the secondary notification assessment are in Appendix B.

Summary of ecotoxicity data

The results from the marine ecotoxicological investigations (designated as **ND**) conducted on a hardening product containing the notified polymer at 40-70%, are summarised in Table 5.3. All studies were considered relevant to CSG sites in the Surat Basin which has salinity averaging 3000 mg/L (Queensland Government, 2006).

Table 5.3 – Toxicity data for aquatic organisms

Endpoint	Result (nominal)*
Marine Fish Toxicity (ND)	96 h LC50 >1.74 ^a mg/L
Freshwater Invertebrate Toxicity	48 h EC50 = 1.2 mg/L
Marine Invertebrate Toxicity (ND)	48 h LC50 = 21.49 ^a mg/L
Marine Algal Toxicity (ND)	72 h ErC50 = 1.74 ^a mg/L
Marine Sediment Re-worker Toxicity (ND)	10 d LC50= 9045 ^a mg/kg (dry wt)

* Results listed are nominal test concentrations

EC50 = median effective concentration; LC50=median lethal concentration

^a Ecotoxicological points are shown for the mixture containing the polymer at 40-70%.

Given that the minimum concentration of the notified polymer is 40% in the mixture that was tested, ecotoxicological endpoints for the neat notified polymer have been calculated and are shown in Table 5.4:

Table 5.4 – Calculated values for ecotoxicity of the neat notified polymer

Endpoint	Result (nominal)	Assessment Conclusion
Marine Fish Toxicity (ND)	96 h LC50 > 0.70 mg/L	Not toxic under study conditions
Freshwater Invertebrate Toxicity	48 h EC50 = 1.2 mg/L	Very toxic to freshwater invertebrates
Marine Invertebrate Toxicity (ND)	48 h LC50 = 8.6 mg/L	Toxic to marine invertebrates
Marine Algal Toxicity (ND)	72 h ErC50 = 0.7 mg/L	Very toxic to marine algae
Marine Sediment Re-worker Toxicity (ND)	10 d LC50= 3618.2 mg/kg (dry wt)	Not harmful to marine sediment re-worker

These ecotoxicity values are comparable to those predicted by Boethling and Nabholz using SAR equations (1997), as cited in the new chemical assessment.

5.2.2 Predicted No-Effect Concentration

For the original use, a predicted no-effect concentration (PNEC) was not calculated by NICNAS, but based on the single study provided a PNEC of 1.21 µg/L may be calculated.

On the basis of the new data, the PNEC for the notified polymer has been calculated from the acute algal toxicity and an assessment factor of 100 as three measured acute toxicity endpoints are available (Table 5.5).

Table 5.5 - Predicted No-Effect Concentration for the aquatic compartment

	Result
ErC50 (Algal)	0.70 mg/L
Assessment Factor	100

Mitigation Factor	1.00
PNEC:	7.0 $\mu\text{g/L}$

5.2.3 Hazard classification

The environmental hazard classification according to the GHS (United Nations, 2009) is shown in Table 5.6. The notified polymer is formally classified under the GHS as “Acute category 1; Very toxic to aquatic life” based on marine acute toxicity data (United Nations, 2009). Based on a NOEC value for marine algae (0.1 mg/L) and biodegradability data, the notified polymer is classified as “Chronic category 1; Very toxic to aquatic life with long lasting effects” (United Nations, 2009). This classification supersedes the GHS classification according to the original assessment, based on the new data. Environmental classification under the GHS is not mandated in Australia and carries no legal status but is presented for information purposes.

Table 5.6 – Recommended environmental hazard classification

Hazard classification	Hazard statement
Acute (Category 1)	H400 – Very toxic to aquatic life
Chronic (Category 1)	H410 – Very toxic to aquatic life with long lasting effects

6. Risk characterisation

The occupational health, public health and environmental risk estimations below account for the new exposure scenarios resulting from the proposed changes to the use of the notified polymer. The environmental risk estimation also includes the new hazards to aquatic life posed by the notified polymer.

6.1 Occupational health risk characterisation

The hazard assessment determined that the notified polymer is likely to be slightly irritating to the skin, severely irritating to eyes and sensitising to the skin.

During on-site trials for use in oil/gas well operations, the product containing the notified polymer will be shipped in intermediate bulk container (IBC) totes and large drums, and will be transported by truck to on-shore drilling sites.

During use (i.e. mixing in a closed system and pumping of resin into the well) incidental dermal, ocular, and inhalation exposure of workers to the notified polymer at concentrations up to 30% may occur. There is a risk of skin and eye irritation and skin sensitisation in these workers if exposure occurs. However, manual handling is expected to be minimal and workers are reported to wear appropriate PPE while handling the product. Generation of mists/aerosols is possible during mixing, however the operations using the product are expected to be performed in ventilated areas and most handling of the product will occur outdoors. It is anticipated that these control measures already in place to minimise exposure will be sufficient to mitigate these health risks for workers. After preparation the product will be used in a closed system and exposure to the notified polymer is expected to be limited. Furthermore, irritation and sensitisation effects are not expected at the final use concentration of <1%.

Overall, given the limited potential for exposure, the risk to workers during the proposed use of the polymer is considered to be low. Moreover, the stated use of PPE by the applicant should further reduce the risk.

6.2 Public health risk characterisation

In this assessment, the product containing the notified polymer is intended for use only at a limited number of region-specific CSG operational sites in a highly controlled environment. As part of a specific treatment application, the notified polymer will react with other resin components, harden and remain within the target formation. Only small quantities of residual polymer at high dilution are expected to come up from the well and, together with any remaining fluid and washings from the mixing equipment, will be disposed of by the operators according to local regulations.

Overall, given the controlled use pattern, public exposure to the notified polymer directly from worksites or indirectly via environmental contamination is not expected. Therefore, the risk to the public is expected to be low.

6.3 Environmental risk characterisation

The notified polymer is very toxic to aquatic species and the PNEC has been calculated as 7.0 µg/L. In use, the majority of the notified polymer will be incorporated into an epoxy resin system that consolidates and binds fine particles, ultimately hardening in the target formation and oil/gas well applications. The notified polymer in this form is not expected to be bioavailable.

Of the polymer pumped downhole, less than 10% of the uncured amount is expected to be present in

the flowback water at a concentration of < 100 mg/L. This is well above the PNEC; however, the flowback water containing the polymer will be captured on-site in retention ponds for treatment, with no release to surface or ground waters provided the control measures described in the Recommendations section are implemented.

Therefore, a PEC and the risk quotient (PEC/PNEC) cannot be calculated because the notified polymer is not expected to be present at ecotoxicologically significant concentrations in the environment.

Therefore, based on the assessed use pattern, the risk to the aquatic environment from the notified polymer is expected to be low.

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Appendix A: Investigations of Physical and Chemical Properties

This appendix presents a robust summary of the physical and chemical properties study submitted for the Secondary Notification assessment of the notified polymer (ND).

Partition coefficient (n-octanol/water)

log Pow = 1.5

METHOD

OECD TG 117 Partition Coefficient (n-octanol/water)

Remarks

The High Performance Liquid Chromatography (HPLC) method used produced chromatographic profiles for the test material that showed 3 peaks. The capacity factor, k, for the first peak was negative therefore the log Pow value could not be accurately quantified. A value of log Pow = -5.17 was assumed to allow the calculation of the CHARM weighted average value for the test material. The reported weighted average log Pow for the test material is calculated from the average retention time and peak area obtained from duplicate runs. The mean CHARM weighted average log Pow for FDP-S948B-09 was calculated to be 1.5 and the range of log Pow for the 3 peaks was from -5.17 to 2.74. However, this method may not be applicable to ionic substances.

TEST FACILITY

Opus Plus Limited (2010a)

Appendix B: Environmental fate and ecotoxicological investigations

This appendix presents the robust summaries of the environmental fate and ecotoxicological studies submitted for the Secondary Notification assessment of the notified polymer (ND).

The tests below were conducted using FDP-S948B-09 containing 40-70% of the notified polymer.

B.1 Environmental fate

B1.1 Ready biodegradability

TEST SUBSTANCE	FDP-S948B-09
METHOD	OECD TG 306 Biodegradability in Seawater-Closed Bottle Method
Inoculum	Natural fauna of microorganisms in aerated aged seawater collected from a pier (Scapa Flow).
Exposure period	28 days
Auxiliary solvent	None
Analytical monitoring	Chemical Oxygen Demand (COD)
Remarks - Method	Conducted in accordance with the test guidelines above, and in compliance with GLP standards and principles.

RESULTS

<i>Test substance</i>		<i>Sodium benzoate</i>	
<i>Day</i>	<i>% Degradation</i>	<i>Day</i>	<i>% Degradation</i>
7	2	7	73
14	2	14	81
21	5	21	74
28	5	28	87

Remarks - Results All validity criteria for the test substance were satisfied. The percentage degradation of the reference compound, sodium benzoate, surpassed the threshold value of 60% by 7 days, and reached 87% biodegradation by 28 days indicating the suitability of the inoculums. The toxicity control containing the test and reference substances exceeded 25% biodegradation within 14 days showing that toxicity was not a factor inhibiting the biodegradability of the test substance. The test substance attained 5 % degradation by 28 days.

CONCLUSION	The mixture containing the notified polymer is considered to be not readily biodegradable
TEST FACILITY	Opus Plus (2010b)

B.2 Ecotoxicological investigations

B2.1 Acute toxicity to fish

TEST SUBSTANCE	FDP-S948B-09
METHOD	OECD TG 203 Fish, Acute Toxicity Test - semi-static OSPARCOM: 2006 (Part B), Protocol for a fish acute toxicity test.
Species	<i>Cyprinodon variegatus</i>
Exposure period	96 h
Auxiliary solvent	None
Water salinity	35-38 ‰
Analytical monitoring	No analytical verification of the test substance concentrations
Remarks - Method	No significant deviation in protocol. The test was conducted under semi-static conditions with replacement of media after 48 h with ten fish exposed to the single concentration along with a control. The test concentration was based on the LC/EC50 of the test material between the most sensitive species <i>Skeletonema costatum</i> and <i>Acartia tonsa</i> .

RESULTS

Concentration mg/L		Number of fish	% Mortality			
Nominal	Mean measured		24h	48 h	72h	96h
0	-	10	0	0	0	0
1.739		10	0	0	0	0

LC50 >1.739 mg/L at 96 hours.

NOEC \geq 1.739 mg/L at 96 hours.

Remarks - Results The dissolved oxygen was between 94-96%. All validity criteria for the test were satisfied. The 96 h LC50 and NOEC for fish were determined to be > 1.739 mg/L and \geq 1.739 mg/L, respectively, based on the nominal loading concentrations.

CONCLUSION Under the study conditions, the mixture containing the notified polymer is not toxic to marine fish

TEST FACILITY Opus Plus (2010c)

B2.2 Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	FDP-S948B-09
METHOD	ISO 14669:1999, Water Quality: Determination of acute lethal toxicity to marine copepods (Copepoda; Crustacea) ISO 5667-16:1998, Water quality sampling – guidance on biotesting on samples

Species	<i>Acartia tonsa</i>
Exposure period	48 hours
Auxiliary solvent	None
Water Salinity	36 ‰
Analytical monitoring	No analytical verification of the test substance concentrations.
Remarks - Method	No significant deviations in protocol. The material was soluble and dilution series were prepared from initial stock solution of 100 mg/L.

RESULTS

Concentration mg/L		Number of <i>A. tonsa</i>	Cumulative Mortality (%)	
Nominal	Actual		24 h	48 h
Control	Control	20	0	0
10	-	20	0	0
18	-	20	15	35
32	-	18	44	100
56	-	19	100	100
100	-	20	100	100

LC50	21.49 mg/L (95% CI: 17.50-25.08 mg/L) at 48 hours (determined by an unspecified statistical method).
NOEC	10 mg/L at 48 hours (determined by an unspecified statistical method).
Remarks - Results	The LC50 of the reference substance (3,5 Dichlorophenol) was within the acceptable range and the water quality (pH, temperature, dissolved oxygen and salinity) was within acceptable limits. Control mortality was $\leq 10\%$. The 48 h LC50 and NOEC was based on the nominal loading concentrations.

CONCLUSION	Under the study conditions, the mixture containing the notified polymer is harmful to marine invertebrates.
TEST FACILITY	Opus Plus (2010d)

B2.3 Algal growth inhibition test

TEST SUBSTANCE	FDP-S948B-09
METHOD	ISO 10253 Water quality – marine algal growth inhibition toxicity test. ISO 5667-16 Water quality sampling – guidance on biotesting on samples.
Species	<i>Skeletonema costatum</i>
Exposure period	72 hours
Concentration range (Nominal)	0.10-10 mg/L

Auxiliary solvent	None
Analytical monitoring	No analytical verification of the test substance concentrations.
Remarks - Method	No significant deviation in protocol. The salinity was 36 ‰.

RESULTS

<i>Biomass</i>		<i>Growth*</i>	
<i>E_bC₅₀</i> mg/L at 72 h	<i>NOEC</i> mg/L	<i>E_rC₅₀</i> mg/L at 72 h	<i>NOEC</i> mg/L
n.d.	n.d.	1.74 (95% CI: 1.61-1.87)	0.1

*Based on nominal concentrations; n.d. = not determined

Remarks - Results The control growth rate was 1.45 d⁻¹. All validity criteria for the test were satisfied. The EC₅₀ of the reference substance (3,5 Dichlorophenol) was within the acceptable range and the water quality (pH, temperature, dissolved oxygen and salinity) was within acceptable limits. The 72 h E_rC₅₀ and NOE_rC were determined to be 1.74 mg/L (95% CI: 1.61-1.87 mg/L) and 0.1 mg/L, respectively, based on the nominal loading concentration.

CONCLUSION Under the study conditions, the mixture containing the notified polymer is toxic to marine algae.

TEST FACILITY Opus Plus (2010e)

B2.4 Sediment re-worker toxicity test

TEST SUBSTANCE FDP-S948B-09

METHOD OSPAR, A Sediment Bioassay Using An Amphipod *Corophium* sp.

Species *Corophium volutator*

Exposure period 10 days

Concentration range (nominal) 16.93 – 16926.33 mg/kg dry weight of sediment.

Auxiliary Solvent None

Analytical monitoring No analytical verification of the test substance concentrations.

Remarks - Method The test organisms were introduced to sediment containing the test substance and exposed for a period of 10 days in a static test at 15 ± 2 °C. Three replicates were prepared for the test concentrations and five replicates for the control.

RESULTS

<i>Nominal concentration mg/kg dry weight of sediment</i>	<i>Total Mortality (%)</i>
<i>Control</i>	3
16.93	7
169.29	8
541.73	5
1692.66	5
16926.33	100

LC50 9045.44 mg/kg (dry wt) (95% CI: 8320.32-9599.95 mg/kg) at 10 days

NOEC 1692.66 mg/kg (dry wt) at 10 days

Remarks - Results All validity criteria for the test were satisfied except that the pH exceeded the guideline criterion by 0.19 units. The 10 d LC50 and NOEC were determined to be 9045.44 mg/kg (dry weight of sediment) and 1692.66 mg/kg (dry weight of sediment), respectively based on the nominal loading concentrations.

CONCLUSION Under the study conditions, the notified polymer is not harmful to the sediment re-worker.

TEST FACILITY Opus Plus (2010f)

Appendix C: Toxicological Investigations

A.1 New Chemical assessment

This appendix contains a robust summary of the toxicological study submitted and evaluated for the assessment of the notified polymer as a new chemical.

A1.1 Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE	Part A of a coating (containing the notified polymer at 10-15%) Part B of a coating (containing no notified polymer) Mixture of Part A and Part B (containing the notified polymer at 1-5%)
METHOD	OECD TG 429 Skin Sensitisation: Local Lymph Node
Species/Strain	Mouse/ CBA/J (female)
Vehicle	None
Remarks - Method	There were no significant deviations from the protocol.

RESULTS

<i>Concentration (% w/w)</i>	<i>Proliferative response (DPM/lymph node)</i>	<i>Stimulation Index (Test/Control Ratio)</i>
<i>Test Substance</i>		
0 (vehicle control)	18000	-
Part A	72500	4.0
Part B	11100	0.6
Mixture of Part A & Part B	34400	1.9
Vehicle	18800	-
Positive Control (25%)	344900	18.3

DPM=disintegrations per minute

Remarks - Results	<p>There were no mortalities, no signs of systemic toxicity and no abnormal body weight changes.</p> <p>In the screening test, hair loss was observed at the dose site for animals in the dose groups for Part A and Part A + Part B mixture groups. In the main study, hair loss was observed at the dose sites for all dose groups.</p> <p>None of the test substances was irritating (as indicated by ear measurements resulting in a less than 25% increase). In the screening test, there was residual test substance observed on the ears for all dose groups, which may have affected thickness measurements.</p> <p>Although there was some test substance residue on the ears in the main study for Part A and Part A + Part B mixture groups, it did not appear to interfere with the ear swelling results.</p>
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Mild to severe, early-onset and transient signs of irritation such as erythema, oedema and scaling were observed throughout the whole study. The test item caused no staining of the treated skin. No corrosive effects were noted on the treated skin of any animal at any of the measuring intervals and observed no other clinical signs of substance related effects.

CONCLUSION

There was evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to Part A.

There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to Part B or the mixture of Part A and Part B.

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