

File No: SN/20

May 2010

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

FULL PUBLIC REPORT

Diutan gum

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

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**Director
NICNAS**

FULL PUBLIC REPORT**Diutan gum****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

Nuplex Industries (Aust) Pty Ltd (ABN 25 000 045 572)
49-61 Stephen Road
Botany, NSW, 2019

Assessment of the notified chemical was carried out under the *Industrial Chemicals (Notification and Assessment) Act 1989* [the IC(NA) Act], as STD/1193, with the Summary Report of the assessment published in the *Chemical Gazette* of 7th November, 2006.

The Director of NICNAS was informed of changes to the method of production of the notified chemical. These changes involve the use of genetically modified organism. Under the IC(NA) Act, the Director declared that a secondary notification was required for the chemical known as Diutan Gum.

In accordance with Section 65 of the IC(NA) Act, a notice requiring the secondary notification of Diutan Gum was published in the *Chemical Gazette*. The notice of 1st September, 2009 stipulated that the following data were required to undertake further assessment of Diutan Gum:

1. Identity

Any change resulting from the change of manufacturing process to the:

- I. Structural formula of the polymer; and
- II. Identity and concentration of impurities.

2. Use

Any changes from that submitted in the original notification for Diutan Gum for the following:

- I. Proposed uses of the polymer; and
- II. Quantity to be imported.

3. Human Health

Information related to any change in the health hazard profile of Diutan Gum when manufactured by the new process, for the following endpoints:

- I. The polymer toxic effects after a single oral administration of the polymer;
- II. The extent of dermal irritation caused by the polymer;
- III. The extent of eye irritation caused by the polymer; and
- IV. The potential for skin or respiratory sensitisation of the polymer;

These data may be provided through studies or other sources of information.

4. Environment

Data related to the actual plasmid concentration in the polymer, and the viability of the plasmid in the polymer, when manufactured *via* the new process. This should preferably be determined through a transformation test, yielding the:

- I. Number of plasmids/mL; and
- II. Number of colony forming units (cfu)/mL.

Any additional data on toxicological and /or environmental effects of the polymer should also be provided.

This report, SN/20, represents the revised assessment for Diutan Gum. As there were no significant changes in the structure of the notified polymer using the new manufacturing process, it is expected that the physico-chemical characteristics, toxicity and ecotoxicity endpoints between the two products will, in general, be similar. Where additional data has been provided, it has been incorporated into the report and the implications of the data for the health and environmental risks of the notified polymer considered.

NOTIFICATION CATEGORY

Secondary Notification.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication by the notifier:

- Other Names
- Structural Formulae
- Molecular Weight
- Spectral Data
- Purity
- Identity and Percent Weight of Toxic or Hazardous Impurities
- Non-Hazardous Impurities
- Identity and Percentage Weight of Additives
- Manufacture and Import Volumes
- Identity of sites
- Weight Percentage and Ingredients of Polymer Constituents
- Residual Monomers and Impurities
- Number Average Molecular Weight
- Low Molecular weight Polymer
- Degradation Products
- Loss of Monomers, Additives and Impurities

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

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

Vapour Pressure

Hydrolysis as a Function of pH

n-Octanol/Water Partition Coefficient

Soil Adsorption/Desorption Coefficient

Dissociation Constant

Flash Point

Explosive Properties

Reactivity

Acute Dermal Toxicity

Skin Irritation

Germ Cell Mutation

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

STD/1193

NOTIFICATION IN OTHER COUNTRIES

Canada, USA, EU (2001), Korea..

2. IDENTITY OF CHEMICAL

CHEMICAL NAME

D-Glucurono-D-gluco-6-deoxy-L-mannan, acetate, calcium magnesium potassium sodium salt (CAS 595585-15-2)

OTHER NAME(S)

D-Glucurono-6-deoxy-L-manno-D-glucan, acetate, calcium magnesium potassium sodium salt

Diutan gum (also known under CAS 125005-87-0).

D-Glucose, polymer with 6-deoxy L-mannose and D-glucuronic acid, acetate, calcium magnesium potassium sodium salt

D-Glucuronic acid, polymer with 6-deoxy L-mannose and D-glucose, acetate, calcium magnesium potassium sodium salt

D-glucuronic acid, polymer with 6-deoxy L-mannose and D-glucose, acetate, Ca Mg K Na salt (IUPAC)

L-Mannose, 6-deoxy-, polymer with D-Glucose and D-glucuronic acid, acetate, calcium magnesium potassium sodium salt

CAS NUMBER

595585-15-2 (associated with chemical name)

125005-87-0 (associated with name Diutan Gum. This CAS number will not be added to AICS)

MARKETING NAME(S)

Diutan gum

Kelco-Crete 80

Kelco-Crete 200

Geovis XT

MOLECULAR FORMULA

 $(C_6H_{12}O_6, C_6H_{12}O_5, C_6H_{10}O_7)_x \cdot xC_2H_4O_2 \cdot xCa \cdot xK \cdot xMg \cdot xNa$

MOLECULAR WEIGHT

> 1,000,000

METHODS OF DETECTION AND DETERMINATION

Remarks The notified polymer is a product of fermentation and there are no specific methods relating to its detection and determination. However, diagnostic IR data were provided.

3. COMPOSITION

DEGREE OF PURITY

> 50 %

4. INTRODUCTION AND USE INFORMATION

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

The notified polymer will be imported by sea in 25kg bags or 907 kg "Super Sacks" as a fine powder.

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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	10-30	30-100	30-100	30-100	30-100

USE

The notified polymer is suitable for a wide variety of thickening and suspending applications. The notified polymer is likely to be used in the following categories of application:

- cementitious packaged products
- viscosifier for spacer fluids
- viscosifier for oil field drilling fluid
- oil field cementing
- fire fighting foams
- concrete
- tyre/pneumatic application sealants
- cleaners
- coatings

Products available for use by the general product will contain up to 0.3% of the notified polymer. Cementitious products, in which the polymer is available in the powder form, will contain up to 0.1% of the notified polymer.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY

Initial port of entry will be Sydney.

IDENTITY OF MANUFACTURER/RECIPIENTS

The notified polymer is likely to be used in the following categories of application and therefore will be used at a number of sites

- **Cementitious packaged products**
It is anticipated that the notified polymer will be imported for processing and used at various construction sites, mainly in the commercial construction area.
- **Oilfield Spacer Fluid/ Oilfield Drilling Fluid/ Oilfield Drilling Cement Application**
It is anticipated that the notified polymer will be imported for processing and used at onshore and offshore rig-sites in Australia, mainly in the Cooper-Eromange Basin area.
- **Fire-fighting foam Application**
It is anticipated that the notified polymer will be imported for processing and used at the premises of fire fighting foam manufacturing companies.
- **Concrete Application**
It is anticipated that the notified polymer will be imported for processing and used at a large number of concrete batching plants, mainly in the metropolitan areas where large construction projects are undertaken.
- **Tyre/pneumatic application sealants**
It is anticipated that the notified polymer will be imported for processing and used at a limited number of sites, mainly in the manufacturing sector where specific products are formulated.
- **Cleaning products**
It is anticipated that the notified polymer will be imported for processing and used at formulators manufacturing facilities where specific types of cleaners are manufactured.
- **Coatings Products**

It is anticipated that the notified polymer will be imported for processing and used at a limited number of manufacturers of paint mainly in the Sydney and Melbourne metropolitan areas.

TRANSPORTATION AND PACKAGING

The notified polymer will be imported by sea in 25kg bags or 907 kg "Super Sacks" as a fine powder. The type of packaging will be contingent on the intended use of the notified polymer. The imported product bags will then be transported by road in commercial-carrier trucks to the notifier's facilities. No repackaging or reformulation of the notified polymer is planned by the notifier. During all stages of transport the polymer will be sealed in tightly closed containers and isolated from any incompatible substances (e.g. strong oxidisers).

The notified polymer is stored away from extreme temperatures, direct sunlight and contact with incompatibles.

5.2. Operation description

Cementitious packaged products

The notified polymer in powder form is added to the mixer at 0.01-0.1% during formulation of these products. In large applications, automatic metering system devices may be used to dispense the notified polymer from 907 kg "Super Sacks". The dry powder product is packaged in 11.3 kg bags or bulk 907 kg tote bags. The cementitious mixed product is activated with water at the job site in mixer, and applied to the surface to be cemented.

Oilfield Spacer Fluid and Oilfield Drilling Fluid

The notified polymer in powder form is added to the mixer at 0.1-0.3% during formulation at the oilfield site. Spacer fluid is pumped into the shaft to displace drilling fluid, and is recycled when displaced by cement. Drilling fluid is pumped into the shaft, and is recycled.

Oil Drilling Cement Application

The notified polymer in powder form is added to the mixer at 0.01-0.1% during preparation of oil drilling cement, and applied to the oil shaft.

Fire-fighting foam Application

The notified polymer in powder form is added to the mixer at 0.1-1.0% during formulation of fire-fighting foam. The slurry mixture is transported in containers to the foam generating equipment, where it is sprayed as foam directly onto the ground to extinguish fires at each site.

Concrete Application

The notified polymer in powder is added to the mixer at 2-10% in the preparation of concrete. The slurry mixture is transported in containers to the concrete batch plant, where it is mixed with cement components, sand, aggregate, and other cement admixtures to create the final concrete poured at the construction site. The cementitious mixed product containing 0.045% of the notified polymer is loaded into concrete mixer trucks in 6.9 m³ and transported to the job site.

Tyre Sealant Products / Pneumatic application

The notified polymer in powder form is included at 0.1-0.3% in sealant formulations. The sealant mixture is packaged into pressurised cans automatically. The sealant may be applied to car, bus or construction equipment tyres or in other pneumatic applications where an inflated part may become punctured.

Cleaner Products

The notified polymer in powder form is included in cleaning formulations at 0.1%. The cleaner mixture is packaged into containers automatically.

Coating Products

The notified polymer in powder form is added at 0.2-0.5% during formulation of coating products. The coating product is packaged into containers automatically and distributed for commercial use.

5.3. Occupational exposure*Cementitious packaged products**Number and Category of Workers*

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration</i>	<i>Exposure Frequency</i>
Adding the notified polymer to the dry mixer	2	4 hours/day	250 days/year
Packaging dry products	2	7 hours/day	250 days/year
Activated product with water in a mixer	2	4 hours/day	250 days/year

Exposure Details

The workers are expected to wear standard personal protective equipment (PPE) such as long sleeves, gloves (latex or nitrile), hard hats, safety glasses and dust masks. Fine stray dust generated is captured by vacuum systems, and collected by a control device for recycling.

In the event of accidental release, the notified polymer is swept up to avoid dust generation, or the spilled material is dampened with water to avoid airborne dust. All waters are sealed in vapour tight labelled plastic containers for eventual disposal. Workers involved in the clean-up of a spill are expected to wear PPE.

Oilfield Spacer Fluid and Oilfield Drilling Fluid

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration</i>	<i>Exposure Frequency</i>
Adding the notified polymer to the dry mixer	2	4 hours/day	250 days/year
Spacer fluid is pumped into the shaft to displace drilling fluid, and is recycled when displaced by cement.	2	7 hours/day	250 days/year
Drilling fluid is pumped into the shaft, and is recycled.	2	7 hours/day	250 days/year

Exposure Details

The workers are expected to wear standard PPE such as long sleeves, gloves, hard hats, safety glasses, dust masks and coveralls. Stray dust generated is released at < 0.1%.

Oil Drilling Cement Application

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration</i>	<i>Exposure Frequency</i>
Adding the notified polymer to the dry mixer	2	4 hours/day	250 days/year

Exposure Details

The workers are expected to wear standard PPE such as long sleeves, gloves, hard hats, safety glasses, dust masks and coveralls. Fine stray dust generated is released at < 0.1%.

Fire-fighting Foam Application

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration</i>	<i>Exposure Frequency</i>
Adding the notified polymer to the dry mixer	2	4 hours/day	250 days/year
The slurry mixture is transported in containers to the foam generating equipment.	2	7 hours/day	250 days/year

Exposure Details

The workers are expected to wear standard PPE such as long sleeves, gloves, hard hats, safety glasses and dust masks. Fine stray dust generated is captured by vacuum systems, and collected by a control device for recycling. Transfer of slurry to containers results in minimal exposure when mixer is washed down and workers are expected to wear standard PPE. Fire personnel wear extensive PPE when using the foam.

Concrete Application

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration</i>	<i>Exposure Frequency</i>
Adding the notified polymer to the dry mixer	2	4 hours/day	250 days/year
The pre-mix slurry mixture is transported in containers to the concrete batch plant	2	7 hours/day	250 days/year
The cementitious mixed product is transported and used at the job site	4	6 hours/day	250 days/year

Exposure Details

The workers are expected to wear standard PPE such as long sleeves, gloves, hard hats, safety glasses and dust masks. Fine stray dust generated is captured by vacuum systems, and collected by a control device for recycling. Transfer of the pre-mix slurry to containers results in minimal exposure when mixer is washed down and workers are expected to wear standard PPE. Wash down material is recycled. Concrete worker PPE is used to minimise contact with the wet concrete (rubber boots, gloves, safety glasses, hardhats).

Tyre / Pneumatic Sealant Products

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration</i>	<i>Exposure Frequency</i>
Adding the notified polymer to the dry mixer	2	4 hours/day	250 days/year
Packaging the sealant mixture into pressurised cans	2	7 hours/day	250 days/year
Commercial use of sealant products	2	7 hours/day	250 days/year

Exposure Details

The workers are expected to wear standard PPE such as long sleeves, gloves, hard hats, safety glasses and dust masks. Fine stray dust generated is captured by vacuum systems, and collected by a control device for recycling. Packaging is automated. Workers will apply sealants to the internal surfaces of tyres or other equipment, as part of puncture repair, however exposure is not expected to occur during these procedures.

Cleaner Products

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration</i>	<i>Exposure Frequency</i>
Adding the notified polymer to the dry mixer	2	7 hours/day	250 days/year
Packaging the cleaner mixture into containers	2	7 hours/day	250 days/year

Exposure Details

The workers are expected to wear standard PPE such as long sleeves, gloves, hard hats, safety glasses and dust masks. Fine stray dust generated is captured by vacuum systems, and collected by a control device for recycling. Packaging is automated.

Coating Products

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration</i>	<i>Exposure Frequency</i>
Adding the notified polymer to the dry mixer	2	4 hours/day	250 days/year
Packaging the coating mixture into containers.	2	7 hours/day	250 days/year

Exposure Details

The workers are expected to wear standard PPE such as long sleeves, gloves, hard hats, safety glasses and dust masks. Fine stray dust generated is captured by vacuum systems, and collected by a control device for recycling. Packaging is automated.

5.4. Release**RELEASE OF CHEMICAL AT SITE AND FROM USE**

The notified polymer will be imported as a component of the commercial form suitable for reformulation in Australia. The notified polymer will be used in a wide variety of thickening and suspending applications. The imported product is transported by road in commercial-carrier trucks to the notifier's facilities. No repackaging or reformulation will take place at the notifier site. However, the notified polymer will be processed and used at various industries around Australia. The notified polymer will be transported to the end user in its original transport containers, and any release during transport is expected to be minor and limited to accidental spills.

Cementitious packaged products

About 20% of the total notified polymer imported will be reformulated and used at various construction sites, mainly in commercial construction areas. The notified polymer in powder form is added to a dry cement mixture at 0.01 to 0.1% per batch during formulation. After processing the product containing the notified polymer will be packaged in 11.3 kg bags and 907 kg bags and distributed to the end user (constructor/homeowners). Any waste produced (0.1%) during this process would be sent to landfill. Further release may occur from used cement which will be deposited on land (including water washings) or landfill.

Oilfield Fluid

About 57% of the total notified polymer imported will be reformulated and used in oilfield fluids for 3 different processes at onshore and offshore rigsites in Australia, mainly in the Cooper-Eromanga Basin area.

Oilfield Spacer Fluid and Drilling Fluid: The notified polymer in powder form is added to the mixer at 0.1 to 0.3% per batch during formulation for spacer fluid application at the oilfield site. Spacer fluid is pumped into the shaft to displace drilling fluid, and is recycled when displaced by cement. Drilling fluid is pumped into the shaft, and is recycled. Any waste produced (95%) can be disposed to wastewater, or landfill, or direct ocean disposal or to an injection well depending on the locations (land or ocean drill site). Additionally, some notified polymer (5%) may be lost to the environment in the drill shaft, and/or released to the surrounding geological strata.

Oil Drilling Cement Application: The notified polymer in powder form is added to a cement mixer at 0.01 to 0.1% per batch during formulation for cement application at the oilfield drilling site. No waste

is produced as the product remains in the ground as a permanent structure, as part of the final cement (100%).

Fire-Fighting Foam Application

About 0.83% of the total notified polymer imported will be reformulated and used in fire fighting foam by manufacturing companies. The notified polymer in powder form is added to the mixer at 0.1 to 1.0% per batch during formulation of fire-fighting foam. The slurry mixture is transported in containers to the foam generating equipment, where it is sprayed as foam directly onto the ground to extinguish difficult fires or to cover exposed garbage in landfill. Any waste produced (0.01%) during equipment washing will be collected and recycled into the system. After fire fighting, foam sprayed on burning ground (100%) could be eventually washed to sewers or water sources (though much would remain in soil).

Concrete Application

About 13% of the total notified polymer imported will be reformulated and used at large number of concrete batching plants, mainly in metropolitan areas where large construction projects are undertaken. The notified polymer in powder is added to the mixer at 2 to 10% per batch in the preparation of concrete. The slurry mixture is transported in containers to the concrete batch plant, where it is mixed with cement components, sand, aggregate, and other cement admixtures to create the final concrete poured at the construction site. The cementitious mixed product containing 0.045% of the notified polymer is loaded into concrete mixer trucks and transported to the job site. Any waste produced (0.1%) during equipment washing, will be collected and recycled into the system. After use any cement that can not be recycled will be sent to landfill or poured onto the ground (0.14%).

Tyre Sealant Products

About 1.7% of the total notified polymer imported will be reformulated and use at a limited number of sites, mainly in the manufacturing sector where specific products are formulated. The notified polymer in powder form is included at 0.1 to 0.3% per batch in sealant formulations. The sealant mixture is packaged into pressurised cans automatically for tyre sealants or repairing. Waste cans/tyres (100%) will be sent to landfill.

Cleaning Products

About 20% of the total notified polymer imported will be reformulated and used at manufacturing facilities where specific types of cleaners are manufactured (such as toilet bowl products that need to cling to slick vertical surfaces). The notified polymer in powder form is included in cleaning formulations at 0.1 to 0.2% per batch. The cleaner mixture is packaged into containers automatically. Empty containers with small amount of product (1%) will be recycled or sent to landfill. Eventually, the entire volume of cleaning products will end up in the STP (99%).

Coating Products

About 6.7% of the total notified polymer imported will be reformulated and used at a limited number of manufacturers of paint mainly in the Sydney and Melbourne areas. The notified polymer in powder form is added at 0.2 to 0.5% per batch during formulation of coating products. The coating product is packaged into containers automatically and distributed for commercial use. Empty containers with small amount of product (1%) will be recycled or sent to landfill. Eventually, the entire volume of coating products will be disposed of coated surfaces by recycling and/or sent to landfill (99%).

5.5. Disposal

As described above.

5.6. Public exposure

Reformulation of the notified polymer will occur in industrial processes under controlled conditions. No exposure to the general public is expected from these processes.

Storage and transport is not expected to result in any public exposure as the notified polymer is either stored in sealed bags or "Super Sacks". However, a spill of the material arising from a transport accident may potentially result in public exposure.

Some products containing the notified polymer at low concentrations (up to 0.5%) will be available to

general public. These may include cleaning products, tyre sealants, coatings and cementitious products. Skin and eye contact may occur through consumer use of these products but would be limited by the low concentrations. Inhalation exposure could also occur during end-use of cementitious products used by home handymen as the product containing the notified polymer at up to 0.1% would be in powder form until mixed with water.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa	White to tan powder
Melting Point	Not available
METHOD	EC Directive 92/69/EEC A.1 Melting/Freezing Temperature: Differential scanning calorimetry
Remarks	The notified polymer decomposed from approximately 175 ± 0.5°C without melting.
TEST FACILITY	SPL (2001a)
Density	1427 kg/m ³ at 20.5 ± 0.5 °C
METHOD	EC Directive 92/69/EEC A.3 Relative Density.
Remarks	Gas comparison pycnometer
TEST FACILITY	SPL (2001a)
Vapour Pressure	≈ 0.1 kPa at 25 °C
Remarks	Using the Modified Watson Correlation (OECD TG 104) and a decomposition temperature of 174.85 °C.
Water Solubility	6.3 g/L at pH 1 @ 20 ⁰ C > 40 g/L at pH range 7 and 10 @ 20 ⁰ C
METHOD	The test was carried out by visual assessment and viscosity measurement method requested and supplied by the sponsor due to the unsuitability of the standard method 105 of OECD guideline for testing chemicals for this material.
Remarks	Notified polymer solubility was determined in a glass double-distilled water adjusted to pH 1.0, 7.0 and 10.0 at 20.5 ± 0.5 °C. Aliquots of notified polymer were slowly poured onto the side of the vortex and stirred continually for 10 min at 800 rpm, the stirring speed was increased to a nominal 2000 rpm for further 2 hours. On completion of the second stirring period, observations of samples were recorded and aliquots of sample solution removed for viscosity analysis. A graph of viscosity vs notified polymer concentration was prepared from the pH 7 results. An estimation of the notified polymer solubility at pH 1 was taken directly from the graph by conversion of the viscosity results to an equivalent hydrate concentration. Due to the high viscosity and slow hydrating nature of the notified polymer, the use of appropriate mixing conditions and equipment was crucial to properly hydrate (dissolve) the notified polymer.
TEST FACILITY	SPL (2001a)
Hydrolysis as a Function of pH	Not determined as it has high biodegradability and therefore hydrolysis is not expected to constitute a significant degradation pathway.
Solubility in n-Octanol	< 11 mg/L @ 20 ⁰ C
METHOD	The solubility of the notified polymer in n-octanol was carried out by visual assessment and viscosity measurements, using a procedure supplied by the notifier.
Remarks	An aliquot of n-octanol was poured in a beaker, the stirring was turned on and an

aliquot of 0.0011 g of notified polymer was slowly poured onto the side of the vortex and stirred continually for 10 min at 800 rpm, the stirring speed was increased to a nominal 2000 rpm for further 2 hours. On completion of the second stirring period, observations of samples were recorded and aliquot of sample solution removed for viscosity analysis.

On completion of the final stirring period, the solution was observed to be clear liquid containing visible undissolved white powder.

TEST FACILITY SPL (2001a)

Partitioning coefficient (n-octanol/water) $\log K_{ow}$ -2.76

METHOD Estimated by using the ratio of solubility of the notified polymer in n-octanol and in water. Calculation uses the solubility results at pH 1, i.e. the neutral molecule (pKa of carboxylic acid is 2.88).

Adsorption/Desorption $\log K_{oc}$ from -0.42 to -0.80
– screening test

METHOD Estimated using QSAR, by using the $\log K_{ow}$ results and the following regression equations for non-hydrophobic chemical ($\log K_{oc} = 0.52 \log K_{ow} + 1.02$) and for alcohol and acids molecules ($\log K_{oc} = 0.47 \log K_{ow} + 0.50$). Therefore, it is expected that the notified polymer will be highly mobile in solids.

Dissociation Constant Hydroxyl group expected to be neutral.
Carboxylic acid expected to be in its anionic state.

METHOD ACD/pKa Predictor V8.02 model method.
Remarks Based on the pKa values obtained by modelling, all of the hydroxyl groups on the notified polymer are expected to be in neutral form throughout the environmentally relevant range of pH 4-9, and the carboxyl anion is expected in its anionic state throughout this pH range.

Particle Size (S657 Diutan) Kelco-Crete 80 and Geovis XT have essentially the same sized particles, while Kelco-Crete 200 is a finer powder.

METHOD Using time-of-flight aerosol analysis.

Material	Average Mean Size (μm)	Average % under 11.0 μm	Average % under 9.02 μm	Average % under ~10 μm
Kelco-Crete 80	47.83	1.8173	1.0594	1.4384
Geovis XT	44.71	2.3942	1.4057	1.9000
Kelco-Crete 200	27.52	5.6755	3.4340	4.5548

Remarks Almost all of the material was below 100 μm in diameter.

TEST FACILITY TSI Aerosizer (2005)

Particle Size (pS8 Diutan)

Remarks Process improvements have allowed for the selection of larger particle sizes from smaller particle sizes via sieving. For the pS8 diutan, particles below 70 μm will be removed.

REFERENCE CP Kelco (2007)

Flash Point Not tested

Flammability Limits Determined to be not highly flammable as it failed to ignite in the preliminary screening test.

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids).
 Remarks Using the burning rate of notified polymer prepared as a pile of set dimensions.
 TEST FACILITY SPL (2001b)

Autoignition Temperature 351°C

METHOD 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
 Remarks The notified polymer was heated in an oven.
 TEST FACILITY SPL (2001b)

Explosive Properties Not expected to show any explosive tendencies from the structure.

Remarks Applying Bretherick's Handbook of Reactive Chemical Hazards to assessing substance explosibility.

Reactivity Not expected to be reactive in use. According to the Guidelines for the Determination of Oxidising Properties.

7. TOXICOLOGICAL INVESTIGATIONS

Toxicity data is for the previous product (S657 Diutan) unless otherwise noted

<i>Endpoint and Result</i>	<i>Assessment Conclusion</i>
Rat, acute oral LD50 > 5000 mg/kg bw	low toxicity
Rat, acute oral LD50 > 400 mg/kg bw*	low toxicity
Rat, acute dermal	not available
Rat, acute inhalation	low toxicity
Rabbit, skin irritation (analogue)	moderately-irritating
Rabbit, eye irritation	slightly-irritating
Guinea pig, skin sensitisation – adjuvant test.	no evidence
Rat, repeat dose <oral> toxicity – 28 days.	NOEL = 1000 mg/kg/day
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro <Mammalian Chromosome Aberration>	non genotoxic
Genotoxicity – in vivo	not available

*Data for pS8 Diutan

7.1A Acute toxicity – oral

TEST SUBSTANCE Diutan gum Lot Ex-4851 (STD/1193 Data submission)

METHOD 40 CFR 163.81-1 (EPA proposed)

Species/Strain Rat/Sprague-Dawley

Vehicle Cottonseed oil

Remarks - Method The substance was administered by gavage. All visible physical and behavioural changes were recorded during the 14 days observation period. Control animals were administered cottonseed oil only.

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
1	6/sex	5000	0
2	6/sex	0	0

LD50 > 5000 mg/kg bw
 Signs of Toxicity There were no abnormal behavioural or physical characteristics observed

Effects in Organs
Remarks - Results

following intubation or during the two week observation period.
All organs and tissues in all animals including controls appeared normal.
There were no deaths in this study.

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

TEST FACILITY ABSL (1983)

7.1B Acute toxicity – oral

TEST SUBSTANCE Diutan gum Lot Ex-9138 (pS8 Diutan) and Kelco Crete 80 (S657 Diutan)

METHOD 40 CFR 160 and 40 CFR 792
Species/Strain Rat/Crl:CD[®](SD)IGS BR Virus Antibody Free (VAF)
Vehicle Corn oil
Remarks - Method The substance was administered by gavage. All visible physical and behavioural changes were recorded during the 14 days observation period. Control animals were administered corn oil only.

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
1 (pS8 Diutan)	5/sex	400	0
2 (S657 Diutan)	5/sex	400	0
3	5/sex	0	0

LD50 > 400 mg/kg bw
Signs of Toxicity There were no abnormal behavioural or physical characteristics observed following intubation or during the two week observation period.
Effects in Organs All organs and tissues in all animals including controls appeared normal.
Remarks - Results There were no deaths in this study.

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

TEST FACILITY TRL (2004)

7.2. Acute toxicity – dermal

There was no acute dermal toxicity test submitted.

7.3. Acute toxicity – inhalation

TEST SUBSTANCE Diutan gum Lot Ex-4851

METHOD 40 CFR part 163, SS163.81-3 as proposed by EPA, August 22, 1978.
Species/Strain Rats/Sprague-Dawley
Method of Exposure Whole-body exposure
Exposure Period 4 hours
Physical Form solid aerosol (particulate).
Particle Size 0.43-9.0 µm
Remarks - Method The method used was analogous to OECD TG 403. The concentration in air achieved of 0.316 mg/L was well below the nominal concentration. Before exposure to the test substance, lung tissue was taken from some animals for histopathological examination, in order to establish the condition of the lungs.

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Concentration <mg/L></i>		<i>Mortality</i>
		<i>Nominal</i>	<i>Actual</i>	
Test group	5/sex	4.9	0.316	0
Control group exposed to air only	5/sex	-	-	0
Control group not exposed to substance or air	5/sex	-	-	0
Signs of Toxicity	Test animals appeared normal throughout the four hour exposure period except for intermittent nose rubbing which would indicate possible nasal irritation. One animal in the test group, two in the air-exposed control group and one in the unexposed control group exhibited a net weight loss.			
Effects in Organs	In the test group, two animals exhibited mottled lungs; one animal exhibited mottled lungs with areas of consolidation; and one animal exhibited a mottled left kidney. All other organs and tissues appeared normal. In the exposed control group, all organs and tissues appeared normal. In the unexposed control group, two animals exhibited mottled lungs. All other organs and tissues appeared normal. Histopathological examination of the lungs of each group revealed some adverse effects - focal tracheitis, small areas of interstitial pneumonia, small areas of lymphoid interstitial infiltrates. The effects occurred in all groups, however one animal in the test group also showed an area of consolidation, with lymphocytic, histiocytic and neutrophilic infiltrates, and many bronchioles filled with suppurative exudate.			
Remarks - Results	There were no deaths on this study. There was found to be tracheitis and focal pneumonitis or peribronchitis in some rats. However, the incidence and severity of lesions does not seem to be significantly different in the four different groups of rats, the controls on arrival, the test animals, those only exposed to air, and unexposed controls. The study authors concluded that the lesions are evidence of intercurrent infection and are not caused by the inhalation exposure.			
CONCLUSION	The notified polymer is of low toxicity via inhalation under the conditions of the test.			
TEST FACILITY	ABSL (1983a)			
7.4. Irritation – skin				
TEST SUBSTANCE	Analogue polymer (containing same monosaccharide units but different molecular weight and branching structure)			
METHOD	FHSA standards set forth by 16 CFR 1500.41.			
Species/Strain	Rabbit/albino			
Number of Animals	6			
Vehicle	Mazola Oil			
Observation Period	72 hours			
Type of Dressing	Occlusive			
Remarks - Method	The test substance was applied to the skin of each animal at two sites, for 24 h. One of the two sites was abraded with a bent tip needle, deeply enough to penetrate the stratum corneum, but not deeply enough to produce bleeding. No information was supplied on whether the test substance was removed at the end of the exposure period. Observations			

were made for 72 h after the patches were removed.

RESULTS

<i>Lesion</i>	<i>Mean Score*</i>	<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
<i>Erythema/Eschar</i>	1.25	2	72 h	2
<i>Oedema</i>	2.09	3	72 h	2

*Calculated on the basis of the scores at 24 and 72 hours for ALL animals using scores from both abraded and non-abraded skin.

Remarks - Results Erythema was generally slight at 24 and 72 hours.
Edema, slight to moderate at 24 hours, was slight at 72 hours.
Mean score for erythema and edema decreased during the study.
The calculated primary irritation index was 3.38.

CONCLUSION The analogue is moderately irritating to the skin under the conditions of the test.

TEST FACILITY MB (1984)

7.5. Irritation – eye

TEST SUBSTANCE Diutan gum Lot Ex-4851

METHOD Modified Draize Eye Test 16 CFR 1500.42
Species/Strain Rabbit/albino
Number of Animals 9
Observation Period 72 hours
Remarks - Method No significant protocol deviations. ABSL chose to modify Draize's procedure by immediately irrigating the eye of 3 of 9 rabbits used in the test. The table below summarises the results where eyes were not washed.

RESULTS

<i>Lesion</i>	<i>Mean Score*</i>	<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
<i>Conjunctiva: redness</i>	0.2	1	24 h	0
<i>Conjunctiva: chemosis</i>	0	0	-	0
<i>Conjunctiva: discharge</i>	0.6	2	24 h	0
<i>Corneal opacity</i>	0	0	-	0
<i>Iridial inflammation</i>	0	0	-	0

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

Remarks - Results Mild conjunctival redness and discharge had resolved within 48 hours.

CONCLUSION The notified polymer is slightly-irritating to the eye.

TEST FACILITY ABSL (1983b)

7.6. Skin sensitisation

TEST SUBSTANCE Diutan gum Lot Ex 8343

METHOD OECD TG 406 Skin Sensitisation - <maximisation>.
EC Directive 96/54/EC B.6 Skin Sensitisation - <maximisation >.
Species/Strain Guinea pig/albino Dunkin Hartley
PRELIMINARY STUDY Maximum Non-irritating Concentration:
intradermal: 1% and 5% were both irritating
topical: 5%

MAIN STUDY	Test Group: 10	Control Group: 5
Number of Animals		
INDUCTION PHASE	Induction Concentration:	
	intradermal: 5%	
	topical: 50%	
Signs of Irritation	Discrete or patchy to moderate and confluent erythema was noted at the intradermal induction sites of test group animals. Discrete or patchy erythema was noted at the intradermal induction sites of control group animals.	
	Discrete or patchy to moderate and confluent erythema was noted at the topical induction sites of test group animals. Discrete or patchy erythema was noted at the topical induction sites of control group animals.	
CHALLENGE PHASE	topical: 25%, 10%	
Remarks - Method	No significant protocol deviations.	

RESULTS

<i>Animal</i>	<i>Challenge Concentration</i>	<i>Number of Animals Showing Skin Reactions after challenge</i>	
		<i>24 h</i>	<i>48 h</i>
<i>Test Group</i>	25%	0/10	0/10
	10%	0/10	0/10
<i>Control Group</i>	25%	0/5	0/5
	10%	0/5	0/5

Remarks - Results No skin reactions were noted at the challenge sites of the test or control group animals at the 24 or 48 hour observations.

CONCLUSION There was no evidence of reactions indicative of skin sensitisation to the notified polymer under the conditions of the test.

TEST FACILITY SafePharm (2001)

7.7. Repeat dose toxicity

TEST SUBSTANCE Diutan gum Lot Ex 8343

METHOD OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents. EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral).

Species/Strain Rats/Sprague-Dawley Crl:CD (SD) IGS BR

Route of Administration Oral – gavage/

Exposure Information Total exposure days: 28 days. Recovery period 14 days

Dose regimen: 7 days per week

Post-exposure observation period: 14 days

Vehicle Arachis oil BP

Remarks - Method No significant protocol deviations. The doses given were corrected for water content of the notified polymer. Dose levels were chosen as a result of a 14-day range-finding study at 1000 mg/kg bw/day.

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw/day</i>	<i>Mortality</i>
I (control)	5/sex	0	0
II (low dose)	5/sex	150	0
III (mid dose)	5/sex	500	0
IV (high dose)	5/sex	1000	0
V (control recovery)	5/sex	0	0
VI (high dose recovery)	5/sex	1000	0

Mortality and Time to Death

There were no deaths during the study.

Clinical Observations

There were no toxicologically significant abnormalities detected throughout the study period. Two males in the high dose group showed signs consistent with male-dosing on Day 7 or Day 23, not considered to be toxicologically significant. All high dose animals showed hunched posture at the behavioural assessment in week 1 only, and one male also showed tiptoe gait. The same effect was not seen in the clinical observations carried out on the same day, and is attributed to a reaction to dosing of the insoluble material.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

No treatment-related effects were detected. A reduction in eosinophils in recovery high dose males and a reduction in alanine aminotransferase in recovery high dose females, compared to the recovery controls, were not associated with other changes and were not considered toxicologically significant.

Effects in Organs

No treatment-related effects were detected.

Remarks – Results

No treatment-related macroscopic and microscopic abnormalities were detected.

CONCLUSION

The No Observed Effect Level (NOEL) was established as 1000 mg/kg bw/day in rats

TEST FACILITY SafePharm (2001a)

7.8. Genotoxicity – bacteria

TEST SUBSTANCE Diutan gum Lot Ex 8343

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
EC Directive 2000/32/EC B.14 Mutagenicity – Reverse Mutation Test using Bacteria.
Direct plate incorporation and incubation procedures
Species/Strain *S. typhimurium*: TA1535, TA1537, TA98, TA100
E. coli: WP2uvrA
Metabolic Activation System S9 homogenate of phenobarbitone / β -naphthoflavone rat liver.
Concentration Range in Main Test a) With metabolic activation: 0, 50, 150, 500, 1500 and 5000 μ g/plate
b) Without metabolic activation: 0, 50, 150, 500, 1500 and 5000 μ g/plate
Vehicle Distilled water
Remarks - Method No significant protocol deviations. Test 1 used the plate incorporation method. Test 2 was performed using a 20-minute pre-incubation procedure prior to plating out.

RESULTS

Metabolic Activation	Test Substance Concentration (μ g/plate) Resulting in:			
	Cytotoxicity in Preliminary Test	Cytotoxicity in Main Test	Precipitation	Genotoxic Effect
<i>Absent</i>				
Test 1	> 5000 μ g/plate	> 5000 μ g/plate	> 5000 μ g/plate	negative
Test 2	> 5000 μ g/plate	> 5000 μ g/plate	> 5000 μ g/plate	negative
<i>Present</i>				
Test 1	> 5000 μ g/plate	> 5000 μ g/plate	> 5000 μ g/plate	negative
Test 2	> 5000 μ g/plate	> 5000 μ g/plate	> 5000 μ g/plate	negative

Remarks - Results

The test substance caused no visible reduction in the growth of the bacterial background lawn at any dose level. The test substance was, therefore, tested up to the maximum recommended dose level of 5000 µg/plate. An opaque sheen to the background lawns were observed at 5000 µg/plate. When viewed under an inverted microscope, a very light globular/oil appearance was noted. This did not prevent the scoring of revertant colonies.

No significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains, with any dose of the test substance, either with or without metabolic activation. All of the positive control chemicals used in the test induced marked increases in the frequency of revertant colonies thus confirming the activity of the S-9-mix and the sensitivity of the bacterial strains.

CONCLUSION The notified polymer was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY SafePharm (2001b)

7.9. Genotoxicity – in vitro

TEST SUBSTANCE Diutan gum Lot Ex 8343

METHOD OECD TG 473 In vitro Mammalian Chromosome Aberration Test.
EC Directive 2000/32/EC B.10 Mutagenicity - In vitro Mammalian Chromosome Aberration Test.

Cell Type/Cell Line Human lymphocyte

Metabolic Activation System Phenobarbitone β-naphthoflavone induced rat liver homogenate metabolising system (S9)

Vehicle Culture medium

Remarks - Method No significant protocol deviations. Test 2 with metabolic activation used 2% S9. The other tests used 1% S9.

Metabolic Activation	Test Substance Concentration (µg/mL)	Exposure Period	Harvest Time
<i>Absent</i>			
Test 1	0*, 156.25, 312.5, 625, 1250*, 2500*, 5000*, MMC 0.4*	4 h	20 h
Test 2	0*, 156.25*, 312.5*, 625*, 1250, 2500, 5000, MMC 0.2*	24 h	20 h
<i>Present</i>			
Test 1	0*, 156.25, 312.5, 625*, 1250*, 2500*, 5000, CP 12.5*	4 h	20 h
Test 2	0*, 156.25*, 312.5*, 625*, 1250, 2500, 5000, CP 12.5*	4 h	24 h

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	Test Substance Concentration (µg/mL) Resulting in:			
	Cytotoxicity in Preliminary Test	Cytotoxicity in Main Test	Precipitation	Genotoxic Effect
<i>Absent</i>				
	> 625 µg/mL			
Test 1		> 5000 µg/mL	> 5000 µg/mL	negative
Test 2		> 625 µg/mL	> 625 µg/mL	negative
<i>Present</i>				
	> 625 µg/mL			
Test 1		> 2500 µg/mL	> 2500 µg/mL	negative
Test 2		> 625 µg/mL	> 625 µg/mL	negative

Remarks - Results All vehicle (culture medium) controls gave frequencies of cells with aberrations within the range expected for normal human lymphocytes. All the positive control treatments gave statistically significant increases in the frequency of cells with aberrations indicating the satisfactory performance of the test and activity of the metabolising system. The test substance did not induce any statistically significant increases in the frequency of cells with aberrations, in either of two separate experiments, using a dose range that included a maximum concentration which was

either the maximum scorable level of exposure or the maximum recommended dose level. Small non-significant increases in aberrations were seen at some dose levels in Test 2 with and without metabolic activation.

CONCLUSION The notified polymer was not clastogenic to human lymphocyte treated in vitro under the conditions of the test.

TEST FACILITY SafePharm (2001c)

7.10. Genotoxicity – in vivo

There was no in vivo genotoxicity test submitted.

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE Notified polymer

METHOD OECD TG 301 B Ready Biodegradability: CO₂ Evolution Test.

Inoculum Activated sludge

Exposure Period 29 days

Auxiliary Solvent none

Analytical Monitoring TOC and analyser

Remarks - Method For this test the notified polymer was prepared using a method based on the notifier's hydration method.

An amount of notified polymer (18.75 g) was slowly added on the side of the vortex created in 750 mL hydration media (deionised reverse osmosis water) to give an initial stock dispersion of 25 g/L. The mixture was stirred for a period of 2 hours. After stirring an aliquot (24 mL) was dispersed in culture media and the volume adjusted to 2 litres to give a 300 mg/L stock dispersion. This mixture was stirred for a period of 30 minutes. An aliquot (246 mL) of stock dispersion was dispersed in inoculated culture media and the volume adjusted to 3 litres to give a final concentration of 24.6 mg/L (equivalent to 10 mg carbon/L).

RESULTS

Day	<i>Test substance</i>		<i>Sodium Benzoate</i>	
	Day	% Degradation	Day	% Degradation
0	0	0	0	0
2	6	38	2	38
6	38	70	6	70
8	67	77	8	77
10	74	77	10	77
14	78	77	14	77
20	83	74	20	74
22	85	73	22	73
24	86	75	24	75
28	95	92	28	92

Remarks - Results

The viscosity of the 25 g/L stock dispersion used to prepare the test vessels was determined in order to confirm complete hydration of the test material. The results of the viscosity analysis showed a measured stock dispersion concentration of 101% of the nominal value, therefore confirming complete hydration of the notified polymer in the hydration media.

The reference substance achieved 92% degradation after 28 days thereby

confirming the suitability of the inoculum and test conditions.
The notified polymer attained 95% degradation after 28 days and satisfied the 10 day window criterion.

CONCLUSION The notified polymer can be considered to be readily biodegradable under the test conditions.

TEST FACILITY SPL (2001b)

8.1.2. Bioaccumulation

No experimental results provided. However, based on the molecular weight, water solubility and K_{ow} value the notified polymer is not expected to bioaccumulate.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE Notified polymer

METHOD OECD TG 203 Fish, Acute Toxicity Test, C.1 Acute Toxicity for Fish – semi-static conditions.

Species Rainbow trout (*Oncorhynchus mykiss*)

Exposure Period 96 hours

Auxiliary Solvent none

Water Hardness 100 mg CaCO₃/L

Analytical Monitoring TOC analyser

Remarks – Method For this test the notified polymer was also prepared using a method based on the notifier's hydration method.
An amount of notified polymer (21.16 g) was slowly added on the side of the vortex created in 750 mL hydration media (deionised reverse osmosis water) to give an initial stock dispersion of 25 g/L. The mixture was stirred for a period of 2 hours. After stirring an aliquot (160 mL) was dispersed in culture media and the volume adjusted to 2 litres to give a 2 g/L stock dispersion. This mixture was stirred for a period of 30 minutes. Duplicate aliquots (1000 mL) of stock dispersion were dispersed in dechlorinated tap water and the volume adjusted to 20 litres to give a final concentration of 100 mg/L. The mixtures were stirred for another 30 minutes.
The exposure concentration to be used in the definitive test was determined by a preliminary range finding test. In this test, 10 fish per concentration were exposed for a period of 96 hours to a series of nominal notified polymer concentrations of 1, 10 and 100 mg/L under static conditions.
Based on the results of the range finding test, a limit test was conducted for the definitive test at a concentration of 100 mg/L.

RESULTS

Concentration mg/L		Number of Fish	Mortality				
Nominal	Actual		1 h	24 h	48 h	72 h	96 h
Control	-	10	0	0	0	0	0
100	105	10	0	0	0	0	0
100	107	10	0	0	0	0	0

LC50 > 100 mg/L at 96 hours.

NOEC 100 mg/L at 96 hours.

Remarks – Results The viscosity of the 25 g/L stock dispersion used to prepare the test vessels was determined in order to confirm complete hydration of the test material. The results of the viscosity analysis showed a measured stock dispersion concentration of 110% of the nominal value, therefore

confirming complete hydration of the notified polymer in the hydration media.

The 0 hour notified polymer solutions were subjected to TOC analysis. The results showed measured concentrations that were 105% and 107% of the nominal test concentration for the 100 mg/L of each replicate sample.

Throughout the study the test preparations were observed to be cloudy, white and homogenous dispersions.

The results of the range finding test showed no mortalities at all of the test concentrations of 1, 10, and 100 mg/L.

There were no mortalities in the definitive test with 20 fish exposed to a test concentration of 100 mg/L for a period of 96 hours.

CONCLUSION The notified polymer is not harmful to Rainbow trout under the test conditions.

TEST FACILITY SPL (2001c)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified polymer

METHOD OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test. Limit Test.

Species *Daphnia magna*

Exposure Period 48 hours

Auxiliary Solvent none

Water Hardness 250 mg CaCO₃/L

Analytical Monitoring TOC analyser

Remarks - Method For this test the notified polymer was again prepared using a method based on the notifier's hydration method as for the fish test.

The exposure concentration to be used in the definitive test was determined by a preliminary range finding test. In this test, 10 daphnia per concentration were exposed for a period of 48 hours to a series of nominal notified polymer concentrations of 1, 10 and 100 mg/L.

Based on the results of the range finding test, a limit test was conducted for the definitive test at a concentration of 100 mg/L.

RESULTS

	Concentration mg/L		Number of <i>D. magna</i>	Number Immobilised	
	Nominal	Actual		24 h	48 h
Control	-	-	10	0	0
100	100	102	10	0	0
100	100	103	10	0	0

LC50 > 100 mg/L at 48 hours

NOEC 100 mg/L at 48 hours

Remarks - Results The results of the viscosity analysis showed a measured stock dispersion concentration of 110% of the nominal value, therefore confirming complete hydration of the notified polymer in the hydration media.

The 0 hour notified polymer solutions were subjected to TOC analysis. The results showed measured concentrations that were 102% and 103% of the nominal test concentration for the 100 mg/L of each replicate sample.

The test preparations were not renewed during the exposure period. Any immobilization or adverse reactions to exposure were recorded at 24 and 48 hours.

Throughout the study the test preparations were observed to be cloudy, white and homogenous dispersions.

The results of the range finding test showed no immobilisation at all of the test concentrations of 1, 10, and 100 mg/L.

There were no mortalities in the definitive test with 20 animals exposed to a test concentration of 100 mg/L for a period of 96 hours.

CONCLUSION The notified polymer is not harmful to *Daphnia magna* under the test conditions.

TEST FACILITY SPL (2001d)

8.2.2. Acute toxicity to marine invertebrates

TEST SUBSTANCE Notified polymer

METHOD TC147/SC5/WG2 Water Quality, Determination of Acute Toxicity to Marine Copepods

Species *Acartia tonsa*

Exposure Period 48 hours

Auxiliary Solvent none

Water Hardness 250 mg CaCO₃/L

Analytical Monitoring TOC analyser

Remarks - Method For this test the notified polymer was prepared using a method based on the notifier's hydration method as for *Daphnia* test solution.

The exposure concentration to be used in the definitive test was determined by a preliminary range finding test. In this test, 20 acartia per concentration were exposed for a period of 48 hours to a series of nominal notified polymer concentrations of 10, 100 and 1000 mg/L. Based on the results of the range finding test, the following test concentrations were assigned to the definitive test: 10, 18, 32, 56, 100, 180, 320, 560 and 1000 mg/L.

RESULTS

Concentration mg/L		Number of <i>Acartia tonsa</i>	Number Immobilised	
Nominal	Actual		24 h	48 h
Control		20	Not	provided
10		20		
18		20		
32		20		
56		20		
100		20		
180		20		
320		20		
560		20		
1000		20		

LC50 250 mg/L at 48 hours

NOEC 100 mg/L at 48 hours

Remarks - Results The results of the viscosity analysis showed a measured stock dispersion concentration of 107% of the nominal value, therefore confirming complete hydration of the notified polymer in the hydration media.

From 10 to 56 mg/L, solutions were observed to be clear, colourless throughout the test. However, from 100 to 1000 mg/L, solutions were observed to be pale with homogeneous dispersions increasing in turbidity with increasing concentration.

In the range finding test, no mortality was observed at the test concentration of 10 and 100 mg/L. However, mortalities were observed at 1000 mg/L.

CONCLUSION The notified polymer is not harmful to *Acartia tonsa* under the test

conditions.

TEST FACILITY SPL (2002a)

8.2.3. Marine algal growth inhibition test

TEST SUBSTANCE Notified polymer

METHOD ISO 10253 Water Quality, Marine Algal Growth Inhibition Test with *Skeletonema costatum* and *Phaeodactylum tricornutum*.

Species *Skeletonema costatum*

Exposure Period 72 hours

Concentration Range Nominal: 1000 mg/L

Auxiliary Solvent none

Water Hardness

Analytical Monitoring

Remarks - Method

For this test the notified polymer was again prepared using a method based on the notifier's hydration method as for the fish test.

The exposure concentration to be used in the definitive test was determined by a preliminary range finding test. In this test, algae were exposed for a period of 72 hours to a series of nominal notified polymer concentration of 10, 100 and 1000 mg/L.

Based on the results of the range finding test, a limit test was conducted for the definitive test at a concentration of 1000 mg/L.

RESULTS

<i>E_bC₅₀</i> (95% CL) mg/L (0-72 h)	<i>Biomass</i>		<i>Growth</i>	
	<i>NOEC</i> mg/L	<i>E_rC₅₀</i> (95% CL) mg/L (0-72 h)	<i>NOEC</i> mg/L	<i>NOEC</i> mg/L
> 1000	1000	> 1000	1000	1000

Remarks - Results

The results of the viscosity analysis showed a measured stock dispersion concentration of 122% of the nominal value, therefore confirming complete hydration of the notified polymer in the hydration media.

It was not possible to monitor algal cells using a particles counter as the test material formed dispersions which interfered with the counts.

At the start of the test the control cultures were observed to be clear colourless solutions and the 1000 mg/L notified polymer test cultures were observed to be cloudy white dispersions. After 72 hours the control cultures were observed to be yellow dispersions and the 1000 mg/L test cultures were cloudy yellow dispersions. The colour was attributed to the growth of algal cells.

All test and control cultures were inspected microscopically at 72 hours. No abnormalities were detected in any of the samples.

The results of the range finding test showed no effect on growth at all of the test concentrations of 10, 100, and 1000 mg/L.

There was no effect on growth exposed to a test concentration of six replicates at 1000 mg/L for a period of 72 hours.

CONCLUSION

The notified polymer is not harmful to *Skeletonema costatum* under the test conditions.

TEST FACILITY

SPL (2002b)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 201 Alga, Growth Inhibition Test. EC Directive 92/69/EEC C.3 Algal Inhibition Test.
Species	<i>Scenedesmus subspicatus</i>
Exposure Period	72 hours
Concentration Range	Nominal: 100 mg/L Actual: 94 mg/L
Auxiliary Solvent	none
Water Hardness	
Analytical Monitoring	TOC analyser
Remarks - Method	For this test the notified polymer was prepared using a method based on the notifier's hydration method as above. An aliquot (1000 mL) of stock dispersion was inoculated with algae suspension (5 mL) to give the requested test concentration of 100 mg/L. The exposure concentrations to be used in the definitive test was determined by a preliminary range finding test. In this test, algae were exposed for a period of 72 hours to a series of nominal notified polymer concentrations of 1, 10 and 100 mg/L. Based on the results of the range finding test, a limit test was conducted for the definitive test at a concentration of 100 mg/L.

RESULTS

<i>Biomass</i>		<i>Growth</i>	
$E_b C_{50}$ (95% CL) mg/L (0-72 h)	NOEC mg/L	$E_r C_{50}$ (95% CL) mg/L (0-72 h)	NOEC mg/L
> 100	100	> 100	100

Remarks - Results	The results of the viscosity analysis showed a measured stock dispersion concentration of 107% of the nominal value, therefore confirming complete hydration of the notified polymer in the hydration media. The 0 hour notified polymer solutions were subjected to TOC analysis. The results showed the measured concentration was 94% of the nominal test concentration for the 100 mg/L sample. At the start of the test the control cultures were observed to be clear, colourless solutions and the 100 mg/L notified polymer cultures were observed to be a slightly cloudy, white dispersion. After 72 hours the control and 100 mg/L test cultures were all observed to be bright green dispersions. All test and control cultures were inspected microscopically at 72 hours. No abnormalities were detected in any of the samples. The results of the range finding test showed no effect on growth at all of the test concentrations of 1, 10, and 100 mg/L. There was no effect on growth exposed to a test concentration of 100 mg/L for a period of 72 hours.
CONCLUSION	The notified polymer is not harmful to <i>Scenedesmus subspicatus</i> under the test conditions.
TEST FACILITY	SPL (2001e)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Notified polymer
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METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test.
Inoculum	Activated sludge
Exposure Period	3 hours
Concentration Range	Nominal: 1000 mg/L
Remarks – Method	An aliquot (250 mL) of stock dispersion was dispersed with synthetic sewer (16 mL) activated sludge (200 mL) and water to a final volume of 500 mL to give the requested test concentration of 1000 mg/L. The exposure concentration to be used in the definitive test was determined by a preliminary range finding test. In this test a series of nominal notified polymer concentration of 1, 10, 100 and 1000 mg/L. Based on the results of the range finding test, a limit test was conducted for the definitive test at a concentration of 1000 mg/L.

RESULTS

Nominal (mg/L)	Consumption Rate (mg O ₂ /L/min)	% inhibition
Control	-	-
R ₁	0.39	-
R ₂	0.40	-
Notified polymer		
1000	0.41	4*
1000	0.44	11*
1000	0.42	6*
Reference		
3.2	3.0	9
10	4.8	47
32	7.1	80

*Increased respiration rate as compared to controls.

IC50	>1000 mg/L
NOEC	1000 mg/L
Remarks – Results	The results of the viscosity analysis showed a measured stock dispersion concentration of 104% of the nominal value, therefore confirming complete hydration of the notified polymer in the hydration media. No significant effect on respiration was observed at any of the range finding test concentration employed (4 to 13% increases in respiration rate). No significant effect on respiration was observed with triplicated samples at 1000 mg/L (4, 6 and 11% increases in respiration rate). A significant effect on respiration was observed with the reference material (3,5-dichlorophenol) at 32 mg/L (80% inhibition).

CONCLUSION	The notified polymer does not inhibit microbial activity at 1000 mg/L under the test conditions.
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TEST FACILITY	SPL (2001f)
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9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified polymer will be imported as a component of the commercial form suitable for reformulation in Australia. The notified polymer will be used in a wide variety of thickening and suspending applications. The imported product will be transported by road in commercial-carrier trucks to the notifier's facilities. No repackaging or reformulation will take place at the notifier's site. However, the notified polymer will be processed and used at various industries around Australia. The notified polymer will be transported to the end user in its original transport containers, any release during transport is expected to be minor and limited to accidental spill.

Notified polymer environmental exposure will be by different entry points depending on the industry, with large part of the imported volume eventually ending up in different environmental compartment.

Industry Type	Notified Polymer (% used)	Batch Volume (kg)	Waste Produced (% /batch)	Waste Type	Waste Fate
Cementitious Products	20	9,272	< 0.1	Cement structure	Landfill
Oilfield Spacer Fluid	17	12,000	95	Waste spacer fluid or ocean based oil rigs	Sewer, landfill, ocean disposal, injection well,
Oilfield Drilling Fluid	23	320,000	95	Waste drilling fluid or ocean based oil rigs	Earth adjacent to the shaft Sewer, landfill, ocean disposal, injection well.
Oil Drilling Cement Application	17	12,804	100	Underground cement structure	Earth adjacent to the shaft. Surrounding geological strata. Permanent structure
Foam Application	0.83	38,556	0.01 100	Rinsing product Foam sprayed into burning ground	Recycle May be washed into sewer or water sources
Concrete Application	13	4536	< 0.1 0.04 0.1	Rinsing product Wasted concrete Left over concrete	Recycle Landfill Recycle
Sealant Products	1.7	1893 litres	100	Waste cans/tyres	Landfill
Cleaning Products	20	18927 litres	99 1	Household cleaning	Sewer
Coating Products	6.7	18927 litres	1 99	Empty containers Empty container Coated surfaces	Landfill Recycle or landfill. Landfill

If notified polymer is disposed of to landfill the residues may be mobile, however, as it is considered to be biodegradable it will degrade via biotic and abiotic processes. The fate of the notified polymer in the different products would be the same as that of the products. If disposed of to landfill, the notified polymer would remain inert or degrade slowly via biotic and abiotic processes.

There two main industries that potentially be disposing the notified polymer into marine environment or the sewer through their product applications:

- Foam and cleaning industry, which uses up to 20.83% of the imported notified polymer and may be disposed to the sewer up to 100% of the end product (as the worse case).
- Oilfield industry, which uses up to 57% of the imported notified polymer (40% in spacer and drilling fluid and 17% in cement application) and could be disposed to the sewer or the marine environment up to 95% of the end product (again as a worse case). However, much will be disposed of to land as the initial main use will be in the inland area, Cooper-Eromanga Basin.

Case Study 1: Release to the STP by foam and cleaning industry

Based on the worst-case scenario that the entire volume used by foam and cleaning industry being released Australian wide to the aquatic environment via the sewer, a predicted environmental concentration (PEC) of the notified polymer has been calculated.

Process or Dilution Factor	Release to the STP
Typical notified polymer use expected per year	20,830 kg
Typical notified polymer release expected per day	57.1 kg

Number of days released in year	365
STP daily Volume	4000 ML
Concentration in effluent from sewage treatment plant	14 µg/L
Predicted environmental concentrations (PECs) in receiving waters	
Ocean (Dilution Factor 1:10)	
PEC	1.4 µg/L
River (Dilution Factor 1:1)	
PEC	14 µg/L

A SIMPLETREAT can be used to obtain the notified polymer concentration release after treatment. Based on the ready biodegradation 10 days criterion met, water solubility, K_{ow} and vapour pressure values, giving a log H < -4 and a log K_{ow} < 0, it may be predicted that 13% will remain in the water and 87% will be degraded. None will absorb to sludge and estimated of concentrations when this is disposed of to land is therefore not relevant.

Case Study 2: Release of oilfield fluids

The oilfield fluid normally contains a maximum of 0.3%. During drilling operations, the mud is pumped down the drill shaft and functions as a combination of lubricant for the drill bit, carrier for the solid cuttings, and sealant to minimise drilling fluid loss into the formations during deep well drilling. The drilling mud is pushed out of the well and transferred to the surface for solids processing. This involves a sifting along with low speed centrifugation in order to remove the drill cuttings. Drilling mud containing the notified polymer is then replenished with additional mud containing more notified polymer and is transferred back down into the well. The drill cuttings that represent about five to ten percent of the material transferred to the surface contain some trapped notified polymer and, in the case of off-shore drilling, are generally discharged into the ocean. In the case of on-shore drilling, these are generally discharged into lined reserve pits for later treatment. Very little, if any, would be discharged to the sewer.

After the completion of the drilling operation, the drilling mud along with the use notified polymer is discharged into the ocean or into the lined reserve pits for on-shore use. Due to the high water solubility and low K_{oc} value, the notified polymer will be released from the mud or spacer fluid into the surrounding water. While hydrolysis is unlikely to occur in the environmental pH range of 4 to 9 as the polymer is readily biodegradable.

To examine if the notified polymer can cause problems to the aquatic organisms living in the surrounding areas of the drilling, an environmental concentration has been calculated. This calculation is based on a model having the following assumptions:

- A daily and continuous discharge of the notified polymer.
- Released into an area having a cone shape model (based on the predicted movement of the discharge).
- A fixed discharge diameter ($r_1 = 0 \text{ m}^2$) (release point of notified polymer) into the ocean.
- A fix dept value ($h = 100 \text{ m}$) (height from the drilling platform to the ocean floor).
- A variable ocean floor diameter ($r_2 = 1 \text{ to } 14$) based on the notified polymer dispersion pattern.
- Current flows are not taken under consideration.
- Steady dissipation rate.
- Degradation rates based on readily biodegradation results.
- The products (containing the notified polymer) are used in 10 wells Australian wide.

Additionally, once the continuous discharge and drift PEC were obtained, a steady degradation was taken under consideration to determine the biodegradation rate of the released concentrations. To achieve this, the readily biodegradation results were plotted and a regression equation was produced ($y = -0.4598x - 9.2015$), which contains a biodegradation rate constant (-0.4598). This was followed by the calculation of steady state concentration (C_{ss}) as giving by the following equation:

$$C_{ss} = K_1/K_2$$

Where K₁ is the entry rate (discharge and drift PEC) and K₂ is the biodegradation rate constant.

Process or Dilution Factor	Release Direct to the Marine Environment per drilling well	Release Direct to the Marine Environment per batch
Typical notified polymer use expected per year	40,000 kg	40,000 kg
Typical notified polymer release	109.6 kg/day	996 kg
Total number of wells	10	1
Number of days used in year	365 days	9.1 days
Typical notified polymer release expected per well	10.96 kg	109.5 kg
Ocean floor diameter	1 to 14 m ²	1 to 18 m ²
Dilution volume in the cone	0.1 to 21 ML	0.1 to 34 ML
PEC	1.1 to 209 mg/L	3.2 to 1,045 mg/L
Steady state concentration	2.3 to 455 mg/L	7.0 to 2,273 mg/L

Additionally, the reserve pits for on-shore drilling operations may be treated in several different ways, including, being allowed to dry by evaporation, being picked up by vacuum trucks and transferred to disposal well sites for discharge, or simply covered with top soil and remediated.

9.1.2. Environment – effects assessment

The results of the aquatic toxicity tests are listed below.

Organism	Duration	End Point	mg/L*
Freshwater Fish	96 h	LC ₅₀	> 100
Freshwater Daphnia	48 h	LC ₅₀	> 100
Marine water Copepod	48 h	LC ₅₀	250
Freshwater Algae	0-72 h	E _b C ₅₀	> 100
		E _r C ₅₀	> 100
Marine water Algae	0-72 h	E _b C ₅₀	> 1000
		E _r C ₅₀	> 1000

Using the lowest value of > 100 mg/L for freshwater organism and 250 mg/L for marine organism and a safety factor of 100 (based on 3 experimental results) for fish/*Daphnia*/algal acute toxicity endpoints, a Predicted No Effect Concentration (PNEC) for freshwater is > 1 mg/L and for marine water is 2.5 mg/L.

9.1.3. Environment – risk characterisation

Case Study 1: Release to the STP by foam and cleaning industry

	Location	PEC* µg/L	PNEC µg/L	Risk Quotient (RQ)*
Australian wide release	Ocean outfall	1.4	> 1000	< 0.001
	Inland River	14	> 1000	< 0.01

* The worst-case PEC and the RQ values calculated assuming the notified polymer is not removed during the wastewater treatment process.

The resulting RQ values for the aquatic environment, assuming that the polymer is not removed by STP, is < 1 for the freshwater and marine environment indicating no concern for these aquatic compartments.

Case Study 2: Release of oilfield fluids

Release Direct to the Marine Environment per drilling well	Ocean bed radio (m ²)	Dilution volume in the cone (ML)	PEC ¹ mg/L	Css ² mg/L	PNEC mg/L	Risk Quotient (RQ) ³
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Direct ocean release	1	0.10	209	455	2.5	182.1
	2	0.42	52	113	2.5	45.5
	4	2	13	28	2.5	11.4
	6	4	6.0	13	2.5	5.1
	8	7	3.0	7.0	2.5	2.85
	10	10	2.0	4.6	2.5	1.82
	12	15	1.5	3.2	2.5	1.30
	14	21	1.1	2.3	2.5	0.93

¹Discharge and drift concentration

²Steady state concentration

³C_{ss}/PNEC

The resulting RQ values for the marine environment, assuming that the polymer has a biodegradation rate of 0.4598 per day and half-life of 1.51 days, is $\gg 1$ up to a radius of 14 m² from the discharge point, indicating a potential risk for the organisms living within this aquatic environment.

The above values have been obtained from a simple model created in order to see the possible distribution and toxicity of the notified polymer. The RQ values will vary depending on the depth of the water and the dispersion/dilution of the notified polymer. Additionally, current flows have not been taken under consideration, which could change the risk factor. However, a greater biodegradation rate has been assumed (based on readily biodegradation results), which could at least in part compensate the dissipation rate from ocean currents.

This is a worst case and assumes all the 40 tonnes is used in 10 oil drilling wells in a marine situation. As noted above, most will be used in well inland. Additionally, if we do the above calculation on a batch situation the width of the release with a potential risk will be more (17 m²). However, in both cases the potential risk is limited to a very narrow cone, which would be further reduced if these worst case calculations were refined.

Change in manufacturing process

There is no environmentally significant change in the chemical structure of the notified polymer manufactured using S657/pS8 strain. The physico-chemical and ecotoxicological properties of diutan gum produced by this new process are therefore not likely to be significantly altered. Based on the above, there is a low risk of transfer of residual pS8 plasmid DNA in Diutan gum by natural transformation or conjugation in the environment.

In addition, information provided by the notifier, including a study conducted to determine the existence of functional DNA (pS8 plasmid) in Diutan, shows that the transfer of the residual DNA (pS8 plasmid) in Diutan gum by the process of transformation or conjugation is highly unlikely. The method used to determine the viability of pS8 plasmid in diutan, provided by the notifier, was based on a comparison of levels of transformation of *E. coli* using diutan solution, with known levels of transformation using known quantities of pS8 plasmid. A transformation reference table using pS8 was produced. This was used as a basis for comparisons with any diutan-based transformation. The result show that the pS8 plasmid contained in Diutan gum is non-functional and/or below the level of detection (1 pg plasmid in 8 µg Diutan) (CP Kelco, 2009a).

Furthermore, according to information provided by the notifier, the *tra* genes encoding for proteins necessary for conjugation have been deleted from the plasmid; therefore making transfer by conjugation an unlikely scenario. In addition, the bacterial cells in Diutan are inactivated by heat and chemical processes, further limiting the possibility of transfer CP Kelco, 2009b). Any low level of viable DNA released from the diutan product into the environment would be degraded by natural processes, such as nucleases present in the environment (Alvarez et al. 1996). These factors would make natural transformation a highly unlikely scenario.

As the percentage of the notified polymer used in each of the various end-use products are not expected to increase, the PEC/PNEC ratio remains unchanged.

Hence, the above conclusions about the environmental risks posed by the notified polymer are considered to be unchanged for polymer manufactured using the new strain of microorganism. This conclusion may not be generally applicable to all possible genetic modifications of microorganisms that can be utilised to manufacture the notified polymer.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Storage and distribution

Exposure of waterside, transport and warehouse workers to the notified polymer is expected to be negligible except in the event of an accident.

Compounding and Formulation

Occupational exposure is expected to be similar during formulation processes for the different end-uses of the notified polymer – i.e. oilfield applications, firefighting foam, concrete and cementitious products, coatings and cleaning products. Dermal and possibly ocular and inhalation exposure to the notified polymer may occur during the transfer of the notified polymer into the mixer. The estimated reasonable worst case and typical case dermal exposure is 3000 mg and 900 mg respectively using measured data for the exposure scenario ‘dumping of powders in a formulation facility’ (European Commission, 2003). Therefore, for a 70 kg worker and a 10% dermal absorption factor (based on the high molecular weight and high log P_{ow}), reasonable worst-case and typical case dermal exposure is estimated to be 4.3 mg/kg bw/day and 1.3 mg/kg bw/day respectively. Exposure would be limited by the use of PPE (gloves, goggles, and coveralls) and would be further reduced in the presence of local exhaust ventilation (LEV).

The estimated atmospheric concentration of the notified polymer during the transfer due to dust is 5-50 mg/m³, based on EASE model (EASE) using the following inputs: dry manipulation, non-fibrous and LEV absent. Therefore for a 70 kg worker, assuming an inhalation rate of 1.3 m³/hour, 4 hour exposure time (EU, 2002) and 100% inhalable fraction, inhalation exposure is estimated to be 0.37-3.7 mg/kg bw/day. In the presence of effective local exhaust ventilation, inhalation exposure is estimated by the EASE model to be 0.15-0.37 mg/kg bw/day.

The extent of exposure is likely to be determined by the proportion of notified polymer used in the formulation, and the type of controls in place. The highest concentration used is in concrete pre-mix (up to 10%), and fire-fighting foam (up to 1%). For other applications 0.01% to 0.3% is used.

Controls used to reduce inhalation and dermal/ocular exposure during formulation may include closed systems, venting systems and personal protective equipment (PPE) including respiratory protection. Safe work practices such as regular cleaning would also minimise contact with spilled material.

Once incorporated in the formulation, inhalation exposure to the notified polymer would not occur for most applications. Dermal/ocular exposure could still occur but would be reduced by the low concentration in most applications. For cementitious products, where the formulation is in powder form, inhalation exposure may occur to up to 0.1% of the notified polymer if dusts are generated.

End use

Workers may have dermal or ocular exposure to the notified polymer during final application of the formulated products or during their addition to water if dilution is required. Although the level and route of exposure will vary depending on the method of application and work practices employed, exposure is likely to be low. At this stage the concentration in fire-fighting foam may be up to 1%, in final concrete formulations at 0.45%, and at lower concentrations for other applications. During the end-use of cementitious products, inhalation exposure may also occur to up to 0.1% of the notified polymer.

9.2.2. Public health – exposure assessment

The public may have dermal and/or ocular exposure to low concentrations (up to 0.5%) of the notified polymer during consumer use of coatings, cleaning products or tyre sealants. Dermal, ocular or inhalation exposure may occur during consumer use of cementitious products, in which the notified polymer may be used at up to 0.1%.

Indirect exposure to the notified polymer and/or its breakdown products may also occur,

however, the notified polymer or the potential breakdown products have not been predicted to bioaccumulate in the food chain.

9.2.3. Human health – effects assessment

Toxicokinetics

No information was provided on the toxicokinetic properties of the chemical. The metabolism in rats of an analogue polymer containing the same monosaccharide units but of different molecular weight and chain structure has been studied using radioisotopes (Kelco, 1984). The results indicated that the majority of the polysaccharide fraction was excreted unhydrolysed. Up to 15% of the non-polysaccharide fraction was absorbed.

Acute toxicity

The notified polymer is of low acute toxicity via the oral route, based on testing of polymer manufactured using both the S657 and S657/pS8 strains. Dermal toxicity was not tested.

An acute inhalation study in rats showed effects that were seen in both the test and control animals to a similar extent, and therefore cannot be attributed to the notified polymer. However the level of airborne dust achieved in this study (0.316 mg/L) was well below the cutoff of 5 mg/L for determining hazard classification for this endpoint.

The U.S. Environmental Protection Agency (USEPA) identified concerns for lung effects from inhalation exposure to the notified polymer when it was assessed as a new chemical in the USA, based on structural analogues and submitted test data. The concern is that fine respirable particles of a high molecular weight substance, when inhaled deep into the lungs, would absorb water and cause congestion (communication from notifier). While the USEPA does not expect water-soluble polymers to exhibit lung toxicity because they are expected to rapidly clear the respiratory tract and therefore not cause an overloading effect, they require testing on new chemicals of this type under their exposure –based authority (USEPA, 2006).

In this case the USEPA considered that significant inhalation exposure would not occur under the use conditions described for the USA, but that significant human exposure could occur under other scenarios. They have therefore recommended that a 90-day inhalation study with 60-day holding period be performed if additional applications for the chemical commence.

Irritation

Based on a study in rabbits of the S657 polymer the notified polymer is considered to be slightly irritating to the eyes, but not classifiable as an eye irritant. The slightly higher pH of the pS8 polymer (8.4 vs 7.3) may increase the irritation potential to some extent.

A dermal irritation study was carried out on an analogue chemical containing the same monosaccharide units, but with a different molecular weight and branching structure. The protocol for this study was more severe than the OECD test method, as it used a 24 h rather than 4 h exposure time, abraded skin and occlusive covering. The test substance was not washed from the skin after the exposure period. Under the conditions of this test the analogue polymer was moderately irritating, with mild erythema and slight to moderate oedema.

Additional information on the irritation potential of the notified polymer is available from the irritation effects of a 50% solution of the notified polymer in the guinea pig sensitisation study (24 h exposure time). In this study there was mild to moderate erythema, but oedema was absent.

Based on the results of these two studies, it is considered that the notified chemical would not be classified as a skin irritant. The slightly higher pH of the pS8 polymer (8.4 vs 7.3) may increase the irritation potential to some extent.

Sensitisation

There was no evidence of sensitisation potential to the notified polymer in the guinea pig maximisation test. Therefore the notified polymer is considered not to be a potential skin sensitiser.

Repeated Dose Toxicity

In a 28-day oral repeat dose study in rats, a No Observed Effect Level (NOEL) was established as 1000 mg/kg bw/day, based on the absence of treatment related effects.

Genotoxicity

The notified polymer was not mutagenic to bacteria and not clastogenic to human lymphocyte treated in vitro.

Allergenicity

As an adjunct to a dietary study in humans on an analogue polymer containing the same monosaccharide units but a different molecular weight and branching structure, serum samples from volunteers were analysed for total IgE and for allergen-specific IgE (Kelco, 1987). There was no evidence of any sensitisation to the analogue polymer, even in individuals with extremely high IgE levels, suggesting that the analogue polymer is non-sensitising, even in susceptible individuals.

Human experience

The notified advised that no adverse effects to human health are known from use of the notified polymer in other countries.

Based on the available data, the notified polymer is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004).

9.2.4. Occupational health and safety – risk characterisation

Available data on the notified polymer indicates that it is of low toxicity, however there are concerns about possible adverse effects on lungs after inhalation exposure. The hydrophilic nature of the notified polymer in powder form can contribute to mechanical irritation and collection in the eyes, on the skin or in the airways when dust is generated. The slightly higher pH of the pS8 product may increase the potential for eye, skin and respiratory irritation to some extent.

Worst-case dermal and inhalation exposure to the notified polymer during compounding was estimated by EASE modelling to be 8 mg/kg bw/day. Based on a NOEL of 1000 mg/kg bw/day, derived from a 28-day rat oral study the margin of exposure (MOE) is calculated as 130. MOE greater than or equal to 100 are considered acceptable to account for intra- and inter-species differences. Therefore, based on the available toxicological information the risk of systemic effects using modelled worker data is acceptable for workers involved in compounding operations. Exposure to the notified polymer is considered to be greatest for workers involved in the compounding process and as such the risk of systemic effects for all workers is considered to be low. It is expected that engineering controls, PPE and safe work practices could reduce the exposure considerably below the modelled level.

There are concerns that inhalation exposure may lead to adverse effects on the lungs, if small particles reach the lungs, absorb water and cause congestion. The particle size of the S657 polymer is low, with almost all particles in the inspirable range (< 100 µm) and up to 5% < 10 µm. The new pS8 polymer has a larger particle size as all particles < 70 µm have been removed, therefore the risk of adverse effects on the lungs from dust inhalation is expected to be reduced. The notified polymer is intended for use in several different industries and processes in Australia. While there are common processes involving the addition of the powdered polymer to liquid formulations, the scale of use, the type of equipment, locations and available engineering controls may vary. The risk to workers will be low if sufficient controls are in place to reduce inhalation exposure to the powdered material. Once the polymer is incorporated into a liquid formulation, inhalation exposure is not expected to occur, as the processes described would not generate aerosols.

9.2.5. Public health – risk characterisation

Available data on the notified polymer indicates that it is of low toxicity, however there are concerns about possible adverse effects on lungs after inhalation exposure. The hydrophilic nature of the notified polymer in powder form can contribute to mechanical irritation and collection in the eyes, on the skin or in the airways when dust is generated.

The public may have exposure to low levels of the notified polymer (up to 0.3%) in consumer products such as cleaning products, tyre sealants, coatings and cementitious products. Inhalation exposure of home handymen to the powder could occur in the use of cementitious products, before they are mixed with water but would not occur in the other uses.

However as the level of the notified polymer in cementitious products is low (up to 0.1%) and it is expected that these products would be used infrequently, the risk to the public would be low.

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

10.1. Hazard classification

Based on the available data the notified polymer is not classified as hazardous according to the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

Adverse lung effects eg congestion are possible if solid particles of the notified polymer are inhaled.

No GHS classification for human health or the aquatic environment is appropriate.

10.2. Environmental risk assessment

For both S657 and pS8 polymers, on the basis of the PEC/PNEC ratio (see section 9.1.3) the use of the chemical in:

- onshore uses will not pose a risk to freshwater organisms;
- offshore use may pose a potential problem in a narrow static cone under the release point to marine organisms. However, if the effects of currents are taken into account there will be an increased dissipation of the chemical, thus decreasing the risk. Therefore, the potential risk associated with the use of the chemical in offshore oil rigs is likely to be acceptable.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described, with adequate controls to reduce inhalation exposure.

10.3.2. Public health

There is No Significant Concern to public health when used in the proposed manner.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

12. RECOMMENDATIONS

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering control to minimise

occupational exposure to the notified polymer during compounding and formulation:

- Operations should take place under local exhaust ventilation
- Employers should implement the following safe work practices to minimise occupational exposure during compounding and formulation:
 - Avoid skin and eye contact
 - Avoid breathing dust
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer during compounding and formulation:
 - Coveralls
 - Impervious gloves
 - Eye protection
 - Suitable respiratory protection against respirable particles of the notified polymer where dust is generated and adequate ventilation is not present.

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

- A copy of the MSDS should be easily accessible to employees.
 - The MSDS should contain the statement “May cause adverse effects on the lung (congestion and mechanical irritation) if inhaled” under the heading “Chronic health effects”
 - The MSDS should provide instructions on avoiding inhalation exposure to the notified polymer, including suitable engineering controls, safe work practices and PPE.
- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Public Health

- The following measure should be taken by formulators and marketers to minimise public exposure to the notified chemical:
 - Where release of dry polymer from consumer products is possible, appropriate labelling regarding ventilation and use of personal protective equipment should be provided.

Disposal

- The notified polymer should be disposed of to landfill

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by removing all sources of heat. Increase ventilation. Sweep up material avoiding dust generation or dampen spilled material with water to avoid airborne dust. Seal wastes in vapour tight labelled plastic containers for eventual disposal. If large quantities of this material enter waterways contact Environmental Protection Authorities, or local Waste Management Authorities.

12.1. Secondary notification

This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals*

(*Notification and Assessment*) Act (1989) the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

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

(1) Under Section 64(1) of the Act; if

- any toxicity data is available on the notified polymer, specifically on inhalation toxicity;
- they become aware that products containing >0.1% of the notified polymer in powder form are available to the public;
- the strain of microorganism used to manufacture the gum is changed

or

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

- the function or use of the polymer has changed from thickening and suspending applications;
- the amount of polymer being introduced has increased from 100 tonnes, 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.

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