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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polymer in Crepetrol A3025

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Street Address:	334 - 336 Illawarra Road MARRICKVILLE NSW 2204, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 8577 8888.
Website:	www.nicnas.gov.au

Director
Chemicals Notification and Assessment

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FULL PUBLIC REPORT

Polymer in Crepetrol A3025

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Hercules Chemicals Australia, a division of Nuplex Industries (Aust) Pty Ltd
1612-1638 Centre Rd
Springvale VIC 3171

NOTIFICATION CATEGORY
Limited: Polymer with NAMW ≥ 1000 (greater than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication:
Chemical identity

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows:
Analogue data has been submitted for some toxicological and ecotoxicological endpoints.
Methods of detection and determination.
Some physico-chemical properties have not been submitted.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
Commercial evaluation category (CEC) permit number 577.

NOTIFICATION IN OTHER COUNTRIES
USA (1993)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Polymer in Crepetrol A3025

SPECTRAL DATA

ANALYTICAL METHOD	IR, ^{1}H and ^{13}C NMR
Remarks	Reference spectra were submitted.
TEST FACILITY	Hercules Analytical Science (undated) (for IR)

METHODS OF DETECTION AND DETERMINATION

Remarks	Not submitted

3. COMPOSITION

DEGREE OF PURITY
> 90 %

ADDITIVES/ADJUVANTS
The polymer is produced in aqueous media.

DEGRADATION PRODUCTS
MSDS states that in fire may emit fumes including carbon monoxide, carbon dioxide, ammonia and hydrogen cyanide.

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
Hazardous impurities have significant vapour pressure and may volatilise from the aqueous solution in use.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED POLYMER (100%) OVER NEXT 5 YEARS
The notified polymer will be imported at <30 % of Crepetrol A3025, which is an aqueous solution. Local manufacture of the notified polymer is planned to occur in future.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	26	26	26	26	26

USE
Creping agent in toilet tissue manufacture.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Melbourne

TRANSPORTATION AND PACKAGING
The notified polymer will be imported as part of the aqueous product Crepetrol A3025 in intermediate bulk containers (IBCs) or 200 L drums, which will be transported by road to the tissue manufacturing site and stored until use. The Crepetrol A3025 is pumped from the IBCs to the process batch at the time of use. If local manufacture occurs, Crepetrol A3025 will be transported by road from the manufacturing site to the end-use site in IBCs.

5.2. Operation description

Local manufacture of Crepetrol A3025
If the notified polymer is imported, further processing will occur only at the tissue manufacturing site. If local manufacture occurs, additional steps will take place at the notifier's Australian plant. Raw materials will be supplied in drums and stored until use. The stainless steel reaction vessel used to manufacture the notified polymer is fully enclosed, with most raw materials fed to it via flow meters or automatic scales. Some ingredients are added through a hatch, which is fitted with exhaust ventilation. The batch manufacture process is carried out in two steps in quantities of 12 tonnes and 24 tonnes respectively and is primarily computer-controlled. The final product will be tested and filled into 1000 L IBCs before being transported to the tissue manufacturing site.
Before local manufacture of the notified polymer commences, trial batches will be prepared in the laboratory of the polymer manufacturing site, to fine-tune the process.
Tissue manufacture
At the tissue manufacturing site, drums or IBCs containing Crepetrol A3025 will be transferred to the process area by forklift, and used as an ingredient in the chemical adhesive system. Crepetrol A3025 solution will be pumped into a mixing tank and blended with other ingredients to form a chemical adhesive solution. The process will involve decanting Crepetrol A3025 into a tank through a pump (weekly) and transfer into a "run tank" (daily). The adhesive solution will be used in a continuous process in the manufacture of toilet tissue. As part of the paper creping process the adhesive solution

will be sprayed onto a heated cylinder (Yankee) at the same time as an aqueous tissue fibre web is applied to the cylinder. The spray will be applied through a series of nozzles attached to a spray bar, in an enclosed shroud under exhaust ventilation. It is estimated that 70% of the polymer will remain on the tissue as it is dried and cut into toilet tissue. The remainder is over-spray that goes into effluent (25%), or a small portion (5%) lost in other ways. After drying, the creped tissue and adhesive will be physically removed from the cylinder by a blade. The creped tissue will undergo further processing in order to form toilet tissue.
It is expected that the toilet tissue will be used in households and commercial and industrial premises.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration hours*	*Exposure Frequency Days/year*
At tissue manufacturing site			
Forklift drivers	1	0.5	235
Technical control personnel	5	0.5	52
Paper machine operators	15	0.5	235
At local manufacture site			
Reactor operators	6	12	8
Laboratory technicians	1	1	8

EXPOSURE DETAILS

Transport and storage
Transport and storage arrangements will vary slightly depending on whether Crepetrol A3025 is imported or manufactured in Australia. In each case there will be land transport to the tissue manufacturing site, either from the docks or from the manufacturing site.

Transport workers including waterside workers, transport drivers and forklift drivers will handle the sealed 200 L drums or 1000 L intermediate bulk containers (IBCs). No exposure is expected except in the case of an accident that breaches the containers.

Local manufacture of Crepetrol A3025
Future local manufacture of Crepetrol A3025 is planned. Full production would be preceded by laboratory trial batches.

The manufacture of Crepetrol A3025 will involve a two-stage reaction controlled by one operator, who would be potentially exposed to the notified polymer. The reaction vessel is fully enclosed during operation. The intermediate pre-polymer will be held in mobile bulk containers prior to the second stage of the polymerisation process. A range of engineering controls will be in place to reduce worker exposure. Where the hatch of the reaction vessel is opened eg to add powders, an extraction system is used. Particulates are captured and contained in dust collectors. Fumes and vapours from vents are incinerated. Personal protective equipment (PPE) will be used during when the operator takes samples for testing during and after manufacture, including gloves, glasses and breathing canisters. Overall little exposure of the operator or others to the notified polymer or its intermediate is expected during the polymerisation process, as the degree of containment is high, and is supplemented by PPE. Exposure of the operator to the pre-polymer could occur during transfer to the mobile bulk container, and transfer back to the reaction vessel. At these stages dermal exposure could occur, and inhalation exposure if aerosols are generated, but would be minimised by the mechanical nature of the process.

Laboratory staff could be potentially exposed during manufacture of trial batches, or testing of samples, and it is expected that engineering and PPE controls would parallel those used in full production, thus minimising exposure.

When polymerisation is complete, the batch will be cooled in the reactor before final adjustment of properties, and transfer into containers for storage and transport to the end-use site. When the polymer

solution is transferred to IBCs for transport to the tissue manufacturing site, there is the potential for dermal exposure to the operator, and possible inhalation exposure if aerosols are generated during the transfer process. Exposure during final testing and transfer to IBCs would be minimised by the PPE worn by the operator.

Tissue manufacture
At the tissue manufacturing site, forklift drivers moving containers of Crepetrol A3025 to the process area are not expected to be exposed to the notified chemical, as they would handle only unopened containers.

Chemical control personnel will potentially be exposed to Crepetrol A3025 containing the notified polymer as they carry out the two step formulation and dilution of the adhesive system. However exposure during these enclosed processes is expected to be low, and limited to accidental spillage during connecting and disconnecting the tanks from the pumps.

Inhalation and dermal exposure of paper machine workers is possible when the polymer is being sprayed onto the Yankee cylinder. Paper machine operators would work in that area in order to change the spray jets (30 minutes once per shift), and while threading the paper sheet and changing the creping doctor blades (up to 45 minutes per shift). The potential for exposure to airborne material would be reduced because the spray system is enclosed in a shroud and the nozzles are surrounded by an extraction system. The PPE usually worn at the site does not include gloves or respiratory protection.

5.4. Release

RELEASE OF POLYMER PRIOR TO USE
Environmental release of the notified polymer is unlikely during importation, storage and transportation, and accidental spills, leaks and catastrophic mechanical failure during a transport accident is the most likely reason for environmental release. Engineering controls (eg. IBC, isotainer and drum specifications) and emergency clean-up procedures (ie. spill response instructions on Safety Data Sheet and container label) will limit the impact on the environment of such incidents.

Local Manufacturing of notified polymer

During domestic manufacturing, spills would be contained on-site in bunded areas for cleanup using established spill response procedures. Manufacture of the notified polymer will occur under controlled conditions within a fully enclosed stainless steel reactor vessel. Dust particulates will be collected in purpose-built dust collectors. Fumes and vapours will be incinerated on-site, and air emissions are monitored under EPA licence conditions.

Emptied containers with residues of the notified polymer, estimated at ≤0.5% of the notified polymer total manufactured volume) will be pH neutralised and sent to an authorised drum reconditioner.

Wastewaters generated from cleaning of reactor equipment will be treated on-site (pH adjustment, solids removal) prior to sewer discharge under EPA licence conditions. The notifier indicates that 0.15% of the notified polymer/formulation may be discharged to the sewerage system (ie. up to 39 kg/yr of notified polymer or up to 156 kg/yr of formulation).

RELEASE OF POLYMER FROM USE

Tissue manufacturing

At the tissue manufacturing site, the notified polymer is stored and pumped into each batch process from the same IBC as delivered, which minimises the risk of spillage and environmental release during handling. No other containers are used. The sprayer area where the notified polymer is used is full enclosed in a shroud and there is no overspray into the working area. However, there may be over spray directly to effluent.

During use, the notifier indicates that approximately 70% of the formulation (~18.2 tpa of the notified polymer or ~72.8 tpa of the formulation) adheres to the finished tissue product, with the remainder (overspray and other losses) entering the site wastewater (~7.8 tpa of notified polymer or ~31.2 tpa of the formulation). Attempts by the notifier to analytically quantify the amount of notified polymer in the effluent stream relative to the amount adhered to finished tissue products have been unsuccessful due to interference by co-associated chemicals (Foray Laboratories Pty Ltd, 2004).

Finished tissue product is packaged and transported off-site to retail outlets and then to consumer sites throughout Australia, where practically all will be disposed of to the national sewerage system (refer to Disposal below).

5.5. Disposal

Local manufacturing facility wastes will be collected by approved recyclers and/or waste disposal contactors. Wastewater containing the notified polymer generated at the local facility will be treated to remove solids in an onsite wastewater treatment plant (discharge ~5 ML/y), which are collected by waste contractor for solidification in fly ash prior to landfill disposal.

The tissue manufacturing facility will generate aqueous wastes containing the notified polymer that will discharged directly to sewer untreated but will be diluted within ~5 ML/d of site wastewater.

After consumer use, practically all the notified polymer associated with toilet tissue products will be disposed of via the sewerage system, and the diffuse use would indicate a widespread disposal pattern.

5.6. Public exposure

Exposure to the public is not expected during transport, local manufacture of the notified polymer, or production of toilet tissue. Approximately 70% of the notified polymer applied to the tissue during the creping process is expected to remain as part of the finished tissue, and the estimated concentration in the tissue is 600 ppm (0.06%). The public will have dermal contact with the notified polymer during normal handling and use of toilet tissue. Although it is not known whether any of the polymer would transfer to human skin during use of the toilet tissue, this would be limited by the affinity of the polymer for the anionic paper fibres.

6. PHYSICAL AND CHEMICAL PROPERTIES

Note: Unless otherwise specified, all physico-chemical properties refer to Crepetrol A3025, which contains the notified polymer in aqueous media at < 30%..

Appearance at 20°C and 101.3 kPa	Amber liquid with a sweet odour.
Melting Point/Freezing Point	Stated to be 0 to -2^0C
Boiling Point	Stated to be 100-105°C at 101.3 kPa

Remarks Information from MSDS

Density	Not supplied
Vapour Pressure	Not supplied, stated to be similar to water; however, the polymer itself is expected to have low vapour pressure based on molecular weight and cationic form.
Water Solubility	Stated to be completely miscible with water (imported as a <30% solution).
Hydrolysis as a Function of pH	Not determined.

Remarks The notifier states that despite hydrolysable functionality, hydrolysis is unlikely at environmentally-relevant pH levels. Hydrolysis will only occur at pH <2.2 and

>10 (Crepetrol A3025 solution is stated to have a pH of 2.2-3.0).

Partition Coefficient (n-octanol/water) Log_{10} Pow = -2.20 (weighted average)

METHOD The notified polymer is a mixture of several repeat units of varying proportion and individual units are estimated to have log Kow values of -1.17 to -4.91, estimated using EPIWIN Pollution Prevention assessment software (V 3.10 Syracuse Research Corporation).

TEST FACILITY Hercules Incorporated (2004)

Adsorption/Desorption Not determined.

Remarks However, the notified polymer is cationic and will adsorb strongly to soils/sediments and dissolved organic carbon (DOC) as demonstrated by inherent biodegradability and aquatic ecotoxicity tests. The high water solubility suggests mobility in soils and sediments.

Dissociation Constant Not determined.

Remarks The notifier states that cationic charge density was measured at pH 1.8 and 8.0. It is expected that all functional groups will be protonated at pH 1.8 and will contribute to the cationic charge density. At pH 8.0 only some functional groups will be protonated. The Crepetrol A3025 solution is stated to have a pH of 2.2-3.0.

Charge Density 2.91 cations /1000 MW at pH 1.8 (cationic equivalent weight 284).
2.35 cations / 1000MW at pH 8.0 (cationic equivalent weight 400).

Remarks No test report supplied.

Particle Size Not applicable as polymer is not separated from solution.

Flash Point Not supplied

Remarks Stated to be non-flammable

Flammability Limits Not supplied

Autoignition Temperature Not supplied

Explosive Properties Not supplied

Remarks Stated to be non-explosive

Reactivity Not supplied, stated to be not reactive

Remarks MSDS states that Crepetrol A3025 will not undergo hazardous polymerisation, but may react with strong oxidising agents or alkali.

7. TOXICOLOGICAL INVESTIGATIONS

In general, studies were not conducted or reported in accordance with current OECD test guideline standards.

Endpoint and Result	*Substance Tested*	*Assessment Conclusion*
Rat, acute oral Test 1	Crepetrol 742 (product containing notified polymer)	low toxicity LD50 > 5000 mg/kg bw
Rat, acute oral Test 2	Kymene 450 (product containing analogue polymer)	low toxicity LD50 > 2000 mg/kg bw
Rat, acute oral Test 3	PMC-D45 (product containing analogue polymer, statement of concentration ambiguous)	low toxicity LD50 > 10 000 mg/kg bw
Rat, acute oral LD50 Test 4	PMC-D45 (product containing analogue polymer)	inconclusive < 10 000 mg/kg bw
Rat, acute dermal LD50	-	not performed
Rat, acute inhalation LC50	-	not performed
Rabbit, skin irritation Test 1 (24 h exposure)	PMC-D46 (product containing analogue polymer, total solids 20.47%)	slightly irritating
Rabbit, skin irritation Test 2 (1 h exposure)	PMC-D45 (product containing analogue polymer)	slightly irritating
Rabbit, skin irritation Test 3 (24 h exposure)	PMC D-45 (product containing analogue polymer, total solids 22.2%)	moderately irritating
Rabbit, skin irritation Test 4 (24 h exposure)	PMC D-45 (product containing analogue polymer, total solids 22.2%)	moderately irritating
Rabbit, skin irritation Test 5 (24 h exposure)	PMC D-45 (product containing analogue polymer, total solids 22.2%)	slight to moderately irritating
Rabbit, skin irritation Test 6 (24 h exposure)	PMC D-45 (product containing analogue polymer, total solids stated as 16.8%)	moderately irritating
Rabbit, skin irritation Test 7 (24 h exposure)	PMC-D45, base activated (product containing analogue polymer, statement of concentration ambiguous)	slightly irritating
Rabbit, eye irritation Test 1	PMC-D-6 (product containing analogue polymer)	slightly irritating
Rabbit, eye irritation Test 2	PMC D-45 (product containing analogue polymer, total solids 22.2%)	slightly irritating
Rabbit, eye irritation Test 3	Polymer I, Intermediate D-45 (product containing intermediate analogue polymer)	slightly irritating
Rabbit, eye irritation Test 4	PMC-D45 (product containing analogue polymer, total solids 16.8%)	slightly irritating

Guinea pig, skin sensitisation – non-adjuvant test.	PMC-D45 (product containing analogue polymer, total solids 16.8%)	limited evidence of sensitisation.
Rat, repeat dose toxicity	-	not performed
Genotoxicity	-	not performed
Pharmacokinetic/Toxicokinetic studies	-	not performed
Developmental and reproductive effects	-	not performed
Carcinogenicity	-	not performed

7.1. Acute toxicity – oral – Test 1

TEST SUBSTANCE	Crepetrol 742 (notified polymer in marketed product, Lot 89M5MY4 (concentration not stated)
METHOD	Method analogous to OECD TG 401 Acute Oral Toxicity – Limit Test. Method stated to be based on Hagan (1959).
Species/Strain	Rat/Wistar albino
Vehicle	None
Remarks - Method	Animals were dosed by gavage and observed for 14 days before necropsy.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5M, 5F	5000	0

LD50	> 5000 mg/kg bw
Signs of Toxicity	All animals showed transitory mucoid diarrhoea 6 h after dosing.
Effects in Organs	At necropsy one male showed a growth attached to fat tissue on right testicle, 1.5 cm in length and 5 mm in width. This was not considered to be test-related.
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	Consumer Product Testing (1998)

7.1. Acute toxicity – oral Test 2

TEST SUBSTANCE	Kymene 450, Batch number 7783. (Product containing analogue polymer. Concentration not stated).
METHOD	OECD TG 401 Acute Oral Toxicity – Limit Test. EC Directive 92/69/EEC B.1 Acute Toxicity (Oral) – Limit Test.
Species/Strain	Rat/HSD/Win:WU
Vehicle	None
Remarks - Method	Animals were dosed by gavage and observed for 14 days before necropsy. Weight was recorded on days 0, 7 and 14.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	2F	2000	0
2	5M, 5F	2000	0

LD50	>2000 mg/kg bw
Signs of Toxicity	No deaths occurred in either the main or range-finding group. All animals had closed eyes after 1h, and this persisted in two females at 6h. Other slight clinical signs were observed up to 6h after dosing, mainly in female animals. Reduced activity, squatting position, piloerection, decreased body tone and decreased respiratory rate were seen most frequently. Reduced weight gain occurred in one female on day 14, however, no historical controls on weight gain were reported.
Effects in Organs	Two female rats showed abnormalities at necropsy, typical of effects that can occur spontaneously in rats of this strain and age. One showed hydrometra of the uterus, the other had extreme enlargement of the right kidney, which was filled with urine, had extreme dilatation of the renal pelvis and degeneration of the renal medulla.
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	IBR Forschungs (1994)

7.1. Acute toxicity – oral – Test 3

TEST SUBSTANCE	PMC-D45, #X24238-55 & NaOH activation solution (Product containing analogue polymer, base activated. Total solids stated to be 16.8% but unclear if this was measured before or after mixing with NaOH solution.)
METHOD	Method analogous to OECD TG 401 Acute Oral Toxicity – Limit Test.
Species/Strain	Rat/Wistar Albino
Vehicle	None
Remarks - Method	Gavage. Observations to 14 days after dosing

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 M, 5 F	10.0 mL/kg bw (approx.10,000 mg/kg bw)	0

LD50	> 10 000 mg/kg bw
Signs of Toxicity	The only clinical signs noted were that all male animals were lethargic on days 1 and 2, and one instance of chromorhinorrhea was noted in one male rat on day 4.
Effects in Organs	At necropsy one male had slightly congested lungs.
Remarks - Results	
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	M B Research Laboratories (1983a)

7.1. Acute toxicity – oral – Test 4

TEST SUBSTANCE	PMC-D45, #X24238-55 (Product containing analogue polymer, acid stabilized commercial product, total solids 16.8%)
METHOD	Method analogous to OECD TG 401 Acute Oral Toxicity – Limit Test.
Species/Strain	Rat/Wistar Albino
Vehicle	None
Remarks - Method	Gavage. Observations to 14 days after dosing. Amendment made to

report re identity of material tested.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 M, 5 F	10.0 mL/kg bw (approx. 10,000 mg/kg bw)	2M, 4F

LD50	< 10 000 mg/kg bw
Signs of Toxicity	Two males and four females died by Day 1 with pre-death physical signs of coma, ptosis, dyspnea, ataxia, chromodiacryorrhea, lethargy and piloerection. Physical signs in survivors included piloerection, ptosis, lethargy, diarrhoea, chromorhinorrhea and brown staining of body areas. Body weight increases of survivors were normal.
Effects in Organs	Necropsies of the dose-related deaths revealed abnormalities of the lungs and gastrointestinal tract, as well as red staining of the nose/mouth area and brown staining of the ano-genital area. Necropsies of the survivors were normal.
Remarks - Results	

CONCLUSION The study was inconclusive.

TEST FACILITY M B Research Laboratories (1983b)

7.4. Irritation – skin – Test 1.

TEST SUBSTANCE PMC-D46 #X2Y535-23A (Product containing analogue polymer, total solids 20.47%)

METHOD Method analogous to OECD TG 404 Acute Dermal Irritation/Corrosion, except that exposure time was longer (24h) and both intact and abraded skin was tested. Observations were made to 72 h only.

Species/Strain	Rabbit/New Zealand White
Number of Animals	6
Vehicle	None
Observation Period	72 h
Type of Dressing	Occlusive
Remarks - Method	Abraded and intact skin on each rabbit was tested. Exposure time was 24 h, after which the substance was wiped from the sites. Sex of animals was not identified. Observations were made at 24 h and 72 h only.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
*Erythema/Eschar***	0.58/0.66	2/2	> 72 h	1/1
*Oedema***	0.50/0.66	2/2	> 72 h	1/1

*Calculated on the basis of the scores at 24 and 72 hours for ALL animals.
** Scores for intact skin and abraded skin respectively.

Remarks - Results	Skin reactions were scored by the Draize scale. With abrasion, the skin of some rabbits appeared white along abrasion lines. Primary irritation score was calculated to be 1.21.

CONCLUSION The notified chemical is slightly irritating to the skin.

TEST FACILITY Biosearch (1983a)

7.4. Irritation – skin – Test 2.

TEST SUBSTANCE PMC D-45 (Product containing analogue polymer, concentration not stated)

METHOD Method analogous to OECD TG 404 Acute Dermal Irritation/Corrosion, except that exposure time was shorter (1 h) and only abraded skin was tested.

Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	None
Observation Period	72 h
Type of Dressing	Semi-occlusive.
Remarks - Method	All test sites were abraded. Test article was washed from the skin after 1 h with Ivory soap and rinsed well. Sex of animals was not identified. Observations were made at 24 h, 72 h and 7 days.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0	0.5	1	2	24 h	0
Oedema	0	0	0	0	-	0

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

Remarks - Results Scoring was by Draize method. Irritation index was calculated to be 0.50.

CONCLUSION The notified chemical is slightly irritating to the skin.

TEST FACILITY Biosearch (1983b)

7.4. Irritation – skin – Test 3.

TEST SUBSTANCE PMC D-45, #X24518-33 (product containing analogue polymer, 22.2% total solids)

METHOD Method analogous to OECD TG 404 Acute Dermal Irritation/Corrosion, except that exposure time was longer, and both intact and abraded skin were tested.

Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	None
Observation Period	7 days
Type of Dressing	Occlusive
Remarks - Method	After 24h application to intact and abraded skin, the test article was washed from the skin with Ivory soap and rinsed well. Sex of animals was not identified. Observations were made at 24 h, 72 h and 7 days.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
*Erythema/Eschar***	0/4	4/4	4/4	4/4	> 7 days / > 7 days	4/4
Oedema	0/0	0/0	0/0	0	-	0/0

*Calculated on the basis of the scores at 24 and 72 hours for EACH animal.
** Scores for intact skin and abraded skin respectively.

Remarks - Results	With intact skin, focal eschar was seen on one rabbit at all observations. With abraded skin, the skin appeared white along abrasion lines in all 3 rabbits at all observations. The Draize method was used for scoring, and the primary irritation score was calculated to be 2.67. However the authors considered the test material to be a primary skin irritant on the basis of apparent necrotic activity on the abrasion lines on abraded skin at 72 h and eschar on these lines at 7 days. They also noted that eschar was evident on intact skin at all observation times.
CONCLUSION	The notified chemical is moderately irritating to the skin.
TEST FACILITY	Biosearch (1983c)

7.4. Irritation – skin – Test 4.

TEST SUBSTANCE	PMC D-45, #X24518-33 (product containing analogue polymer, 22.2% total solids)
METHOD	Method analogous to OECD TG 404 Acute Dermal Irritation/Corrosion, except that exposure time was longer, and both intact and abraded skin were tested.
Species/Strain	Rabbit/New Zealand White
Number of Animals	6
Vehicle	None
Observation Period	7 days
Type of Dressing	Occlusive
Remarks - Method	After 24h application to intact and abraded skin, the test article was wiped from the skin but not washed. Sex of animals was not identified. Observations were made at 24 h, 72 h and 7 days.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
*Erythema/Eschar***	0/3.3	0/4	- / > 7 days	0/4
*Oedema***	0/0	0/0	-	0

*Calculated on the basis of the scores at 24 and 72 hours for ALL animals.
** Scores for intact skin and abraded skin respectively.

Remarks - Results	With abraded skin, the skin appeared white along the abrasion lines in all rabbits at 24 h and in 4/6 rabbits at 72 h. At 7 days eschar on abrasion lines was noted in all rabbits. No effects were seen on intact skin. Scoring was carried out by the Draize method, and the primary irritation score was calculated as 1.67. However the authors considered the test article to be a primary skin irritant based on necrotic effects on abraded skin at 72 h, and eschar on the abrasion lines at 7 days.

CONCLUSION	The notified chemical is moderately irritating to the skin.
TEST FACILITY	Biosearch (1983d)

7.4. Irritation – skin – Test 5.

TEST SUBSTANCE	PMC D-45, #X24518-33 (product containing analogue polymer, 22.2% total solids)
METHOD	Method analogous to OECD TG 404 Acute Dermal Irritation/Corrosion, except that exposure time was longer (24 h), and both intact and abraded skin were tested. Observations were made only to 72 h.
Species/Strain	Rabbit/New Zealand White
Number of Animals	6
Vehicle	None
Observation Period	72 h
Type of Dressing	Occlusive
Remarks - Method	After 24h application to intact and abraded skin, the test article was wiped from the skin but not washed. Sex of animals was not identified. Observations were made at 24 h and 72 h only.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
*Erythema/Eschar***	0.83/1.08	2/2	> 72 h / > 72 h	2/2
*Oedema***	0.92/1.00	3/3	> 72 h / > 72 h	2/2

*Calculated on the basis of the scores at 24 and 72 hours for ALL animals.
** Scores for intact skin and abraded skin respectively.

Remarks - Results	With abraded skin, the skin was white along abrasion lines at both observations. Scoring was carried out by the Draize method, and the primary irritation score was calculated as 1.92. As observations were not continued after 72 h, it is not clear whether the observed white lines and oedema on abraded skin would persist.
CONCLUSION	The notified chemical is slightly to moderately irritating to the skin.
TEST FACILITY	Biosearch (1983e)

7.4. Irritation – skin – Test 6.

TEST SUBSTANCE	PMC-D45, #X24238-55 (Product containing analogue polymer, acid stabilized commercial product, total solids 16.8%)
METHOD	Method analogous to OECD TG 404 Acute Dermal Irritation/Corrosion, except that exposure time was longer (24 h), and both intact and abraded skin were tested.
Species/Strain	Rabbit/New Zealand White
Number of Animals	6 male
Vehicle	None
Observation Period	28 days
Type of Dressing	Occlusive
Remarks - Method	Amendment made to report re identity of material tested. Observations were made at 24 h, 72 h, 7 days, 14 days, 21 days, 28 days.

Two intact and two abraded sites per rabbit were treated, giving a total dose of 2.0 ml/rabbit. As the rabbit pretest body weights were 2.2-2.7 kg, this is equivalent to approximately 800 mg/kg bw.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
*Erythema/Eschar***	1.83/1.83	> 4/ > 4	21 days/ >28 days	0/2
*Oedema***	1.58/1.58	2/2	21 days/ > 28 days	0/2

*Calculated on the basis of the scores at each of the 2 sites at 24 and 72 hours for ALL animals.
** Scores for intact skin and abraded skin respectively.

Remarks - Results

Abraded and intact skin responses were comparable.
One animal died on day 14. The test was not repeated with an additional animal, as it was thought the death may have been due to the severity of the dermal response, which was typical in this animal. Most animals showed slight to moderate erythema at 24 h and 72 h, and severe erythema on day 7. Pale areas were common at 24 h and 72 h. On days 14 and 21, erythema ranged from absent to severe, with some sites showing moderate eschar formation. By day 28 all sites showed signs of healing, with only two instances of well-defined erythema, both at abraded sites.
Oedema was slight at 24 h, and was absent to slight at 72 h and on days 7, 14, 21 and 28.
Mean scores for erythema increased up to day 7, and then decreased over the remainder of the study, while those for oedema decreased from 24 h to day 7, increased on day 14, and then decreased over the remainder of the study.
Scoring was carried out by the Draize method, and the primary irritation score was calculated as 3.42. However the study authors considered the subsequent observations of moderate eschar formation indicated a potential severe hazard to the skin, even though these effects were reversible. In addition severe erythema at day 7 was not reflected in the primary irritation score.
Illegible comment on systemic effects in the body of the report were probably minor, as they were not repeated in the summary.

CONCLUSION

The notified chemical is moderately irritating to the skin.

TEST FACILITY

M B Research Laboratories (1983c)

7.4. Irritation – skin – Test 7.

TEST SUBSTANCE

PMC-D45 #X24238-55 & NaOH Activation Solution (product containing analogue polymer, base activated. Total solids stated to be 16.8% but unclear if this was measured before or after mixing with NaOH solution)

METHOD

Method analogous to OECD TG 404 Acute Dermal Irritation/Corrosion, except that exposure time was longer (24 h), and both intact and abraded skin were tested.

Species/Strain: Rabbit/New Zealand White
Number of Animals: 6 female
Vehicle: None
Observation Period:
Type of Dressing: Occlusive
Remarks - Method:
Amendment made to report re identity of material tested.
Observations were made at 24 h, 72 h, and 7 days.
Two intact and two abraded sites per rabbit were treated, giving a total

dose of 2.0 ml/rabbit. As the rabbit pretest body weights were 2.2-2.7 kg, this is equivalent to approximately 800 mg/kg bw.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
*Erythema/Eschar***	0.75/0.71	2/2	72 h / 72 h	0/0
*Oedema***	0.37/0.29	2/2	72 h / 24 h	0/0

*Calculated on the basis of the scores at each of the two sites at 24 and 72 hours for ALL animals.
** Scores for intact skin and abraded skin respectively.

Remarks - Results
Scoring was carried out by the Draize method, and the primary irritation score was calculated as 1.06.
Mean scores for erythema and oedema decreased from 24 h to the end of the study.
Abraded and intact skin scores were comparable.
The only systemic effect noted was diarrhoea at 72 h in one rabbit.

CONCLUSION
The notified chemical is slightly irritating to the skin.

TEST FACILITY
M B Research Laboratories (1983d)

7.5. Irritation – eye – Test 1.

TEST SUBSTANCE
PMC-D46 (product containing analogue polymer, concentration not stated)

METHOD
Method analogous to OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain
Rabbit/New Zealand White
Number of Animals
Six. for main test. Additional 3 rabbits used with eyes washed.
Observation Period
7 days
Remarks - Method
No observations were made 1 h after instillation. Observations were made at 24 h, 48 h, 72 h, 4 days and 7 days, and did not continue until effects were completely reversed.
For the group with washed eyes, the treated eye was washed 30 seconds after instillation for one minute with tepid tap water (flow approximately 1000 mL per minute)

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	0.83	2	> 7 days	1
Conjunctiva: chemosis	0.94	1	> 7 days	1
Conjunctiva: discharge	0.05	1	24 h	0
Corneal opacity	0	0	-	0
Iridial inflammation	0	0	-	0

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

Remarks - Results
Scoring was carried out by the Draize method.
Results on washed eyes were comparable to unwashed eyes.
Slight conjunctival redness and chemosis were evident at the end of the 7 day observation period,

CONCLUSION
The notified chemical is slightly irritating to the eye.

TEST FACILITY
Biosearch (1983g)

7.5. Irritation – eye – Test 2.

TEST SUBSTANCE	PMC D-45 (X24518-33) (Product containing analogue polymer, total solids 22.2%)
METHOD	Method analogous to OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	Six. for main test. Additional 3 rabbits used with eyes washed.
Observation Period	7 days
Remarks - Method	No observations were made 1 h after instillation. Observations were made at 24 h, 48 h, 72 h, 4 days and 7 days, and did not continue until effects were reversed. For the group with washed eyes, the treated eye was washed 30 seconds after instillation for one minute with tepid tap water (flow approximately 1000 mL per minute)

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	0.97	2	> 7 days	1
Conjunctiva: chemosis	1.40	4**	> 7 days	3
Conjunctiva: discharge	1.33	3	> 7 days	3
Corneal opacity	0	0	> 4 days	Not determined**
Iridial inflammation	0	0	> 4 days	Not determined**

*Calculated on the basis of the scores at 24, 48, and 72 hours for ALL animals.
** Animal died on day 6.

Remarks - Results	Scoring was carried out by the Draize method. Average irritation scores were 7.7 (24 h), 8.0 (48 h), 7.3 (72 h), 8.2 (4 days) and 7.6 (7 days). Although individual 1 h observations were not reported, a separate study summary stated that the average ocular irritation was 14.3. The death on day 6 did not appear to be compound related. At the day 4 observation this rabbit had a hazy cornea but no opacity, slight iris effects (not specified), and mucus as part of the discharge. At the end of the study, significant effects on the conjunctivae were still evident and in some animals were more severe than the effects in the first 72 h. Results on washed eyes were comparable to unwashed eyes.
CONCLUSION	The notified chemical is slightly irritating to the eye.
TEST FACILITY	Biosearch (1983g)

7.5. Irritation – eye – Test 3

TEST SUBSTANCE	Polymer I, #X24238-58-1, Intermediate D-45 (Product containing intermediate analogue polymer). However report also describes the test material as Intermediate Polymer II in Ltr RSW/WM, 14.6% solids.
METHOD	Method analogous to OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	2 female and 1 male for main test. Additional 3 female rabbits used with eyes washed.
Observation Period	7 days
Remarks - Method	For the group with washed eyes, the eyes were rinsed one minute after

instillation with 300 mL of water for two minutes. The eyelids were everted during rinsing.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	0.67	0.33	0.33	1	48 h	0
Conjunctiva: chemosis	0.33	0	0.33	1	24 h	0
Conjunctiva: discharge	0.67	0.33	0.67	1	48 h	0
Corneal opacity	0	0	0	0	-	0
Iridial inflammation	0	0	0	0	-	0

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

Remarks - Results
The Draize method was used for scoring. No systemic effects, mydriasis or miosis were observed.
Results on washed eyes were comparable to unwashed eyes.

CONCLUSION
The notified chemical is slightly irritating to the eye.

TEST FACILITY
M B Research Laboratories (1983e)

7.5. Irritation – eye – Test 4

TEST SUBSTANCE
PMC-D45 #X24238-55 (Product containing analogue polymer, total solids 16.8%).

METHOD
Method analogous to OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain
Rabbit/New Zealand White
Number of Animals
Three females in main test. An additional 3 female rabbits used with eyes washed.
Observation Period
7 days
Remarks - Method
Amendment made to report re identity of material tested.
For the group with washed eyes, the eyes were rinsed one minute after instillation with 300 mL of water for two minutes. The eyelids were everted during rinsing.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	1.67	0.33	1.67	2	72 h	0
Conjunctiva: chemosis	1.0	0	1.67	3	72 h	0
Conjunctiva: discharge	1.67	0.33	1.67	2	72 h	0
Corneal opacity	0	0	0	0	-	0
Iridial inflammation	0	0	0	1	1 h	0

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

Remarks - Results
The Draize method was used for scoring.
Slight iritis occurred at 1 h in some animals.
No systemic effects, mydriasis or miosis were observed.
Results on washed eyes were comparable to unwashed eyes.

CONCLUSION
The notified chemical is slightly irritating to the eye.

TEST FACILITY M B Research Laboratories (1983f)

7.6. Skin sensitisation

TEST SUBSTANCE PMC-D45, X24238-55 (Product containing analogue polymer, acid stabilized commercial product, total solids 16.8%)

METHOD Method analogous to OECD TG 406 Skin Sensitisation - Buehler type. The study was stated to be modelled after Buehler (1965). No controls were used, and there were only 10 animals in the main test group.

Species/Strain Guinea pig/Hartley Albino

PRELIMINARY STUDY A screen was conducted to determine the highest non-irritating concentration of the test article, using one to four animals. No further details were provided.

MAIN STUDY

Number of Animals Test Group: 10 male Control Group: 0

INDUCTION PHASE Induction Concentration:
topical: 25%

Signs of Irritation

CHALLENGE PHASE

1st challenge topical: 25%

2nd challenge topical: 25%

Remarks - Method Amendment made to report re identity of material tested.
Induction was carried out through nine topical applications over three weeks. The first challenge was carried out two weeks after the last induction. In both challenges topical application was made at both the induction site and a new site.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*			
		1st challenge		*2nd challenge*	
		24 h	*48 h*	*24 h*	*48 h*
*Test Group**					
- original site	25%	1/10	1/10	0/10	0/10
- new site	25%	1/10	1/10	1/10	0/10

Remarks - Results Erythema was minimal during the induction phase of the study.
One animal showed well-defined erythema at 24 h and 48 h in the first challenge at both sites. During the second challenge there was very slight erythema at the original site at 24 h, but no reaction after 48 h, and at the new site there was well-defined erythema at 24 h and no reaction after 48 h. All other scores during the challenges were scattered instances of very slight erythema.

CONCLUSION The material tested may have skin sensitising ability but the test conditions employed are inadequate, particularly due to the absence of controls. Therefore, on the basis of these results, no conclusion is made. However the effects observed are not sufficient to allow classification as a skin sensitiser.

TEST FACILITY M B Research Laboratories (1983g)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1a. Ready biodegradability

TEST SUBSTANCE	Crepetrol 742 formulation (contains notified polymer)
METHOD	OECD (1992) TG 301B Ready Biodegradability: CO_2 Evolution Test (Modified Sturm Test) and EC Directive 67/548/EEC Annex V, Guideline C.4-C.
Inoculum	Supernatant from activated sewage sludge (2 m sieved; aerated; homogenised), Prospect Bay WWTP, USA; receiving mainly domestic sewage).
Exposure Period	28 d
Auxiliary Solvent	None
Analytical Monitoring	CO_2 traps were removed on days 2, 5, 8, 12, 15, 19, 22, 26 and 29 for analysis for inorganic carbon.
Remarks - Method	Study performed under GLP. Tests were conducted using a control and a killed control, to test for abiotic degradation. Stock solution was prepared at a nominal concentration of 400 mg C/L in nanopure water. To each test vessel was added: 2470 mL nanopure water, 3 mL ammonium sulphate solution, 3 mL calcium chloride solution, 12 mL ferric chloride solution, 3 mL magnesium sulphate solution, 6 mL phosphate buffer and 30 mL activated sludge supernatant inoculum. Stock solution cell count: $1.2x10^6$ CFU/mL (acceptable). Test concentration was 10 mg C/L. Dosing volumes were calculated based on measured TOC concentrations. Stock solution TOC was 413.1 mg/L. Test chambers consisted on 4 L amber glass bottles. Test temperature: 20±3°C. pH range 5.1-7.0. All test chambers were aerated with CO_2-free air for 24 h prior to the tests to purge CO_2. After aeration, the inflow was stopped and outflow of CO_2 monitored and compared to the theoretical CO_2 evolution. The reference toxicant (sodium benzoate) had a measured TOC of 397.8 mg/L.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% of Theoretical CO_2 Evolved*	*Day*	*% of Theoretical CO_2 Evolved*
2	0.55	2	40.2
5	0.25	5	71.1
12	0	12	97.7
19	0	19	100
29	0	29	100

Remarks - Results	The biodegradability of the reference substance was 100% after 28 days, indicating that the activity of the inoculum used in the test was acceptable.
CONCLUSION	The Crepetrol 742 formulation containing the notified polymer is not readily biodegradable under the test conditions, achieving no biodegradation within the 28 day test period.
TEST FACILITY	Wildlife International Ltd (1998)

8.1.1b. Ready biodegradability

TEST SUBSTANCE	PMCD-45 formulation containing an analogue polymer that has a different polymer backbone but the same cationic functionalities, though at a much higher level.
METHOD	Ready Biodegradability: CO_2 Evolution Test (Modified Sturm Test)

Inoculum	Activated sewage sludge (O'Bannon Creek STP, USA; receiving mainly domestic sewage).
Exposure Period	28 d
Auxiliary Solvent	None
Analytical Monitoring	CO_2 traps were removed on days 3, 4, 7, 10, 12, 14, 17, 21, 24, 27 and 28 for analysis for inorganic carbon.
Remarks - Method	Stock solution cell count: $4.4x10^6$ organisms/mL (acceptable). Test concentrations of PMCD-45 were 10 and 20 mg/L active compound. "Activated" PMCD-45 was prepared by weighing out and adding 15.0011 g of PMCD-45 to a 250 mL beaker containing 73.2 mL deionised water. 11.8 mL of NaOH was slowly added with stirring. This solution was used to prepare the 1000 mg/L active stock solution. Stock solution was prepared by adding 33.34 g of test material to ~500 mL deionised water in a 1000 mL flask. Stock solution TOC was 490 mg/L. Test chambers consisted on 4 L Erlenmeyer flasks (2000 mL volume). A blank solution containing no reference or test material was also tested. Test temperature: 20-24°C. Test solution pH 7.65. All test chambers were aerated with CO_2-free air for 24 h prior to the tests to purge CO_2. On day 0, all test chambers were inoculated with 20 mL of inoculum. After aeration, the inflow was stopped and outflow of CO_2 monitored and compared to the theoretical CO_2 evolution. The reference toxicant (sodium benzoate; 20 mg/L) had a measured TOC of 590 mg/L.

RESULTS

	Test substance		*Sodium benzoate*
Day	*10 mg/L*	*20 mg/L*	*20 mg/L*
	Cumulative % of Theoretical CO_2 Evolved	*Cumulative % of Theoretical CO_2 Evolved*	*Cumulative % of Theoretical CO_2 Evolved*
3	6.7	0	30.7
4	6.7	0	49.9
7	6.7	0	67.3
10	6.7	0	72.2
12	6.7	0	72.2
27	6.7	0	74.4
28	6.7	0	74.4

Remarks - Results	The biodegradability of the reference substance was 74.4% after 28 days, indicating that the activity of the inoculum used in the test was acceptable.

CONCLUSION The test substance (PMCD-45 formulation containing an analogue polymer) is not readily biodegradable under the test conditions.

TEST FACILITY Hill Top Research Inc. (1987a).

8.1.1c. Ready biodegradability

TEST SUBSTANCE PMCD-45 formulation containing an analogue polymer (see above)

METHOD Ready Biodegradability: CO_2 Evolution Test (Modified Sturm Test)

Inoculum	Activated sewage sludge (O'Bannon Creek STP, USA; receiving mainly domestic sewage)
Exposure Period	28 d
Auxiliary Solvent	None
Analytical Monitoring	CO_2 absorbers were removed on days 2, 3, 6, 8, 10, 14, 17, 20, 24, 27 and 28 for analysis for inorganic carbon.
Remarks - Method	Stock solution cell count: $7.1x10^6$ organisms/mL (acceptable). The inoculum was acclimated to PMCD-45 formulation for 14 d at 20 mg active/L in a semi-continuous activated sludge system. Test

concentrations of PMCD-45 were 10 and 20 mg/L active compound. Activated PMCD-45 was prepared by weighing out and adding 15.0007 g of PMCD-45 to a 250 mL beaker containing 73.2 mL deionised water. 11.8 mL of NaOH was slowly added with stirring. This solution was used to prepare the 1000 mg/L active stock solution. Stock solution was prepared by adding 16.67 g of test material to ~250 mL deionised water in a 500 mL flask. Stock solution TOC was 470 mg/L. Test chambers consisted on 4 L Erlenmeyer flasks. Test temperature: 22±1°C. A blank solution containing no reference or test material was also tested. Test solution pH was 7.5. All test chambers were aerated with CO_2-free air for 24 h prior to the tests to purge CO_2. On day 0, all test chambers were inoculated with 20 mL of inoculum, providing a 1% inoculum concentration. After aeration, the inflow was stopped and outflow of CO_2 monitored and compared to the theoretical CO_2 evolution. The reference toxicant (sodium benzoate; 20 mg/L) had a measured TOC of 560 mg/L.

RESULTS

	Test substance		*Sodium benzoate*
Day	*10 mg/L*	*20 mg/L*	*20 mg/L*
	Cumulative % of Theoretical CO_2 Evolved	*Cumulative % of Theoretical CO_2 Evolved*	*Cumulative % of Theoretical CO_2 Evolved*
3	0	0	28.1
4	4.1	1.7	46.2
7	4.1	1.7	66.1
10	4.1	1.7	75.0
17	4.1	1.7	87.9
21	20	1.7	89.4
27	20	1.7	94.2
28	20	1.7	96.4

Remarks - Results The biodegradability of the reference substance was 96.4% after 28 days, indicating that the activity of the inoculum used in the test was acceptable.

CONCLUSION The test substance (PMCD-45 formulation containing an analogue polymer) is not readily biodegradable under the test conditions, which included 14 days pre-test acclimatisation of the inoculant to the polymer.

TEST FACILITY Hill Top Research Inc. (1987b).

8.1.1d. Ready biodegradability

TEST SUBSTANCE KYMENE 450 formulation containing an analogue polymer

METHOD OECD 301D Ready Biodegradability: Closed Bottle Test

Remarks - Results Report in German. The test substance achieved <5% biodegradation after 28 days and is not readily biodegradable under the test conditions.

TEST FACILITY IWL (1994), Germany.

8.1.1e. Inherent biodegradability

TEST SUBSTANCE PMCD-45 formulation containing an analogue polymer

METHOD OECD TG 302A: Inherent Biodegradability: Modified SCAS Method. Semi-continuous activated sludge process.

Inoculum Secondary-treated (activated) sewage sludge (Colerain Township WWTP, USA; receiving mainly domestic sewage).

Exposure Period 28 d

Auxiliary Solvent None

Analytical Monitoring: DOC

Remarks - Method: Secondary activated sludge (20 L) with a suspended solids content of 4203 mg/L was added to 7 units, each receiving 892 mL. This provided a suspended solids concentration of 2500 mg/L for each unit after adjusting the final volume to 1500 mL with influent.

Prior to stock solution preparation, the sample of PMCD-45 was prepared to a 3.0% final activated solids solution. The activated solution was prepared by adding 73.2 mL of deionised water to separate quantities of ~15 g and ~15 g of PMCD-45. To this solution, 11.8 mL of 1 M NaOH was added. The activated solution was used within 6 hours of production to prepare the stock solution, which was prepared in deionised water at a nominal concentration of 1000 mg active/L. TOC analyses were performed on the stock solution, and TOC was within the acceptable limits. TOC of the stock solutions ranged from 475-490 mg/L.

The sludge from units 1-7 was allowed to settle and effluent was removed. The sludge from the units was pooled and mixed (suspended solids content 7317 mg/L). Based on this value, 513 mL of the sludge was added to each of 7 units. This provided the necessary amount of sludge such that the final suspended solids level of 2500 mg/L was achieved for each unit after adjusting the final volume to 1500 mL with influent.

The test material was acclimated to PMCD-45 formulation for 21 d at concentrations increasing from 0 to the final test concentration of 20 mg active/L. Units 1-2 did not receive test material and were used as controls. Each unit was brought to a final volume of 1500 mL with raw sewage. Units 3, 4 and 7 were not used in this study. Units were fed on a daily feed/draw cycle. Day 21 of the acclimation period was used as day 1 of the test. The feed and draw procedure was performed on a daily basis with the exception that units 5-6 received 9.5 mg DOC/L (20 mL of stock solution at 1000 mL active/L) of PMCD-45. Test temp: 22±2°C.

Samples of treated effluent were collected for DOC analysis. Calculation of percentage removals were based on initial TOC analyses of the stock solution (0.475 mg TOC/mg active, which if 20 mL of stock solution is added to the test units, would correspond to an addition of 9.5 mg carbon.

RESULTS

Test Day	*Blanks DOC (mg/L) Units 1 & 2*	*Test Units DOC (mg/L) Units 5-6*	*% Removal of DOC Units 5-6*
1	5.3	4.0	113.7
2	4.2	4.0-5.4	94.8
3	4.7	4.3-4.4	103.7
6	5.0	4.0-4.4	108.4
7	5.0	4.8-5.8	96.9
8	5.6	4.7-5.1	107.4
9	5.7	5.0-5.2	106.4
10	4.6	4.8-6.0	91.6
13	4.6	3.9-4.0	106.9
14	5.2	4.4-5.3	103.7

Remarks - Results: The TOC of blanks (units 1-2) was constant throughout the tests, validating the removal of the substance.

CONCLUSION PMCD-45 formulation was removable at 20 mg/L in a semi-continuous activated sludge system; however, removal may have been due to adsorption and/or biodegradation. This could not be ascertained from this test due to the design of the study. The Modified Sturm Tests (Hill Top Research Inc., 1987a-b) confirmed that the test material is not readily biodegradable, probably with adsorption being the main loss mechanism.

TEST FACILITY Hill Top Research Inc. (1987c).

8.1.2. Bioaccumulation

TEST SUBSTANCE Not determined. The notified polymer is unlikely to bioaccumulate in animals and plants as it has a large molecular weight and an estimated negative log Kow.

8.2. Ecotoxicological investigations

Considerable data have been made available, all of it tested on formulations. While some is for the notified polymer, the bulk is for an analogue polymer with a different polymer backbone but the same cationic functionalities, though at a much higher level.

8.2.1a. Acute toxicity to fish

TEST SUBSTANCE Crepetrol 80E formulation (contains notified polymer)

METHOD 96 h Acute Toxicity for Fish – Static (Environment Canada, 1990a)

Species	Rainbow Trout (*Onchorhynchus mykiss*). Mean Wt. 0.50±0.44 g. Mean length: 38.3±9.2 mm.
Exposure Period	96 h
Auxiliary Solvent	None
Water Hardness	270 mg $CaCO_3$/L (hard water)
Analytical Monitoring	None
Remarks – Method	Stock solution was prepared by adding 1 g of test substance in 1 L dilution water (filtered and UV sterilised groundwater), and test concentrations were prepared by appropriate dilution of aliquots of stock solution. Data are reported as nominal test concentrations. Range finding and definitive tests were performed. Temperature, DO and pH were measured at 0, 24, 48, 72 and 96 h. Temp. (range) 15±1.0°C; DO 8.9-10.2 mg/L; pH 8.3-8.5. 16 h daylight photoperiod. Observations of mortality and sublethal effects were monitored daily. LC50 values were calculated using a computerised method of Stephan (1977).

RESULTS

Concentration mg/L	*Number of Fish*	*Mortality**					
Nominal		*0 h*	*24 h*	*48 h*	*72 h*	*96 h*	*%*
Control	20 (10 per replicate)	0	0	0	0	0	0
1.0	"	0	0	0	0	0	0
1.8	"	0	0	4	10	11	55
3.2	"	0	9	19	20	20	100
5.6	"	0	20	20	20	20	100
10	"	0	20	20	20	20	100

* Replicate values were not pooled.

LC50	1.7 mg/L formulation (95% CI 1.0-3.2 mg/L; nominal); Expressed as mg/L of solids: 0.43 mg solids/L (0.25-0.8 mg/L). The Crepetrol 80E formulation contained ~25% solids.
NOEC	Not determined

CONCLUSION The test substance (Crepetrol 80E formulation containing the notified polymer) was toxic (LC50 1-10 mg/L) to rainbow trout (United Nations,

2003).

TEST FACILITY B.A.R. Environmental Inc. (1997a).

8.2.1b. Acute toxicity to fish

TEST SUBSTANCE Crepetrol 80E formulation (contains notified polymer)

METHOD 96 h Acute Toxicity for Fish – Static (Environment Canada, 1990a) and USEPA (1996).

Species Rainbow Trout (*Onchorhynchus mykiss*). Mean Wt. 0.3-0.5 g.

Exposure Period 96 h

Auxiliary Solvent None

Water Hardness 270 mg $CaCO_3$/L (hard; dilution water)

Analytical Monitoring None

Remarks – Method Range finding and definitive tests were performed. Tests included a test of dilution water (filtered and sterilised groundwater) and a negative control test of dilution water with dissolved organic carbon (humic acid, HA). A stock solution of HA was prepared by reverse osmosis (RO) treated water. The HA solution was adjusted to pH 11 with NaOH) and mixed for 24 h. Appropriate quantities of HA stock were then added to the dilution water and thoroughly mixed. Each test concentration was prepared by adding the appropriate quantity of test substance directly to the dilution water containing the HA. The test substance and HA were allowed to equilibrate for 4 h prior to test initiation (addition of the fish). Test aquaria consisted of 20 L glass vessels containing 10 L of test solutions. Data are reported as nominal test concentrations. Aquaria were aerated during the tests. From each replicate chamber, test solutions were sampled and analysed for TOC prior to the addition of the fish. Toxicity values were calculated using the method of Stephan (1977). Temperature, DO and pH were measured at 0 and 96 h. Temp. 15±1.0°C; DO 9.1-10.4 mg/L; pH 7.8-8.5. 16 h daylight photoperiod. Observations of mortality and sublethal effects were monitored daily. The test substance contained ~25% solids.

RESULTS

Concentration mg/L Nominal	*Mean TOC (mg/L)*	*Number of Fish*	*Mortality (No. dead)**			
			24 h	*48 h*	*96 h*	*%*
Control 1	12.5	20 (10 per replicate)	0	0	0	0
Control 2	12.5	"	0	0	0	0
Tests with 10 mg/L DOC						
Negative control	3.4	20 (10 per replicate)	0	0	0	0
10	4.7	"	0	0	0	0
18*	5.4	"	0	0	0	0
32*	7.6	"	0	0	0	0
56	8.3	"	20	20	20	100
100	14.8	"	20	20	20	100
Tests with 20 mg/L DOC						
Negative control	7.2	20 (10 per replicate)	0	0	0	0
100*	20	"	0	0	0	0
180*	30	"	20	20	20	100
320	52	"	20	20	20	100
560	87	"	20	20	20	100
1000	152	"	20	20	20	100

* Brown particulates observed in bottom of test aquaria.

LC50 (no humic acid) 1.7 mg/L formulation (95% CI 1.0-3.2; nominal) or 0.43 mg/L solids basis (95% CI 0.25-0.8; nominal)

LC50 (with 10 mg/L humic acid) 42 mg/L formulation (95% CI 32-56; nominal) or 10.5 mg/L solids basis (95% CI 8-14; nominal)

LC50 (with 20 mg/L humic acid) 134 mg/L formulation (95% CI 100-180; nominal) or

	33.5 mg solids/L (95% CI 25-45; nominal)
Remarks - Results	A dark coloured precipitate formed in test aquaria containing HA, and the presence of the precipitate coincided with a decrease in toxicity. The TOC analytical method was validated using a known standard solution. A reference toxicant (phenol) was also tested, finding toxicity within the normal range and indicating that the fish used in the tests were healthy.
CONCLUSION	Crepetrol 80E formulation containing the notified polymer became less toxic as the concentration of dissolved organic matter in the test solution increased. Toxic (LC50 1-10 mg/L; United Nations, 2003) to bluegill sunfish at low DOC.
TEST FACILITY	ESG International (1998)

8.2.1c. Acute toxicity to fish

TEST SUBSTANCE	KYMENE 450 formulation containing an analogue polymer
METHOD	96 h Acute Toxicity for Fish – Static In-house method based on ASTM (1988), APHA (1985), USEPA (1985, 1982), European Communities (1984), OECD (1984b).
Species	Fathead minnow (*Pimephales promelas*)
Exposure Period	96 h
Auxiliary Solvent	None
Water Hardness	130 mg $CaCO_3$/L
Analytical Monitoring	None
Remarks – Method	Two range finding tests were performed to determine definitive test concentrations. The KYMENE® 450 formulation was activated by addition of NaOH to each of the test chambers. Temperature, DO and pH were measured at 0, 24, 48, 72 and 96 h. Temp. (range) 22±1.0°C; DO 7.2-8.7 mg/L; pH 8.0-8.7. 16 h daylight photoperiod. DOC concentration in unaltered laboratory diluent was 1.4 mg/L. Percent solids content of the formulation was 20±1%. LC50 values were calculated by the method of Stephan (1977) and ASTM (1987).

RESULTS

Concentration mg/L	*Number of Fish*	*% Mortality***				
Nominal		*6 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control	20 (10 per replicate)	0	0	0	0	0
0.94	"	0	0	0	0	0
1.88	"	0	0	10-30	30-40	30-40
3.75	"	0	0	10-40	40-50	40-50
7.5	"	0	0	30-70	40-70	40-90
15	"	0	0	50-90	60-90	60-100

* All test substance concentrations are reported as 100% solids (total solids content of 20±1% ie. weight x 5).
** Replicate values were not pooled.

LC50	3.0 mg/L formulation (95% CI 2.1-4.4; Replicate A) and 8.7 mg/L formulation (95% CI 4.5-62; Replicate B which is very wide).
NOEC	0.94 mg/L (based on lethal & sublethal effects)
CONCLUSION	The test substance (KYMENE 450 formulation containing an analogue polymer) was toxic (LC50 1-10 mg/L) to fathead minnow (United Nations, 2003).
TEST FACILITY	Eastman Kodak Company (1989a)

8.2.1d. Acute toxicity to fish

TEST SUBSTANCE	KYMENE 450 formulation containing an analogue polymer
METHOD	96 h Acute Toxicity for Fish – Static In-house method based on ASTM (1988), APHA (1985), USEPA (1985, 1982), European Communities (1984), OECD (1984b).
Species	Fathead minnow (*Pimephales promelas*)
Exposure Period	96 h
Auxiliary Solvent	None
Water Hardness	130 mg $CaCO_3$/L
Analytical Monitoring	Exposure II used radiolabelled test substance (^{14}C KYMENE), and test solution samples were analysed by LSC at 0 h and 96 h. Dissolved organic carbon (DOC) in test samples was monitored.
Remarks – Method	The study was conducted with GLP. Test chambers consisted of aquaria containing 20 L of the test solution. Diluent water (filtered Lake Ontario water) was modified prior to use by addition of two concentrations of DOC (as humic acid). DOC target levels were Exposures I and III (7±1 mg/L; actual 6.6 mg/L) and Exposure II (14±2 mg DOC/L; actual 12 mg/L). Acute toxicity in the absence of DOC has previously been determined by Eastman Kodak Company (1989a). During exposures I and II, the test substance was introduced in the test chambers (duplicated) giving nominal concentrations of 0.94, 1.88, 3.75, 7.5 and 15 mg/L. Exposure III used higher nominal test concentrations (15, 30, 60, 120 and 240 mg/L). A stock solution containing KYMENE 450 was activated by addition of NaOH to each of the test chambers. Appropriate volumes of stock solution were added to aquaria containing modified diluent water. The pH of each test solution was adjusted with 1 M H_2SO_4. Diluent water controls with DOC were also prepared and tested. One concentration of the test substance without DOC was also prepared and tested. 16 h daylight photoperiod. Temperature, DO and pH were measured at 0, 24, 48, 72 and 96 h. Exposure I: Temp. 22±1.0°C; DO 7.6-8.9 mg/L; pH 8.0-8.8. Exposure II: Temp. 22±1.0°C; DO 7.1-8.6 mg/L; pH 8.0-8.7. LC50 values were calculated by the method of Stephan (1977) and ASTM (1987).

RESULTS

*Concentration mg/L ** Nominal (actual)*	*Number of Fish*	*No. Surviving**				
		6 h	*24 h*	*48 h*	*72 h*	*96 h*
Test Substance (DOC 1.4 mg/L)						
3.0	20 (10 per replicate)	20	19	17	17	13
Exposure I (DOC 6.6 mg/L)						
Control	20 (10 per replicate)	20	20	20	20	20
0.94	"	20	20	20	20	20
1.88	"	20	20	20	20	20
3.75	"	20	20	20	20	20
7.5	"	20	20	20	20	20
15	"	20	20	20	20	20
Exposure II (DOC 12 mg/L)						
Control	20 (10 per replicate)	20	20	20	20	20
0.94	"	20	20	20	20	20
1.88	"	20	20	20	20	20
3.75	"	20	20	20	20	20
7.5	"	20	20	20	20	20
15	"	20	20	20	20	20
Exposure III (DOC 6.6 mg/L)						
Unaltered diluent water	20 (10 per replicate)	20	20	20	20	20
Control	"	20	20	20	20	20
15	"	20	20	20	20	20
30	"	20	20	20	20	20
60	"	20	20	20	20	20
120	"	20	20	18	17	16
240	"	20	20	19	16	14

* Replicate values were pooled.
** All test substance concentrations are expressed as 100% solids (total solids content of the test substance was 20±1%, ie. 5 times the weight).

LC50 (no humic acid)	3.0 mg/L formulation (with background DOC of 1.4 mg/L; lowest replicate); NOEC 0.94 mg/L
Exposure I LC50	>15 mg/L formulation (> highest test concentration; 6.6 mg/L DOC)
Exposure II LC50	>15 mg/L formulation (> highest test concentration; 12 mg/L DOC)
Exposure III LC50	230 mg/L formulation (95% CI 160-850; lowest replicate; 6.6 mg/L DOC)
NOEC	15 mg/L formulation (based on lethal & sublethal effects)
Remarks - Results	The humic acid is all exposure solutions flocculated and settled to the bottom of each test chamber during the 96 h test. LSC analyses indicated no appreciable loss of the test substance from the test chambers during the 96 h duration of the tests.
CONCLUSION	The "activated" test substance (KYMENE® 450 formulation containing an analogue polymer) was practically non-toxic (LC50 >100 mg/L; Mensink *et al*., 1995) to fathead minnow in the presence of dissolved organic carbon (DOC) at concentrations ≥6.6 mg/L.
TEST FACILITY	Eastman Kodak Company (1989b)

8.2.1e. Acute toxicity to fish

TEST SUBSTANCE	PMCD-45 formulation containing an analogue polymer (activated)
METHOD	96 h Acute Toxicity for Fish – Static (USEPA, 1975; APHA, 1980).
Species	Rainbow Trout (*Salmo gairdneri* = *Onchorhynchus mykiss*). Mean Wt. 1.1±0.19 g. Mean length: 43±2.7 mm.
Exposure Period	96 h
Auxiliary Solvent	None
Water Hardness	40-45 mg $CaCO_3$/L (soft water)
Analytical Monitoring	None

Remarks – Method	Test aquaria consisted of 5 gallon glass vessels containing 15 L soft diluent (deionised) water and various concentrations of test material. Stock solution was prepared by adding measured quantities of activated PMCD-45 (as supplied) to dilution water, and test concentrations were prepared by appropriate dilution of aliquots of stock solution applied directly into the test aquaria. Data are reported as nominal test concentrations. Range finding and definitive tests were performed. Data from a reference toxicant (Antimycin A) indicated an LC50 value within acceptable limits indicating that the fish tested were initially healthy. Temperature, DO and pH were measured at 0, 48 and 96 h. Temp. 12±1.0°C; DO 7.3-9.2 mg/L; pH 7.5-8.0. 16 h daylight photoperiod. Observations of mortality and sublethal effects were monitored daily.

RESULTS

Concentration mg/L Nominal	*Number of Fish*	*% Mortality**		
		24 h	*48 h*	*96 h*
Control	10	0	0	0
1.0	"	0	0	0
1.8	"	0	0	0
3.2	"	0	0	0
5.6	"	0	0	30
10	"	10	100	100

LC50	6.4 mg/L formulation (95% CI 3.2-10)
NOEC	3.2 mg/L formulation
Remarks - Results	Results are presented as nominal concentrations of the analogue polymer formulation PMCD-45. Analytical Bio-Chemistry Laboratories, Inc (1983b) is a comparable, non-activated study.

CONCLUSION PMCD-45 formulation was toxic (LC50 1-10 mg/L; United Nations, 2003) to rainbow trout.

TEST FACILITY Analytical Bio-Chemistry Laboratories, Inc (1983a).

8.2.1f. Acute toxicity to fish

TEST SUBSTANCE PMCD-45 formulation containing an analogue polymer; non-activated)

METHOD 96 h Acute Toxicity for Fish – Static (USEPA, 1975; APHA, 1980).

Species	Rainbow Trout (*Salmo gairdneri* = *Onchorhynchus mykiss*). Mean Wt. 0.86±0.17 g. Mean length: 40±2.7 mm.
Exposure Period	96 h
Auxiliary Solvent	None
Water Hardness	40-45 mg $CaCO_3$/L (soft water)
Analytical Monitoring	None
Remarks – Method	Test aquaria consisted of 5 gallon glass vessels containing 15 L soft diluent (deionised) water and various concentrations of test material. Stock solution was prepared by adding measured quantities of "activated" PMCD-45 (as supplied) to dilution water, and test concentrations were prepared by appropriate dilution of aliquots of stock solution applied directly into the test aquaria. Data are reported as nominal test concentrations. Range finding and definitive tests were performed. Data from a reference toxicant (Antimycin A) indicated an LC50 value within acceptable limits indicating that the fish used were healthy. Temperature, DO and pH were measured at 0, 48 and 96 h. Temp. 12±1.0°C; DO 7.8-9.7 mg/L; pH 7.5-7.9. 16 h daylight photoperiod. Ammonia ≤0.49 mg/L. Observations of mortality and sublethal effects were monitored daily.

RESULTS

Concentration mg/L *Nominal*	*Number of Fish*	*% Mortality** *24 h*	*48 h*	*96 h*
Control	10	0	0	0
0.18	"	0	0	0
0.32	"	0	0	0
0.56	"	0	0	0
1.0	"	0	0	10
1.8	"	20	100	100

LC50 1.3 mg/L (95% CI 1.0-1.8 mg/L; "non-activated" PMCD-45; nominal formulation basis).

NOEC 0.56 mg/L (nominal; formulation basis).

Remarks - Results Analytical Bio-Chemistry Laboratories, Inc (1983a) is a comparable study but undertaken with "activated" PMCD-45 formulation and results indicate that "activated" PMCD-45 was slightly less toxic to rainbow trout than "non-activated" test substance. This is due to the former having fewer cationic sites.

CONCLUSION The PMCD-45 formulation containing an analogue polymer is toxic (LC50 1-10 mg/L; United Nations, 2003) to rainbow trout.

TEST FACILITY Analytical Bio-Chemistry Laboratories, Inc (1983b).

8.2.1g. Acute toxicity to fish

TEST SUBSTANCE PMCD-45 formulation containing an analogue polymer; "non-activated")

METHOD 96 h Acute Toxicity for Fish – Static (USEPA, 1975; APHA, 1980).

Species Bluegill sunfish (*Lepomis macrochirus*). Mean Wt. 0.10±0.01 g. Mean length: 17±0.94 mm.

Exposure Period 96 h

Auxiliary Solvent None

Water Hardness 40-45 mg $CaCO_3$/L (soft water)

Analytical Monitoring None

Remarks – Method Test aquaria consisted of 5 gallon glass vessels containing 15 L soft diluent (deionised) water and various concentrations of test material. Stock solution was prepared by adding measured quantities of non-activated PMCD-45 to dilution water, and test concentrations were prepared by appropriate dilution of aliquots of stock solution applied directly into the test aquaria. Data are reported as nominal test concentrations. Range finding and definitive tests were performed. Data from a reference toxicant (Antimycin A) indicated an LC50 value within acceptable limits indicating that the fish used were healthy. Temperature, DO and pH were measured at 0, 48 and 96 h. Temp. 22±1.0°C; DO 6.6-8.8 mg/L; pH 7.5-8.0. 16 h daylight photoperiod. Observations of mortality and sublethal effects were monitored daily.

RESULTS

Concentration mg/L *Nominal*	*Number of Fish*	*% Mortality** *24 h*	*48 h*	*96 h*
Control	10	0	0	0
0.32	"	0	0	0
0.56	"	0	0	0
1.0	"	0	0	0
1.8	"	0	70	100
3.2	"	100	100	100

LC50 1.3 mg/L (95% CI 1.0-1.8 mg/L; nominal; formulation basis)

NOEC 0.56 mg/L (nominal; formulation basis)

CONCLUSION	The test substance (PMCD-45 formulation containing an analogue polymer; "non-activated") was toxic (LC50 1-10 mg/L; United Nations, 2003) to bluegill sunfish.
TEST FACILITY	Analytical Bio-Chemistry Laboratories, Inc (1983c).

8.2.1h. Chronic Toxicity to fish

TEST SUBSTANCE	PMCD-45 formulation containing an analogue
METHOD	Early Life Stage Toxicity for Fish – continuous flow through test. In-house method based on USEPA (1972) and ASTM (1983).
Species	Fathead minnow (*Pimephales promelas*) embryos and fry.
Exposure Period	35 days (2-4 days exposure to eggs and 31-33 days exposure to fry)
Auxiliary Solvent	None
Water Hardness	254-316 mg $CaCO_3$/L (very hard water)
Analytical Monitoring	Liquid Scintillation Counting (LSC) determination of radiolabelled test material (^{14}C-PMCD-45; duplicate 10 mL samples).
Remarks – Method	Stock solution was prepared by addition of test material (6.731 g) in a 50 mL flask with deionised water. Test concentrations were prepared by dilution of aliquots of the stock solution. Sixty (60) eggs were used per test concentration (4 replicates). A preliminary acute toxicity test was performed using PMCD-45 and minnow fry under flow-through conditions to determine definitive test concentrations. Ten fathead minnow eggs per test concentration were added to duplicated test chambers and exposed to concentrations of the test substance (0.025 to 0.42 mg/L) for 13 days. The 13 d NOEC based on nominal concentration was less than the lowest test concentration of 0.025 mg/L activated solids. Temperature, DO, pH and conductivity were measured on days 0, 1, 7, 14, 21, 28 and 35. Hardness, alkalinity, TOC and suspended solids were measured on days 0, 7, 14, 21, 28 and 35. Temp. (range) 25±1.0°C; DO 7.7-9.6 mg/L; pH 7.9-8.1. 16 h daylight photoperiod. Alkalinity: 304-406 mg/L. TOC: 0.9-5.2 mg/L (mean 2.2 mg/L). Suspended solids: 0.0-0.8 mg/L (mean 0.44 mg/L). Data for hatchability, survival, standard length and wet weight were analysed using SYSTAT® (V. 2.1) after homogeneity testing using Bartlett's Test. Growth data were analysed by 2-way ANOVA, and replicate data were pooled for one-way ANOVA (data transformed) if no significant interaction between replicate data were present.

RESULTS

*Concentration mg/L**		*Test Responses at Hatching (Day 0-7) and 35 Days Post-Hatching*	
Nominal	*Actual (mean)*	*% Hatchability*	*% Normal Survival*
0	0	100	80-87
0.0045	0.0035	100	67
0.0090	0.0073	100	70
0.018	0.016	98	70
0.036	0.030	100	78
0.072	0.062	98	22**

* All concentrations are presented on a total solids basis of PMC polymer.
** Denotes values significantly different from control (P<0.05).

MATC	0.030-0.062 mg/L (solids) or 0.15-0.31 mg/L (formulation basis)
NOEC	0.030 mg/L (solids) or 0.15 mg/L (formulation basis)
Remarks – Results	The PMCD-45 formulation had no effect on the rate of hatching of eggs. Survival was significantly reduced compared to the control at the highest test concentration (0.062 mg/L). Most deaths occurred between days 7 and 16. The growth rate of fry was reduced when exposed to ≥0.062 mg/L for

35 days. No effect on growth was evident at 0.030 mg/L. Analytical monitoring determined test concentrations were consistent during the period of the tests.

CONCLUSION The test material (PMCD-45 formulation containing an analogue polymer) is very toxic (LC50 <1 mg/L; Mensink et al., 1995) to fathead minnow fry.

TEST FACILITY Analytical Bio-Chemistry Laboratory, Inc (1987c)

8.2.1i. Chronic Toxicity to fish

TEST SUBSTANCE PMCD-45 formulation containing an analogue polymer

METHOD Early Life Stage Toxicity for Fish – continuous flow through test.
In-house method based on USEPA (1972) and ASTM (1983).

Species	Fathead minnow (*Pimephales promelas*) embryos and fry
Exposure Period	30 days post-hatch (2-4 days exposure to eggs)
Auxiliary Solvent	None
Water Hardness	225-275 mg $CaCO_3$/L (Hard water)
Analytical Monitoring	Test concentrations of radiolabelled test material (^{14}C-PMCD-45) were measured using Liquid Scintillation Counting (LSC).
Remarks – Method	Stock solution was prepared by addition of test material (9.01268 g) in a 50 mL flask with deionised water. Test concentrations were prepared by dilution of aliquots of the stock solution. Sixty (60) eggs were used per test concentration (4 replicates). Temperature, DO, pH and conductivity were measured on days 0, 1, 7, 14, 21, 28 and 35. Temp. (range) 25±0.5°C; DO 8.0-9.2 mg/L; pH 8.0-8.2. 16 h daylight photoperiod.

RESULTS

*Concentration mg/L**		*Test Responses at Hatching (Day 0-4) and 30 Days Post-Hatching*	
Nominal	*Actual (mean)*	*% Hatchability*	*% Normal Survival*
0	0	98	85
0.00103	0.00087	90	77
0.00185	0.0018	87	65
0.00391	0.0034	93	83
0.00783	0.0065	93	83
0.0154	0.014	93	83**

* All concentrations are presented on a total solids basis. Solids content 20.6%.
** Denotes values significantly different from control (P<0.05).

MATC	>0.014 mg/L (solids basis) or 0.07 mg/L (formulation)
NOEC	0.014 mg/L (highest concentration tested; (solids basis) or 0.07 mg/L (formulation basis)

CONCLUSION No definitive conclusion can be made as there was no adverse effect at the highest concentration of PMCD-45 formulation tested.

TEST FACILITY Analytical Bio-Chemistry Laboratory, Inc (1987d)

8.2.2a. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Crepetrol 80E formulation (contains notified polymer)

METHOD Acute Toxicity Test with *Daphnia magna* – Static conditions (Environment Canada, 1990b).

Species	Waterflea *Daphnia magna* (1st instar <24 h old)
Exposure Period	48 h

Auxiliary Solvent	None
Water Hardness	~270 mg $CaCO_3$/L (hard water)
Analytical Monitoring	None
Remarks - Method	Range-finding and definitive tests were performed. Test chambers consisted of 55 mL glass test tubes. The test substance consisted of ~25% solids. All test concentrations were individually prepared from stock solution (1000 mg/L). A concentrated stock solution was prepared by adding 1 g of test material in 1 L dilution water (filtered and sterilised groundwater). Each test concentration was prepared by dilution of a measured volume of stock solution. Test solution volume was 50 mL (16.7 mL/animal). Daphnids were fed prior to the test but not during the test. L(E)C50 values were calculated using Probit method with the program STEP (Stephan, 1977). Temperature (20-20.5°C), DO (9.0-9.4 mg/L) and pH (8.4-8.5) were monitored daily (within acceptable limits). 16 h light illumination. Test chambers aerated (acceptable). Observations of effects were made at 24 and 48 h. Death was defined as no visible heart beat and adverse effects included surfacing, clumping or bottom-dwelling.

RESULTS

Concentration mg/L *Nominal*	*Number of Daphnids*	*Percent Mortality (%) 48 h*	*Percent Effects (%) 48 h*
0	24 (2 replicates of 12 animals)	0	0
0.18	"	0	0
0.32	"	17	21
0.56	"	29	46
1.0	"	58	71
1.8	"	83	96
3.2	"	83	100

LC50	0.92 mg/L formulation at 48 hours (95% CI 0.2-1.2; nominal).
EC50	0.62 mg/L formulation at 48 hours (95% CI 0.51-0.75; nominal).
NOEC (mortality)	0.18 mg/L formulation (nominal)
NOEC (sublethal)	Not determined
Remarks - Results	Crepetrol 80E formulation contains ~25% solids. When expressed as mg/L of solids, the reported LC50 and EC50 values were divided by a factor of 4 and reported as 0.23 mg solids/L (0.18-0.3) and 0.16 mg solids/L (0.13-0.19), respectively. A sodium chloride reference toxicant was used, giving an LC50 of 5.9 g/L (acceptable).
CONCLUSION	Very acutely toxic (LC50 <1 mg/L) to *Daphnia magna* in hard water (United Nations, 2003).
TEST FACILITY	B.A.R. Environmental Inc. (1997b)

8.2.2b. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	PMCD-45 formulation containing an analogue polymer
METHOD	Acute Toxicity Test with *Daphnia magna* – Flow Through Test (USEPA, 1975; APHA, 1980).
Species	Cladoceran *Daphnia magna* (1st instar <24 h old)
Exposure Period	48 h
Auxiliary Solvent	None
Water Hardness	44-48 mg/L (as $CaCO_3$; soft water)
Analytical Monitoring	Liquid Scintillation Counting (LSC) analysis of ^{14}C-PMCD-45.
Remarks - Method	Test chambers consisted of 1 L beakers (mesh covered). Influent water

was introduced into the test chambers via 14 gauge hypodermic syringes. Aerated soft water was delivered to each test chamber (125 mL/chamber/10 mins). The supplied test material had a total solids content of 20.5%. Stock solution was prepared using a mixture of well water and deionised water made up to a hardness of 40-50 mg/L (as $CaCO_3$). Stock solution was prepared from test substance (9.0 g; 1.337 mCi), which was quantitatively transferred to a 50 mL volumetric flask (activity 1.292 mCi). An LSC analysis solution was prepared from a 0.1 mL aliquot of the stock solution diluted to 25 mL with deionised water. The activation procedure for both the radiolabelled and non-radiolabelled tests involved mixing 15 g of test substance in 73.2 mL deionised water with 11.8 mL NaOH solution. These amounts were proportionally changed for the ^{14}C material to accommodate the requirements of the definitive study. To activate the ^{14}C-PMCD-45, 0.28 mL of stock solution (37.1 mg/mL) was combined initially with 0.20 mL of 1 N NaOH and 1.2 mL of deionised water in a scintillation vial. After mixing, the contents were transferred with deionised water to a 50 mL flask. For mixing purposes, the amount of 1 N NaOH and deionised water was increased by 4.8 times to assure adequate volumes for activation. Daphnids were fed prior to the test but not during the test. Temperature (20-21°C), DO (8.7-9.1 mg/L) and pH (7.6-7.9) were monitored daily. Test illumination was 16 h light: 8 hours darkness with 30 minute dust/dawn transition periods. Test chambers aerated during the tests. LC50 values were calculated using a computerised method of Stephan et. al. (1978). Death was defined as no visible heart beat and adverse effects included surfacing, clumping or bottom-dwelling.

RESULTS

Concentration mg/L		*Number of Daphnids*	*Percent Mortality (%)*	*Percent Effects (%)*
Nominal	*Actual*		*48 h*	*48 h*
0	0	20 (4 replicates)	0	0
0.012	0.016	"	0	0
0.021	0.026	"	0	0
0.043	0.047	"	0	15
0.074	0.095	"	5	70
0.17	0.20	"	40	100

LC50 0.23 mg/L activated solids at 48 h (95% CI 0.18-0.54; mean measured conc.).
EC50 0.075 mg/L activated solids at 48 h (95% CI 0.063-0.090; mean measured conc.).
NOEC 0.026 mg/L activated solids at 48 h (mean measured conc.).

Remarks - Results All test concentrations/values are presented on an activated resin solids basis. The total solids content of the test substance was ~20.6%. Test values expressed on a formulation basis have derived by multiplying the reported test values by a factor of 5 as indicated below:

LC50 1.15 mg/L formulation at 48 hours (95% CI 0.9-2.7; mean measured concentration).
EC50 0.375 mg/L formulation at 48 hours (95% CI 0.315-0.45; mean measured concentration).
NOEC 0.13 mg/L formulation at 48 hours (mean measured concentration).

CONCLUSION The test substance (PMCD-45 formulation containing an analogue polymer) is acutely toxic (LC50 <1-10 mg/L) to *Daphnia magna* in soft water (United Nations, 2003).

TEST FACILITY Analytical Bio-Chemistry Laboratory, Inc (1987a)

8.2.2c. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	PMCD-45 formulation containing an analogue polymer
METHOD	Acute Toxicity Test with *Daphnia magna* – Flow Through (USEPA, 1975; APHA, 1980)
Species	Waterflea *Daphnia magna* (1st instar <24 h old)
Exposure Period	48 h
Auxiliary Solvent	None
Water Hardness	~250 mg $CaCO_3$/L (hard water)
Analytical Monitoring	Liquid Scintillation Counting (LSC) analysis of ^{14}C-PMCD-45
Remarks - Method	Test chambers consisted of 1 L beakers (mesh covered; aerated). Influent water was introduced into the test chambers via 14 gauge hypodermic syringes. Aerated hard water was delivered to each test chamber (125 mL/chamber/10 mins). The supplied test material had a total solids content of 20.6%. Stock solution was prepared from test substance (9.01268 g; 1.337 mCi), which was quantitatively transferred to a 50 mL volumetric flask (activity 1.292 mCi). An LSC analysis solution was prepared from a 0.1 mL aliquot of the stock solution diluted to 25 mL with deionised water. The activation procedure for both the radiolabelled and non-radiolabelled tests involved mixing 15 g of test substance in 73.2 mL deionised water with 11.8 mL NaOH solution. These amounts were proportionally changed for the ^{14}C material to accommodate the requirements of the definitive study. To activate the ^{14}C-PMCD-45, 0.28 mL of stock solution (37.1 mg/mL) was combined initially with 0.20 mL of 1 N NaOH and 1.2 mL of deionised water in a scintillation vial. After mixing, the contents were transferred with deionised water to a 50 mL flask. For mixing purposes, the amount of 1 N NaOH and deionised water was increased by 4.8 times to assure adequate volumes for activation. Daphnids were fed prior to the test but not during the test. Temperature (20-21°C), DO (8.2-8.5 mg/L) and pH (8.1-8.4) were monitored daily (within acceptable limits). 16 h light illumination with 30 minute dust/dawn transition periods. Death was defined as no visible heart beat and adverse effects included surfacing, clumping or bottom-dwelling.

RESULTS

Concentration mg/L		*Number of Daphnids*	*Percent Mortality (%)*	*Percent Effects (%)*
Nominal	*Actual*		*48 h*	*48 h*
0	0	20 (4 replicates)	0	0
0.012	0.015	"	0	0
0.021	0.026	"	0	0
0.043	0.047	"	0	15
0.074	0.079	"	0	74
0.17	0.19	"	80	100

LC50	0.14 mg/L solids at 48 hours (95% CI 0.079-0.19).
EC50	0.065 mg/L solids at 48 hours (95% CI 0.047-0.19).
NOEC	0.026 mg/L solids at 48 hours
Remarks - Results	All test concentrations/values are presented on an activated resin solids basis. The total solids content of the test substance was ~20.6%. Test values expressed on a formulation basis have derived by multiplying the reported test values by a factor of 5 as indicated below:
LC50	0.7 mg/L formulation at 48 hours (95% CI 0.0.395-0.95; mean measured concentration).
EC50	0.325 mg/L formulation at 48 hours (95% CI 0.235-0.95; mean measured concentration).
NOEC	0.13 mg/L formulation at 48 hours (mean measured concentration).

CONCLUSION The test substance (PMCD-45 formulation containing an analogue polymer) is very acutely toxic (LC50 <1 mg/L) to *Daphnia magna* in hard water (United

Nations, 2003). The test substance was slightly more toxic in hard than soft water (see above test in soft water) (Analytical Bio-Chemistry Laboratory, 1987a).

TEST FACILITY Analytical Bio-Chemistry Laboratory, Inc (1987e)

8.2.2d. Chronic toxicity to aquatic invertebrates

TEST SUBSTANCE PMCD-45 formulation containing an analogue polymer

METHOD Chronic Toxicity/Reproductive Test with *Daphnia magna* – Semi-static Test. In-house method based on ASTM (1981). Proposed Standard practice for Conducting *Daphnia magna* Chronic Toxicity Tests in a Flow-through System and USEPA (1975).

Species	Waterflea *Daphnia magna* (1st instar <24 h old)
Exposure Period	21 d
Auxiliary Solvent	None
Water Hardness	206-275 ppm (as $CaCO_3$; hard water)
Analytical Monitoring	Analysis of duplicate samples collected on days 0, 1, 4, 7, 11, 14, 18 and 21 for ^{14}C-PMCD-45 by Liquid Scintillation Counting (LSC).
Remarks - Method	The PMCD-45 formulation contained ~20.5% total solids. Stock solution was prepared by adding test material (6.731 g) to a 50 mL flash with deionised water. The test concentrations were made up by appropriate dilution of stock solution. Daphnids were fed during the test. Test solutions were continuously aerated during the tests. Daphnids in test chambers were monitored daily for mortality. Exposure concentrations were determined on Day 0, 1, 4, 7, 11, 14, 18 and 21. Temperature (20°C), DO (7.8-8.3 mg/L) and pH (8.2-8.4). 16 h illumination. The total organic carbon content of the test water was an average of 2.3 mg/L.

RESULTS

*Concentration *** mg/L*		*No. of D. magna*	*% Survival*	*Mean Days to First Brood*	*Mean Young per Adult per Reproduction Day*	*Mean young per adult*	*Adult mean length*
Nominal	*Mean Measured*						*mm*
0	0	40 (10/rep)	98	8.8	7.4	100	3.8
0.0095	0.0089	"	100	8.8	7.0	92	3.7
0.019	0.016	"	100	8.0**	3.5*	49	3.5*
0.038	0.033	"	98	9.0	1.7*	23	3.4*
0.075	0.059	"	95	10.5*	1.2*	14	3.2*
0.15	0.12	"	0*	All died	All died	All died	All died

* Denotes values significantly different (P≤0.05) from the control using one-way analysis of variance (ANOVA) and Dunnett's Multiple Means Test. ** First brood earlier than control. *** All concentrations are presented on a solids basis of PMCD-45 polymer and reflect the actual (ie. measured) concentrations.

LC50	0.077 mg/L solids at 21 days (95% CI 0.070-0.086 mg/L)
MATC (growth and reproduction)	0.012 mg/L at 21 days (limits 0.0089-0.016 mg/L)
NOEC (growth and reproduction)	0.0089 mg/L at 21 days

Remarks- Results	Daphnids in the 0.033, 0.059 and 0.12 mg/L concentrations appeared smaller and lighter in colour. The only abnormal behaviour was observed at the highest test concentration (0.12 mg/L). Adult daphnids were observed on the bottom of the test chambers with very little movement. All other adults and young appeared normal throughout the tests. Time to first brood was significantly slower at a concentration of 0.059 mg/L. The mean number of young per adult per reproduction day and adult daphnia size was significantly reduced at exposure concentrations of ≥0.016 mg/L. PMCD-45 appeared to be totally soluble throughout the tests as there was no precipitate observed in test chambers or stock solution. All test concentrations/values are presented on a solids basis. The total solids content of the test substance was 20.5%. Test values expressed on a formulation basis have derived by multiplying the reported test values by a factor of 5 as indicated below:
LC50	0.385 mg/L formulation at 21 days (95% CI 0.35-0.43 mg/L)
MATC (growth and reproduction)	0.06 mg/L formulation at 21 days (limits 0.045-0.08 mg/L)
NOEC (growth and reproduction)	0.045 mg/L formulation at 21 days
CONCLUSION	The test substance (PMCD-45 formulation containing an analogue polymer) was chronically very toxic (LC50 <1 mg/L) to *Daphnia magna* (Mensink et al., 1995).
TEST FACILITY	Analytical Bio-Chemistry Laboratory, Inc (1987b)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	Crepetrol A3025 formulation (contains notified polymer)
METHOD	OECD (1984). Alga, Growth Inhibition Test (Guideline 201). USEPA (2002). Short-term methods for estimating the chronic toxicity of effluents and receiving water to freshwater organisms, 4th Ed. EPA-821-R-02-013. Environment Canada (1992). Biological Test Method: Growth Inhibition Test using the Freshwater Alga *Selenastrum capricornutum*. EPS 1/RM/25.
Species	Green algae *Raphidocelis subcapitata* (formerly *Selenastrum capricornutum*)
Exposure Period	72 hours
Concentration Range	
Nominal	0, 0.08, 0.16, 0.31, 0.63, .3, 2.5 and 5.0 mg formulation/L
Actual	Not determined
Auxiliary Solvent	None
Water Hardness	Not stated
Analytical Monitoring	None
Remarks - Method	Tests conducted under GLP. Test solutions were prepared from a 5.0 mg/L stock solution. Stock solution was prepared by dissolving test substance (5.0 mg) in 1 L deionised water. After stirring, 10 mL was dispensed into a 30 mL container for the highest test concentration (5.0 mg/L). A second 10 mL volume of the stock solution was dispensed into another 30 mL container and serially diluted with 10 mL volumes deionised water to obtain the remaining test concentrations. Test solutions were spiked with nutrient solution and inoculated (0.1 mL; obtained from an exponentially growing culture) to give an initial cell density of ~10^4 cells/mL. Tests performed under continuous lighting (4000±500 lux). Cells were counted using a coulter particle counter. EC50 and 95% CI values were calculated from the areas under the growth curves by linear interpolation with the ICPIN Program. NOEC values were calculated using ToxStat Version 3.4 after checking for normality (Shapiro-Wilk's test) and the NOEC obtained with the William's Test. Zinc was used as a reference toxicant and the test results were within the historical limits for the test organism. Temperature: 24±2°C. Initial and final pH 6.0. Initial and

final cell densities: 9160-416478 cells/mL (>16-fold increase = acceptable).

RESULTS

Growth	
Endpoint	*Value (mg/L, 95% CI; nominal)*
72 h EC50	1.0 (0.9-1.1)
NOEC	0.63

Remarks - Results: Toxicity data are in units of mg Crepetrol A3025 per litre of test solution based on nominal concentrations.

CONCLUSION: The Crepetrol A3025 formulation (containing 25% notified polymer) is toxic to freshwater algae (EC50 1-10 mg/L; United Nations, 2003).

TEST FACILITY: HydroQual Laboratories Ltd (2004)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE: PMCD-45 formulation containing an analogue polymer

METHOD: In-house procedure based on Larson and Schaeffer (1982).

Inoculum: Mixed biological population from a secondary treated (activated) sludge, Colerain Township WWTP, receiving mainly domestic sewage. Suspended solids and volatiles content: 2628 mg/L and 2152 mg/L, respectively. Sludge Temp: 19.5°C (day 0)

Exposure Period: 15 mins

Concentration Range

Nominal: 0.1, 1.0, 5.0, 10.0, 20.0 and 50 ppm of formulation.

Remarks – Method: Activated sludge mixed liquor was pre-incubated with a series of concentrations of test material. A known amount of ^{14}C-glucose was added and the reduction in the amount of ^{14}C activity removed from solution (presumably due to bacterial uptake or adsorption to particulate matter) was measured after a specific time period. A range finding test was performed at test substance concentrations (0.1, 1.0, 5.0, 10.0, 20.0 and 50 ppm) and the HA50 (heterotrophic activity) was ≥50 ppm and consequently the definitive study used these same concentrations. The test material contained 20.5% active constituent. The formulation was activated by adding PMCD-45 (15.0060 g) to 73.2 mL of deionised water and 11.8 mL of 1 M NaOH in a 100 mL bottle. ^{14}C-glucose stock solution was prepared by adding 0.0254 g cold anhydrous dextrose to 100 mL of deionised water with 40 µL of 257.7 mCi/mmol of uniform ^{14}C-D-glucose. The solution was sterilised through a 0.22 µm membrane filter and collected in a sterile serum bottle. One, 1 mL aliquot was placed in a LSC vial containing 10 mL (activity 0.04 µCi/mL). Tests were performed in 3 replicates per concentration. An HCl control was also used.

RESULTS

Heterotrophic Activity HA50: >50 ppm

HA25: 11.2 ppm of formulation

HA10: 4.7 ppm of formulation

CONCLUSION: The test substance (PMCD-45 formulation containing an analogue polymer) gave ≤10% inhibitory effect on a mixed biological population of sewage sludge at formulation concentrations ≤4.7 ppm.

TEST FACILITY: Hill Top Research Inc (1986)

8.2.5. Summary of Ecotoxicity Data

Animal	Test Substance Formulation	L(E)C50 (mg/L)	NOEC (mg/L)	Organic Carbon	Water Hardness	Activated? Yes/No	Reference
Fish	Notified polymer	1.7	---	No DOC	Hard	No	BAR (1997a)
Fish	Notified polymer	42	32	DOC added (10 mg/L)	Hard	Yes	ESG (1998)
Fish	Notified polymer	134	100	DOC added (20 mg/L)	Hard	Yes	ESG (1998)
Fish	Analogue	1.3	0.56	No DOC	Soft	No	ABC (1983b)
Fish	Analogue	1.3	0.56	No DOC	Soft	No	ABC (1983c)
Fish	Analogue	3	0.94	No DOC	Medium	No	Eastman (1989a)
Fish	Analogue	6.4	3.2	No DOC	Soft	Yes	ABC (1983a)
Fish	Analogue	>15	15	DOC added (6.6 mg/L)	Medium	Yes	Eastman (1989b)
Fish	Analogue	230	15	DOC added (12 mg/L)	Medium	Yes	Eastman (1989b)
Fish ELS	Analogue	>0.07	0.07	No DOC	Hard	No	ABC (1987d)
Fish ELS	Analogue	---	0.15	TOC 0.9-5.2 mg/L	Hard	No	ABC (1987c)
Daphnid	Notified polymer	0.62	0.18**	No DOC	Hard	No	BAR (1997b)
Daphnid	Analogue	0.325	0.13	No DOC	Hard	Yes	ABC (1987e)
Daphnid	Analogue	0.375	0.13	No DOC	Soft	Yes	ABC (1987a)
Daphnid (chronic)	Analogue	0.385	0.045	TOC 2.3 mg/L	Hard	No	ABC (1987b)
Algae	Notified polymer	1	0.63	DOC	Soft	No	HydroQual (2004)
Microbes	Analogue	>50	4.7	DOC	---	Yes	Hill Top (1986)

* Data presented as % solids has been converted to % formulation basis by multiplying by a factor of 5 (as solids content is usually 20%).
** Highest concentration tested.

Based on comparative fish and daphnia tests, no clear trend could be established as to whether the notified polymer or analogue polymer formulations were more or less toxic in soft or hard water. Results of comparative tests after activation with NaOH of the test substance were inconclusive, with no apparent trend of higher or lower toxicity. However, toxicity was clearly lower in the presence of DOC. As tests were conducted with formulations, interference by other constituents could not be discounted.

9. RISK ASSESSMENT

9.1. Environment

The notified polymer will be imported and/or manufactured at < 30% of Crepetrol A3025 and it is not isolated. No ecotoxicity data are available specifically for the notified polymer. Aquatic toxicity data are only available for finished product formulations either containing the notified or analogue polymers. As such, it is not possible to distinguish between toxicity of the notified or analogue polymer and the other formulation constituents that may elicit adverse effects. There is also uncertainty regarding the fate of the other formulation constituents when the formulation is used and wastes are disposed of. To account for this data limitation, all ecotoxicity values used are expressed as a total formulation basis (100% solids basis) rather than on a % solids basis, and predicted environmental exposure concentrations are based on the quantities of formulation proposed to be used.

9.1.1. Environment – exposure assessment

The notified polymer has a low octanol:water partition co-efficient (low affinity for lipids), will remain dissociated in water and is very stable towards hydrolysis over a wider pH range than normally found in the environment.

Formulations containing the notified and analogue polymers are not readily biodegradable based on static studies with activated sewage sludge microbes. The PMCD-45 formulation containing an analogue polymer was 100% removable from influent at 20 mg/L in a semi-continuous activated sludge system; however, removal is probably due to aggregation to sludge based on other ready biodegradability tests undertaken.

The maximum introduction volume of Crepetrol A3025 formulation (containing < 30% notified polymer) is > 87 tpa (based on 26 tpa of notified polymer).

Sewer disposal

Notified chemical may potentially enter the sewer through three main pathways:

- Residues in treated effluent discharged from a local manufacturing facility; and
- Residues in treated effluent from a toilet tissue manufacturing facility; and
- Disposal of finished tissue product chemical after consumer use.

The notified chemical is expected to have a wide spread and diffuse use pattern, and the majority would be disposed of to the Australian sewerage system attached to tissue products.

Local manufacturing facility

Based on notifier's data, an estimated 0.15% of the notified polymer/formulation manufactured per annum will be discharged to sewer (ie. ~39 kg/yr of notified polymer or ~156 kg/yr of formulation). This is diluted within a site wastewater discharge of 5 ML/yr, giving an estimated average concentration of formulation of ~31200 μg/L (ie. $1.56X10^{11}$ μg ÷ $5X10^{6}$ L). This sewerage system (Werribee, VIC) treats ~500 ML/d (~$1.825X10^{11}$ L/yr). Assuming no attenuation and solids removal, an estimated concentration of ~0.85 μg/L (ie. $1.56X10^{11}$ μg ÷ $1.825X10^{11}$ L) may be derived. There is insufficient data available (eg. vapour pressure, water solubility) to estimate the fate of the notified polymer in municipal sewerage treatment systems (eg. using SimpleTreat model). Adsorption to sewage sludge by a factor of at least 90% may be expected for cationic polymers (Boethling and Nabholz, 1997). Assuming 90% attenuation to sludge, a treated effluent concentration of ~0.085 μg/L is estimated. Assuming a dilution factor of 10 following ocean disposal, a PEC_{marine} of ~0.009 μg/L may be derived; however, the sewerage system includes large pondages that would enhance solids settlement, and thus the notified polymer, prior to discharge.

Tissue manufacturing facility

For this assessment, it is assumed that 70% of the notified polymer is adhered to finished tissue

products (ie. 72.8 tpa). As such, site wastewaters generated are assumed to contain 30% of the notified chemical formulation (ie. 31.2 tpa). This site wastewater is not treated on-site but is discharged within a total site discharge of 5 ML/d (ie. $1.825X10^9$ L/yr). The estimated average concentration of formulation is 1710 µg/L (ie. $3.12X10^{12}$ µg ÷$1.825X10^9$ L). This is discharged into one sewerage system (Eastern Treatment Plant, VIC) which treats ~370 ML/d; ~$1.35X10^{11}$ L/yr of sewage effluent, and treated effluent is discharged to an ocean outfall. Assuming no attenuation by this plant, and effluent discharge concentration of ~23 µg/L ($3.12X10^{12}$ µg ÷ $1.35X10^{11}$ L) has been estimated. However, sewerage system attenuation is expected to be high based on the affinity to particulate matter and aggregation with sewage sludge. Adsorption to sewage sludge by a factor of at least 90% may be expected for cationic polymers (Boethling and Nabholz, 1997). The sewage treatment plant includes secondary treatment including collection of suspended solids (≥85%) and micro-screening prior to effluent reuse or discharge to ocean. Collected sludge is subjected to anaerobic digestion, drying and production of biosolids. Assuming 90% attenuation to sludge within the plant, a treated effluent concentration of ~2.3 µg/L is estimated. Assuming a dilution factor of 10 following ocean disposal, a PEC_{marine} of ~0.23 µg/L may be derived.

Tissue disposal

Following drying and curing of the formulation containing the notified polymer (130°C for 5 min), the notified polymer is not expected to resolubilise in water whilst in the presence of anionic fibre due to its affinity to anionic material in dilute solutions. Thus, partitioning of the notified polymer to sludge is anticipated, as supported by continuous activated sludge biodegradability test data. As a worst-case, if the total quantity of notified chemical on tissue products (ie. 70% of 104 tpa) were attenuated in sludge, a national biosolids concentration of ~4.5 mg/kg may be estimated. This assumes a daily solids production from 100% of the population of 402 tonnes per day. Some biodegradation of the notified polymer is expected to occur in sewage sludge and/or biosolids over time.

9.1.2. Environment – effects assessment

Aquatic ecotoxicity data were available for 4 taxonomic groups including freshwater fish, invertebrates (*Daphnia*), green algae and sewage sludge microbes, with a least 1 test performed with the formulation containing the notified chemical for fish, daphnia and algae (refer Table in Section 8.2.5). No ecotoxicity data were made available for marine organisms, sediment- or soil-dwelling organisms.

Formulations containing the notified polymer and/or analogue polymer are very toxic to daphnids, early life stages of fish and algae, with L(E)C50 values ≤1 mg/L. The lowest L(E)C50 for the formulation containing the notified chemical for daphnids was 0.62 mg/L (NOEC 0.18 mg/L). However, a chronic daphnid test conducted with a formulation containing an analogue polymer resulted in an LC50 of 0.385 mg/L (NOEC 0.045 mg/L; total organic carbon content of the test water averaged 2.3 mg/L).

The presence of DOC (eg. ≥6.6 mg/L) significantly reduced the toxicity of the notified polymer to fish (ie. LC50 >42 mg/L in 6.6-10 mg DOC/L) relative to tests with fish conducted in low DOC waters. Although the concentration of DOC in sewage effluent is expected to be comparable or higher, DOC in natural ecosystem surface waters is not. DOC in interstitial water in biosolids and in treated effluent used for irrigation is expected to be comparable, and relatively low toxicity is expected where biosolids or treated effluent are applied to land inhabited by soil-dwelling organisms.

A predicted no effect concentration ($PNEC_{freshwater}$) for aquatic organisms of 0.0045 mg/L (4.5 µg/L) has been derived by dividing the lowest available chronic NOEC (0.045 mg/L) by an uncertainty factor of 10 to account for factors such as interspecies sensitivity. This PNEC refers to the total formulation (equivalent to 0.00089 mg/L expressed on a solids basis). In the absence of marine toxicity data, the $PNEC_{freshwater}$ is tentatively extrapolated to the marine environment, an approach is supported by a preliminary review of comparative data by ECETOC (2003).

9.1.3. Environment – risk characterisation

As an indication of risk, comparison can be made between a PEC and the corresponding PNEC of the notified polymer using a risk quotient (RQ) approach, where RQ=PEC÷PNEC. Risk quotient values for ocean disposal of sewerage treatment plant effluents derived from local notified polymer manufacturing and tissue manufacturing facilities of 0.002 (ie. 0.009/4.5) and 0.05 (ie. 0.23/4.5), respectively, may be derived. Overall, a low risk to the environment is predicted with the proposed use and disposal pattern of the notified polymer based on worst-case exposure estimates, which indicate RQ values of ≤0.05. Notified polymer sent to landfill is unlikely to leach, but will degrade over time to simpler compounds.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Workers will be potentially exposed to the notified polymer during local manufacture and during use of the polymer in the production of toilet tissue. Although worker exposure is also possible during transport of Crepetrol A3025 containing the notified chemical, this would only occur in the case of accidental breaching of the drums or IBCs.

Local manufacture of Crepetrol A3025

At the planned future local manufacturing site, the highest potential for exposure is for operators during handling of test samples, during transfer of the polymer mixture and intermediate to storage and transport containers, and during cleaning processes. Exposure, principally dermal, will only be incidental during the polymerisation process due to the robust engineering controls in the plant, consistent with the hazardous starting products of the polymer. Standard PPE includes glasses and gloves, with respiratory protection also used for certain processes. The extent of operator exposure will depend on the efficacy of the engineering and PPE controls.

Tissue manufacture

At the tissue manufacturing site the highest potential for worker exposure would occur in the vicinity of the Yankee cylinder, where the notified polymer is sprayed onto the cylinder at low concentrations. At this part of the site, paper machine operators adjusting the equipment may have intermittent inhalation and dermal exposure to the notified polymer, in both liquid and aerosol form. Dermal exposure of technical control personnel to solutions of the polymer during transfer and dilution processes is also possible. This would be limited to splashes or drips during manipulation of pumps and hoses, however the concentration of polymer in the solutions would be higher than when it is sprayed onto the Yankee cylinder. Current PPE at the site does not include gloves or respiratory protection.

9.2.2. Public health – exposure assessment

No public exposure to the notified polymer is expected during manufacture, transport or production of toilet tissue. There is potential dermal exposure to the public through daily handling and use of toilet tissue containing approximately 600 ppm (0.06%) of the notified polymer. It is also possible that a proportion of the polymer could be transferred to the skin during use, however no data is available on whether this occurs.

9.2.3. Human health - effects assessment

Most toxicological testing submitted was on analogue polymers, and all tests submitted were carried out on product containing varying concentrations of polymer, rather than the polymers themselves. In some cases the concentration of the products was not stated. The studies were of poor quality overall, with many of the studies not conducted or reported according to current OECD standards.

The analogues tested are expected to contain higher levels of hazardous impurities than the notified polymer and thus to be potentially more toxic. The higher level of one of the monomers in the analogues is also expected to lead to higher levels of reactive groups.

The notified polymer is of low oral acute toxicity to rats, based on testing of one product containing the notified polymer and three analogue tests. Products containing analogue polymers were tested for skin and eye irritation in rabbits, and for skin sensitisation in guinea pigs (Buehler method). Based on several tests with varying concentrations, the analogue

polymers caused slight to moderate skin irritation and slight eye irritation. No firm conclusion on skin sensitisation could be made on the basis of one study conducted some years ago, as controls were not included in the test. However, no strong sensitising responses were seen in this study.

No test reports were submitted for several endpoints, including acute dermal and inhalation toxicity, repeated dose toxicity, genotoxicity, reproductive toxicity, and toxicokinetics. No observations on human exposure from use in other countries were provided.

The NAMW molecular weight of the notified polymer is > 4000, with 4.7% of species > 1000 and 1 % of species < 500, limiting its absorption. However, some of the low molecular weight species present as impurities may be absorbed.

Hazardous impurities are present in Crepetrol A3025 containing the notified polymer, including carcinogenic impurities. However these are present below the concentration cut-off for classification in the NOHSC *List of Designated Hazardous Substances* (NOHSC, 1999) and the notifier has stated that levels of these impurities will not increase on storage.

The pH of the Crepetrol A3025 is 2.0-3.0, which could affect the irritancy of the product containing the notified polymer.

Based on the available data, the notified chemical is a slight skin and eye irritant, however it is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2002).

9.2.4. Occupational health and safety – risk characterisation

The health effects of the notified polymer have not been fully characterised. Based on available data it is a slight skin and eye irritant.

Absorption of the notified polymer would be limited by its high molecular weight. However, up to 5% has a molecular weight < 1000. In addition the polymer contains hazardous low molecular weight impurities, although these are present at levels well below the concentration cut-off in the NOHSC *List of Designated Hazardous Substances* (NOHSC, 1999).

Initially the notified polymer will be imported in an aqueous solution, but will in future be manufactured in Australia. The imported or manufactured solution containing the notified polymer will be used as a creping agent in the manufacture of toilet tissue at one site.

There is potential for dermal exposure at some stages of local manufacture, however the engineering controls in place should limit this exposure and therefore minimise the risk of skin and eye irritation.

At the tissue manufacturing site there is potential for dermal exposure during the initial transfer and dilution steps, and for both inhalation and dermal exposure during the spray application of the polymer to the tissue at the creping stage. However, the engineering controls in place are expected to minimise the risk of skin and eye irritation.

Overall the health risk to workers is considered low, if appropriate engineering controls are in place to prevent routine and incidental exposure.

9.2.5. Public health – risk characterisation

Public exposure is not expected during transport, manufacture or use of the polymer in the production of toilet tissue. Dermal exposure to the public can occur to the low level of polymer present in toilet tissue, estimated to be approximately 600 ppm, during handling and use of the tissues. Such exposure would be brief, but may occur frequently. It is possible that small amounts of the polymer may be transferred to the skin, but no data is available on this aspect. Dermal absorption of the polymer would be low based on its molecular weight and the fact that it is bound in the matrix of the tissue. Although low levels of hazardous low molecular weight

impurities are present during earlier stages of processing, it seems unlikely that they would persist through the tissue drying process, and they are not expected to be present in the final tissue.

Overall the risk to the public is considered low, based on the low concentration of the notified polymer in toilet tissue, its expected low toxicity, its binding within the toilet tissue, and the expected low absorption of the polymer across biological membranes.

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 under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

and

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

Based on available data the notified polymer is not classified for human health effects under the GHS.

As the notified polymer's toxicity cannot be isolated from the formulation, no classification of the notified polymer for the environment using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations, 2003) can be made.

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio, the notified polymer is not expected to pose an unacceptable risk to the environment based on it use and disposal pattern.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

10.3.2. Public health

There is No Significant Concern to public health when used in toilet tissue paper.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of product containing the notified polymer provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994a). It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

The label for the product containing the notified polymer provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994b). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

REGULATORY CONTROLS
Hazard Classification and Labelling

- Based on the pH of the notified polymer as marketed in solution, the supplier should review whether classification of this mixture is warranted under Class 8 (Corrosive) of the ADG Code.

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following isolation or engineering controls to minimise occupational exposure to the notified polymer in the marketed product, as manufactured or as used in the manufacture of toilet tissue:
  - Local exhaust ventilation should be used if inhalation exposure may occur;
  - Enclosure of the spray area at the tissue manufacturing site.

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer as imported or manufactured, and as used in the manufacture of toilet tissue
  - Avoid spills, splashes and aerosol generation that would increase exposure;
  - At the tissue manufacturing site, workers should not unnecessarily enter areas where dermal or inhalation exposure is likely.
  - Analysis of the levels of hazardous impurities in the marketed product should be carried out, at a frequency sufficient to confirm that the levels of these impurities do not increase significantly on storage.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer in the marketed product as imported or manufactured, and in use during the manufacture of toilet tissue:
  - Protective clothing including gloves and eye protection, where dermal contact is possible;
  - Respiratory protection where inhalation exposure including exposure to aerosols may occur.

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

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

- If products and mixtures containing the notified chemical 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.

Environment

Disposal

- The notified polymer (neat) should be disposed of in a manner consistent with local jurisdiction waste management regulations by incineration or recycling.
- Emptied containers should be cleaned and recycled, with rinsate treated, or sent to landfill for disposal.
- Unused tissue paper should be disposed of to landfill, recycled or incinerated.

Storage

- The following precautions should be taken regarding storage of the notified polymer:
  - Storage conditions listed on the label and MSDS should be observed.

Emergency procedures

- Spills/release of the notified polymer should be contained and absorbed within an inert absorbent material.
- Do not allow the polymer to enter drains or waterways.

Sweep up the absorbed material and contaminated soil and place in a suitable labelled container for disposal in accordance with relevant waste management regulations.

12.1. Secondary notification

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

(1) Under Subsection 64(1) of the Act; if
  - uses are proposed where effluent will be disposed of to freshwater waterways where less dilution occurs, secondary notification with reassessment of risk will be required.

or

(2) Under Subsection 64(2) of the Act:
  - if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

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