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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polymer in Crepetrol X-Cel

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Director
NICNAS

TABLE OF CONTENTS

Polymer in Crepetrol X-Cel

1. APPLICANT AND NOTIFICATION DETAILS

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

NOTIFICATION CATEGORY
Limited: Polymer with NAMW ≥ 1000

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication:
Chemical Identity
Molecular Weight
Polymer Constituents
Purity and Identity of Impurities
Introduction Volume

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Canada (2006)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Crepetrol X-Cel (25% aqueous solution of the notified polymer)

METHODS OF DETECTION AND DETERMINATION
A reference Infrared (IR) Spectra was provided. Molecular weight distribution was determined by GPC.

3. COMPOSITION

DEGREE OF PURITY
> 99%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
All residual monomers and hazardous impurities are present below the relevant cut-offs for classification of the notified polymer as a hazardous substance.

DEGRADATION PRODUCTS
The notified polymer is expected to be stable under normal conditions of use. If heated to decomposition, oxides of nitrogen and carbon may be released.

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
Residual monomers present may volatilise from the aqueous solution during use, however, these monomers are present only at very low concentrations.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will be manufactured as 25% aqueous solution. The notified polymer may also be imported in this form.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	6.25	12.5	37.5	75	75

USE
Creping agent in tissue manufacture

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
The notified polymer is either manufactured locally or imported through the Port of Melbourne.

IDENTITY OF MANUFACTURER/RECIPIENTS
The notified polymer will initially be supplied to a tissue manufacturer in Springvale, Victoria. Five other tissue manufacturers (one in Victoria, two in Queensland and one in New South Wales and South Australia) have been identified as potential users.

TRANSPORTATION AND PACKAGING
The locally manufactured product containing the notified polymer will be stored and transported in 1000 L Intermediate Bulk Containers (IBCs)/Schutz tanks and 200 L drums. The product containing the notified polymer will be imported in IBCs.

5.2. Operation description

Polymer manufacture
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/200 L drums before being transported to the tissue manufacturing site.

Tissue manufacture
At the tissue manufacturing site, drums or IBCs containing Crepetrol X-Cel will be transferred to the process area by forklift, and used as an ingredient in the chemical adhesive system. Crepetrol X-Cel 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 X-Cel into a tank through a pump (weekly) and transfer from this tank 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*	*Exposure Frequency*
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 X-Cel 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 X-Cel

The manufacture of Crepetrol X-Cel 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. 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.

Exposure of the operator to the pre-polymer (concentration unknown) could occur during transfer to the mobile bulk container, and transfer back to the reaction vessel. Exposure of the operator to the final polymer solution (up to 25%) could occur during transfer of the polymer solution 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. A range of engineering controls will be in place to reduce worker exposure. Fumes and vapours from vents are incinerated. Personal protective equipment (PPE) is expected to be used during transfer operation and when taking samples for testing during and after manufacture, including gloves, glasses and breathing canisters.

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.

Tissue manufacture

At the tissue manufacturing site, forklift drivers moving containers of Crepetrol X-Cel to the process area are not expected to be exposed to the notified polymer, as they would handle only unopened containers.

Technical control personnel will potentially be exposed to Crepetrol X-Cel due to dermal contact with drips, spills and splashes during connection and disconnection of 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. PPE such as gloves and safety glasses may be worn.

5.4. Release

RELEASE OF CHEMICAL AT SITE

Environmental release of the notified polymer is unlikely during importation, storage and transportation, 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 manufacture of Crepetrol X-Cel

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 South East Water sewerage system, in Victoria.

RELEASE OF CHEMICAL FROM USE

Tissue manufacture

Six potential tissue manufacturing sites have been identified as users of the notified polymer. Five potential tissue manufacturing sites are located in metropolitan areas and any effluent discharged after on-site treatment is expected to be into more sophisticated effluent treatment plants. The sixth potential tissue manufacturing site is expected to discharge directly into an inland water body, without secondary treatment.

At the tissue manufacturing sites, 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 enclosed in a shroud, however, there may be over spray directly to effluent.

During use, the notifier indicates that approximately 70% of the formulation adheres to the finished tissue product, with the remaining ≤30% (overspray and other losses) entering the site wastewater. 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.

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, with waste water discharged to sewer.

Tissue manufacturing facilities will generate aqueous wastes containing the notified polymer that will discharge with minimal on-site treatment directly to sewer. However, this discharge is expected to be diluted with ~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 would depend on the actual grade being modified but is expected to be < 1%. 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

Appearance at 20°C and 101.3 kPa Amber Liquid (Crepetrol X-Cel)

Melting Point/Freezing Point Not determined

Remarks The notified polymer is never isolated from solution. The melting point of Crepetrol X-Cel is expected to be below that of water (0°C).

TEST FACILITY

Boiling Point Not determined

Remarks The notified polymer is never isolated from solution. The boiling point of Crepetrol X-Cel is expected to be above that of water (100°C).

Density 1100 kg/m^3 (Crepetrol X-Cel)

Remarks Data from MSDS. Study report not reviewed.

Vapour Pressure Not determined

Remarks The notified polymer is never isolated from solution. Based on the high molecular weight, the vapour pressure is expected to be low.

Water Solubility Not determined

Remarks The notified polymer is introduced as a 25% dispersion in water. The notified polymer is considered to be 100% water available.

Hydrolysis as a Function of pH Not determined

Remarks The notified polymer is not expected to hydrolyse within the environmental pH range of 4-9.

Partition Coefficient (n-octanol/water) log Pow = -1.47 (Estimated)

METHOD Computer based Quantitative Structure Activity Relationship modelling

Remarks A weighted-average of the repeat units based on the composition of this copolymer.

TEST FACILITY EPI Suite v3.12

Dissociation Constant Not determined

Remarks The notified polymer is expected to be cationic in the environmental pH range (4-9)

Fat (or n-octanol) Solubility 179 mg/L n-octanol at 20°C

METHOD OECD TG 105
Remarks Analytical Method: Shaken Flask method. 1.0 g notified polymer was added to 100 mL n-octanol. After shaking, the concentrations of notified polymer were then determined.
TEST FACILITY University of Guelph Laboratory Services Division (2005)

Dissociation Constant Not determined

Remarks The notified polymer is expected to be cationic in the environmental pH range (4-9)

Particle Size Not determined

Remarks The notified polymer is never isolated from solution.

Flash Point Not determined.

Remarks The notified polymer is never isolated from solution. Based on the expected low volatility of the polymer, the notified polymer is not expected to form a flammable air/vapour mixture.

Flammability Limits Not determined.

Remarks Not determined. The notified polymer is never isolated from solution. Based on the expected low volatility of the polymer it would also be expected to have limited flammability. In addition, the notified polymer is introduced in an aqueous solution and hence is known not to react upon contact with water.

Autoignition Temperature Not determined.

Remarks The notified polymer is introduced in an aqueous solution and therefore is unlikely to self ignite in this form.

Explosive Properties Not determined.

Remarks The notified polymer contains no functional groups that would infer explosive properties.

Reactivity

Remarks The notified polymer is expected to be stable under normal conditions of use. Further cross-linking may occur when sprayed onto the toilet tissue.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral	low toxicity, LD50 >2000 mg/kg bw

7.1. Acute toxicity – oral

An acute oral toxicity study of a product containing 25% notified polymer was conducted with Sprague-Dawley rats according to the up and down procedure (OECD 425). At 48 hour intervals, one female animal was administered a single 2000 mg/kg bw dose of the test substance by gavage until five animals had been treated. No mortality or clinical signs of systemic toxicity were observed during the 14 day observation period, and no treatment related gross pathological abnormalities were observed upon necropsy. Under the study conditions, the LD50 for the product exceeded 2000 mg/kg bw, which is suggestive of low acute toxicity (Nucro Technics, 2005).

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE

METHOD	OECD TG 301 D Ready Biodegradability: Closed Bottle Test.
Remarks	After 28 days, the tested substance indicated -11.5% degradation based on dissolved oxygen content. The substance also underwent inhibition testing and was not found to be toxic to the bacterial inoculum (i.e., >25% biodegradation in 28 days).
CONCLUSION	It was concluded that it was not readily biodegradable (i.e., <60% degradation within 28 days).
TEST FACILITY	Stantec (2005a)

8.1.2. Bioaccumulation

Remarks	Given the low Log P_{OW} and high molecular weight, the notified polymer is not expected to bioaccumulate.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

Remarks	A 96 h acute toxicity study (Method/Guideline: EEC 92/69 C.1/OECD 203) performed on rainbow trout (Oncorhynchus mykiss) was provided by the notifier. Fish were exposed to "Crepetrol X-CEL" (2.5-25% a.i. formulation) at measured concentrations of 0, 0.22, 0.46, 1.0, 2.2, 4.6 and 10 mg/L under static conditions. Ten fish were exposed to each dose (1 replicate). The reported 96 h NOEC value, based on 0% mortality and no sub lethal effects (immobility), was 0.46 mg/L. The 96 h LC50 was calculated using non-linear interpolation to be 0.84 mg/L with a confidence interval of 0.33-1.6 mg/L. The test was conducted under Good Laboratory Practices and the report included a signed Compliance with Good Laboratory Practice Standards.
CONCLUSION	Based on the results of this study, "Crepetrol X-CEL" would be classified as a high hazard to rainbow trout in accordance with the ecotoxicity classification system of the US EPA.
TEST FACILITY	Stantec (2005b)

8.2.2. Acute toxicity to aquatic invertebrates

Remarks - Results	A 48 h acute toxicity study (Method/Guideline: EEC 92/69 C.2/OECD 202; Study Number) performed on daphnia (*Daphnia magna*) was provided by the notifier. Daphnia were exposed to "Crepetrol X-CEL" (2.5-25% a.i. formulation) at nominal concentrations of 0, 0.08, 0.25, 0.8, 2.5, 8.0, 25, 80 and 250 mg/L under static conditions. The nominal concentrations were measured and corrected. Five daphnia were exposed to each dose (4 replicates). The reported 48 h NOEC value, based on immobilization and no sub lethal effects, was 8 mg/L. The 48 h EC50 was calculated using non-linear interpolation to be 39.4 mg/L with a confidence interval of 25-80 mg/L. The test was conducted under Good Laboratory Practices and the report included a signed Compliance with Good Laboratory Practice Standards. Furthermore, the report states that all test solutions (from 0.08 to 250 mg/L) were clear and colourless which would indicate that no adverse physical effects are expected.
CONCLUSION	Based on the results of this study, "Crepetrol XCEL" would be classified as a moderate hazard to daphnia in accordance with the ecotoxicity

	classification system of the US EPA.
TEST FACILITY	Stantec (2005c)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Manufacture and Use

The notified polymer will be imported and/or manufactured as a 25% aqueous dispersion in Crepetrol X-Cel and will not be isolated. During manufacture at Springvale, Victoria, it is estimated that as a result of cleaning of manufacture equipment ≤0.15% of the total manufacture volume may be released as trade-waste to the Eastern Treatment Plant via the on-site waste water treatment facility. As the notified polymer will be produced in batches of 24 tonnes, it is expected that release of the notified polymer will occur on approximately 3 days per year.

Up to 0.5% of the total volume is expected to remain as residual within containers. The containers will either be returned to the manufacturer for refilling or will be sent to a licences drum reconditioning facility, where the residual notified polymer is expected to be removed and disposed of by incineration.

During use, the notified polymer is applied by spray to a Yankee Roller in the toilet tissue paper manufacturing process. Up to 30% of the notified polymer is expected to be oversprayed, and will be released as trade waste to sewer. Minimal on-site treatment of waste water is expected and release is expected to be continuous over the year. The following table lists the locations of the manufacturing plant and potential user mills, and indicates which STP each releases to, along with its average daily flow. Average daily flow data has been sourced from the most recently published annual reports for the respective STPs, available online. With the exception of the mill at Millicent, South Australia, all STPs release directly to open water.

	Manufacturer/Mill Location	*Releases to*	*Average Daily Flow*
1.	Manufacturer: Springvale, Victoria	Eastern Treatment Plant	358 ML
2.	Mill: Box Hill, Victoria	Eastern Treatment Plant	358 ML
3.	Mill: Laverton, Victoria	Western Treatment Plant	329 ML
4.	Mill: Crestmead, Queensland	Brisbane Water	115 ML
5.	Mill: Wacol, Queensland	Brisbane Water	115 ML
6.	Mill: Wetherill Park, New South Wales	Malabar (Fast Primary Plant)	456 ML
7.	Mill: Millicent, South Australia	Lake Bonney	40 ML

Using the above average daily flows, the following PECs arising from release from manufacture and from overspray during use have been calculated assuming no mitigation of notified polymer within treatment facilities, and assuming that the notified polymer is distributed evenly between the six potential mills.

1. Manufacturer: Springvale, Victoria

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	75,000	kg/year
Proportion expected to be released to sewer	0.150%	
Annual quantity of chemical released to sewer	112.5	kg/year
Days per year where release occurs	3	days/year
Daily chemical release:	37.5	kg/day
Individual Sewage Treatment Plant Average Daily Flow:	358	ML/day
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	104.7486	µg/L
PEC - Ocean:	10.4749	µg/L

2. Mill: Box Hill, Victoria

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	12,500	kg/year
Proportion expected to be released to sewer	30%	
Annual quantity of chemical released to sewer	3,750	kg/year
Days per year where release occurs	360	days/year
Daily chemical release:	10.417	kg/day
Individual Sewage Treatment Plant Average Daily Flow:	358	ML/day
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	29.10	µg/L
PEC - Ocean:	2.91	µg/L

3. Mill: Laverton, Victoria

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	12,500	kg/year
Proportion expected to be released to sewer	30 %	
Annual quantity of chemical released to sewer	3,750	kg/year
Days per year where release occurs	360	days/year
Daily chemical release:	10.417	kg/day
Individual Sewage Treatment Plant Average Daily Flow:	329	ML/day
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	31.66	µg/L
PEC - Ocean:	3.17	µg/L

4. Mill: Crestmead, Queensland

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	12,500	kg/year
Proportion expected to be released to sewer	30 %	
Annual quantity of chemical released to sewer	3,750	kg/year
Days per year where release occurs	360	days/year
Daily chemical release:	10.417	kg/day
Individual Sewage Treatment Plant Average Daily Flow:	115	ML/day
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	90.58	µg/L
PEC - Ocean:	9.06	µg/L

5. Mill: Wacol, Queensland

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	12,500	kg/year
Proportion expected to be released to sewer	30 %	
Annual quantity of chemical released to sewer	3,750	kg/year
Days per year where release occurs	360	days/year
Daily chemical release:	10.417	kg/day
Individual Sewage Treatment Plant Average Daily Flow:	115	ML/day
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	90.58	µg/L
PEC - Ocean:	9.06	µg/L

6. Mill: Wetherill Park, New South Wales

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	12,500	kg/year
Proportion expected to be released to sewer	30 %	
Annual quantity of chemical released to sewer	3,750	kg/year
Days per year where release occurs	360	days/year
Daily chemical release:	10.417	kg/day
Individual Sewage Treatment Plant Average Daily Flow:	456	ML/day
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	22.84	µg/L
PEC - Ocean:	2.28	µg/L

7. Mill: Millicent, South Australia

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	12,500	kg/year
Proportion expected to be released to sewer	30 %	
Annual quantity of chemical released to sewer	3,750	kg/year
Days per year where release occurs	360	days/year
Daily chemical release:	10.417	kg/day
Individual Sewage Treatment Plant Average Daily Flow:	40	ML/day
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	260.42	µg/L
PEC - Ocean:	26.04	µg/L

The above PECs were calculated assuming that mitigation would not occur. However, as is consistent with literature for polycationic polymers (Boethling and Nabholz, 1997), 90% mitigation (adsorption to sludge) within treatment facilities is reasonable. However, as the STP for the Mill at Wetherill Park, NSW is only a "Fast Primary" treatment facility, 90% adsorption may be a "best case" scenario. Therefore, 50% adsorption has been allowed in this case. The resultant mitigated PECs are shown in the table below.

Source	*PEC - River*	*PEC - Ocean*
1. Manufacturer: Springvale, Victoria	10.4749 µg/L	1.0475 µg/L
2. Mill: Box Hill, Victoria	2.9097 µg/L	0.2910 µg/L
3. Mill: Laverton, Victoria	3.1662 µg/L	0.3166 µg/L
4. Mill: Crestmead, Queensland	9.0580 µg/L	0.9058 µg/L
5. Mill: Wacol, Queensland	9.0580 µg/L	0.9058 µg/L
6. Mill: Wetherill Park, New South Wales	11.4218 µg/L	1.1422 µg/L
7. Mill: Millicent, South Australia	26.0417 µg/L	2.6042 µg/L

It should be noted that both Queensland mills are assumed to release to the STP system operated by Brisbane Water, of which the aggregate average daily flow has been used (115 ML/day). Therefore, the combined release should be used in calculating the PEC, as shown in the table below.

Released to	*PEC – River*	*PEC - Ocean*
Brisbane Water, Queensland (4 & 5)	18.1159 µg/L	1.8116 µg/L

Similarly the manufacturer and the mill located in Box Hill release to the same STP (Eastern Treatment Plant). However, as release from manufacture is only expected to occur on three days in the year, this has not been considered here.

The above model used to calculate the PEC for the mill at Millicent, South Australia, is overly simplistic as it does not take account of the fact that Lake Bonney is dune bound and the water level is managed in such a way as to minimise the need for marine discharge. Release to the marine environment has occurred only twice in the last decade and, therefore, the total volume of water flowing into the lake is roughly in balance with the evaporation rate. After treatment the effluent then

passes into an 11 km drain before discharging into Lake Bonney. The flow in the drain is significant and contains little sediment. Based on the US EPA (Boethling and Nabholz 1997) adsorption rates range a more conservative estimate of 50% was used to estimate adsorption within the drain. Mixing in the lake is not efficient as evidenced by the measurement of faecal coliform levels around the drain (faecal coliform are also discharged in paper printing plant effluent). The concentration of bacteria decreases rapidly with distance from the drain (LBMC 1996). Consequently, for the purpose of making some estimate of the residual chemical concentration in the lake water, a dilution factor of 1:5 will be assumed.

As the notified polymer is not readily biodegradable, it is expected that the rate of inflow of notified polymer into Lake Bonney will exceed the biodegradation rate, and therefore, the concentration of notified polymer is likely to increase until an equilibrium point is reached. This is further exacerbated by the poor mixing within the lake. Therefore, the PEC is likely to be significantly higher than that which has been calculated above. This will result in a correspondingly higher Q value, than that which has been calculated in Section 9.1.3.

Disposal
The remaining 70% of the total volume of notified polymer is expected to be adhered to finished toilet tissue, which after use, is expected to be disposed of to domestic sewer throughout Australia. No data has been provided as to whether any of the notified polymer is released from the toilet tissue within the sewer. Given the level of water solubility and low Log K_{OW}, it may be expected that at least some will be released. The following PEC for release from disposal of paper treated with the notified polymer has been made assuming that 90% of the notified polymer will remain adhered to the paper fibre, and of the 10% that is released, 90% of it is mitigated in sewage treatment plants.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	75,000	kg/year
Proportion expected to be released to sewer	70%	
Annual quantity of chemical released to sewer	52,500	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	143.84	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	20.496	million
Removal within STP	90%	
Daily effluent production:	4,099	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	3.51	µg/L
PEC - Ocean:	0.35	µg/L

9.1.2. Environment – effects assessment

Only two trophic levels (fish and aquatic invertebrates) were tested, therefore an assessment factor of 1000 was chosen in order to determine the Predicted No-Effect Concentration.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
(A) LC50 (Fish).	0.84	mg/L
Assessment Factor	1,000.00	
PNEC (A):	0.84	µg/L

However, polycationic polymers are known to be approximately 6 times more toxic to algae than to either fish or aquatic invertebrates (Boethling and Nabholz, 1997). Allowing for this, a revised PNEC would be.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
(B) LC50 (Algae) Estimated.	0.14	mg/L
Assessment Factor	1000.00	
PNEC (B):	0.14	µg/L

Using ECOSAR for polycationic polymers (containing > 3.5% a-N), the predicted LC50 for algae is 0.04 mg/L (Environment Canada, 2006). The resultant PNEC for this would be:

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
(C) LC50 (Alga - Modelled).	0.04	mg/L
Assessment Factor	1,000.00	
PNEC (C):	0.04	µg/L

The literature (Boethling and Nabholz 1997) supports a mitigation factor of 110 for cationic polymers containing >3.5%a-N. Therefore, this has been applied and the resultant PNEC for this would be:

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
(D) LC50 (Alga - Modelled).	0.04	mg/L
Assessment Factor	1,000.00	
Mitigation Factor	110.00	
PNEC (D):	4.40	µg/L

The following table summarises the four possible PNEC values that will be used when calculating the Risk Quotient (Q), below.

End Point	*(A) LC50 (Fish) Measured*	*(B) LC50 (Algae) Estimated*	*(C) LC50 (Algae) Modelled*	*(D) LC50 (Algae) Modelled*
Value	0.84 mg/L	0.14 mg/L	0.04 mg/L	0.04 mg/L
Assessment Factor	1000	1000	1000	1000
Mitigation Factor	1	1	1	110
PNEC	0.84 µg/L	0.14 µg/L	0.04 µg/L	4.4 µg/L

9.1.3. Environment – risk characterisation

Risk can be determined by dividing the PEC by the PNEC resulting in a Risk Quotient (Q) value. A risk quotient value ≥ 1 represents unacceptable risk.

Manufacture and Use

In the following series of tables, PNEC (D), based on the fully mitigated modelled alga LC50 value has been used. For comparison purposes, the other PNEC values (A-C), as discussed in Section 9.1.2, have been shown.

Released from	*Q for*	*Using PNEC (A)*	*Using PNEC (B)*	*Using PNEC (C)*	*Using PNEC (D)*
1. Manufacturer: Springvale, Victoria	River	**124.701**	**748.204**	**2618.715**	**23.807**
	Ocean	**12.470**	**74.820**	**261.872**	**2.381**
2. Mill: Box Hill, Victoria	River	**34.639**	**207.835**	**727.421**	**6.613**
	Ocean	**3.464**	**20.783**	**72.742**	0.661
3. Mill: Laverton, Victoria	River	**37.692**	**226.154**	**791.540**	**7.196**
	Ocean	**3.769**	**22.615**	**79.154**	0.720
4. Mill: Crestmead, Queensland	River	**107.833**	**646.998**	**2264.493**	**20.586**
	Ocean	**10.783**	**64.700**	**226.449**	**2.059**
5. Mill: Wacol, Queensland	River	**107.833**	**646.998**	**2264.493**	**20.586**
	Ocean	**10.783**	**64.700**	**226.449**	**2.059**
6. Mill: Wetherill Park, New South Wales	River	**27.195**	**163.168**	**571.089**	**5.192**
	Ocean	**2.719**	**16.317**	**57.109**	0.519

7. Mill: Millicent, South Australia	Lake	**310.020**	**1860.119**	**6510.417**	**59.186**

Allowing for mitigation within STPs, as discussed in Section 9.1.1, the Risk Quotients become:

Released from	*Q for*	*Using PNEC (A)*	*Using PNEC (B)*	*Using PNEC (C)*	*Using PNEC (D)*
1. Manufacturer: Springvale, Victoria	River	**12.470**	**74.820**	**261.872**	**2.381**
	Ocean	**1.247**	**7.482**	**26.187**	0.238
2. Mill: Box Hill, Victoria	River	**3.464**	**20.783**	**72.742**	0.661
	Ocean	0.346	**2.078**	**7.274**	0.066
3. Mill: Laverton, Victoria	River	**3.769**	**22.615**	**79.154**	0.720
	Ocean	0.377	**2.262**	**7.915**	0.072
4. Mill: Crestmead, Queensland	River	**10.783**	**64.700**	**226.449**	**2.059**
	Ocean	**1.078**	**6.470**	**22.645**	0.206
5. Mill: Wacol, Queensland	River	**10.783**	**64.700**	**226.449**	**2.059**
	Ocean	**1.078**	**6.470**	**22.645**	0.206
6. Mill: Wetherill Park, New South Wales	River	**13.597**	**81.584**	**285.545**	**2.596**
	Ocean	**1.360**	**8.158**	**28.554**	0.260
7. Mill: Millicent, South Australia	Lake	**31.002**	**186.012**	**651.042**	**5.919**

Combining the two Queensland mills' release, as discussed in Section 9.1.1, the Risk Quotients, after full mitigation, for Brisbane Water are:

Released to	*Q for*	*Using PNEC (A)*	*Using PNEC (B)*	*Using PNEC (C)*	*Using PNEC (D)*
Brisbane Water, Queensland (4 & 5)	River	**21.567**	**129.400**	**452.899**	**4.117**
	Ocean	**2.157**	**12.940**	**45.290**	0.412

With the exception of the mill at Millicent, South Australia, it is expected that all other locations will discharge, via their downstream STP to ocean. Only when full mitigation is applied are the Q for Ocean values less than 1, suggesting that their discharge is unlikely to have an adverse affect on the environment, at the assumed use rates and related discharge rates. This indicates the inherent risk associated with the notified polymer.

As the Q for River value for the mill at Millicent, South Australia is above 1, this suggests that its discharge is likely to have an adverse affect on the environment, at the assumed use rates and related discharge rates. In order to reduce the Q for River to 1, all other things held constant, the Mill, should only use a maximum of 2.1 tonne of the notified polymer per year. However, as discussed in Section 9.1.1, the model used to calculate the PEC for the Mill at Millicent, South Australia, is overly simplistic, and for the reasons mentioned, the PEC and subsequently Q values are expected to be significantly higher. Therefore it is recommended that the notified polymer not be discharged in effluent to Lake Bonney.

Disposal

Using the mitigated PEC, as discussed in Section 9.1.1, the Risk Quotients for the disposal of toilet tissue manufactured using the notified polymer are shown below.

Risk Assessment	*PEC µg/L*	*Using PNEC (A)*	*Using PNEC (B)*	*Using PNEC (C)*	*Using PNEC (D)*
Q - River:	3.51	**4.177**	**25.063**	**87.722**	0.797
Q - Ocean:	0.35	0.418	**2.506**	**8.772**	0.080

As the Q values are less than 1 using the fully mitigated PNEC (D) for both river and ocean discharge, the disposal of toilet tissue to the sewer is unlikely to have an adverse effect on the aquatic environment.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Transport and storage

Transport and storage worker exposure to the notified polymer is expected to be negligible

except in the case of an accident that breaches the containers.

Local manufacture of Crepetrol X-Cel
Due to the largely automated processes the highest potential for exposure to the notified polymer 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 expected 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
The highest potential for worker exposure would occur in the vicinity of the Yankee cylinder, where the notified polymer (concentration unknown) 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. 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. Dermal exposure to the notified polymer (up to 25%) by technical control personnel could occur during connection and disconnection of transfer lines. PPE such as gloves and safety glasses may be worn.

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 < 1% of the notified polymer. The notified polymer is expected to be bound to the paper however, it is also possible that a proportion of the polymer could be transferred to the skin during use.

9.2.3. Human health – effects assessment

The notified substance is unlikely to exhibit significant acute toxicity by the oral route of administration. The polymer has a high number average molecular weight (Mn) of >1000, and low levels of low molecular weight species, and is unlikely to cross biological membranes. However, since the notified polymer is a polyamine epoxy resin, it may possess irritant and sensitising properties.

Hazardous impurities are present in the notified polymer, however these are present below the concentration cut-off for classification (HSIS, 2006). The polymer may also contain carcinogenic impurities but these were below the limit of detection (0.0001%).

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

9.2.4. Occupational health and safety – risk characterisation

The notified polymer is expected to be of low toxicity but may possess irritant and sensitising properties. As contact with the notified polymer can occur during polymer and tissue manufacture, the risk of sensitisation and irritation effects cannot be ruled out. However, the risk to workers involved in these processes is considered to be low if appropriate engineering controls are in place to prevent routine and incidental exposure and PPE such as gloves, coveralls and eye protection are used to limit skin and eye contact.

9.2.5. Public health – risk characterisation

Overall the risk to the public is considered low, based on the low concentration of the notified polymer in toilet tissue, its expected binding within the toilet tissue, and its expected low toxicity at the concentrations present.

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 a hazardous substance for acute toxicity in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004). Toxicological data was not available for the other endpoints.

and

As a comparison only, the classification of 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.

	Hazard category	***Hazard statement***
Acute hazards to the aquatic environment	1	Very toxic to aquatic life
Chronic hazards to the aquatic environment	1	Very toxic to aquatic life with long lasting effects

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio, and with exception to release from the mill at Millicent, South Australia, the notified polymer is not expected to pose an unacceptable risk to the environment based on the notified use pattern. On the basis of the PEC/PNEC ratio, discharge of the notified polymer in effluent from the mill at Millicent, South Australia, is expected to pose an unacceptable risk to the environment based on the notified use pattern, and it is therefore recommended that the notified polymer is not discharged to the aquatic environment from this mill. Also, on the basis of the PEC/PNEC ratio, there is an unacceptable risk to the environment where discharge to rivers occurs, based on the proposed volumes and use patterns.

Further work or actions (such as additional testing in the area of concern e.g. ecotoxicity testing for algae, supporting data for the binding of the notified polymer to paper fibres, and removal of the notified polymer during sewage treatment, detailed exposure analysis, in-depth risk assessment or further risk management actions) should be considered.

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 the proposed manner.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the aqueous notified polymer solution Crepetrol X-Cel provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 2003). 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 aqueous polymer solution Crepetrol X-Cel provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC 1994). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following isolation and engineering controls to minimise occupational exposure to the notified polymer as imported or manufactured, and 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 skin and eye contact
  - 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.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as imported or manufactured, and as used in the manufacture of toilet tissue:
  - Coveralls,
  - Impervious gloves
  - Eye protection
  - 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 polymer are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Environment

- The following concentration limits should be implemented by any manufacturer or user for release of the notified polymer to the aquatic environment:
  - The concentration of notified polymer within the aquatic environment should not exceed 0.04 µg/L.

Disposal

- The notified polymer should be disposed of by incineration or to secure landfill.

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by physical containment, collection and subsequent safe disposal. Release in concentrated form to

the aquatic environment should be prevented

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 Section 64(1) of the Act; if
- Release to fresh water (river or lake) is proposed

or

(2) Under Section 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. Where release to fresh water is proposed, ecotoxicity testing for algae, supporting data for the binding of the notified polymer to paper fibres, and removal of the notified polymer during sewage treatment will be required.

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