File No: NA/759

23 April 2020

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Polymer in Styleze CC-10

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act* 1989 (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the National Occupational Health and Safety Commission which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment and the assessment of public health is conducted by the Department of Health and Aged Care.

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Director
Chemicals Notification and Assessment

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Polymer in Styleze CC-10

1. APPLICANT

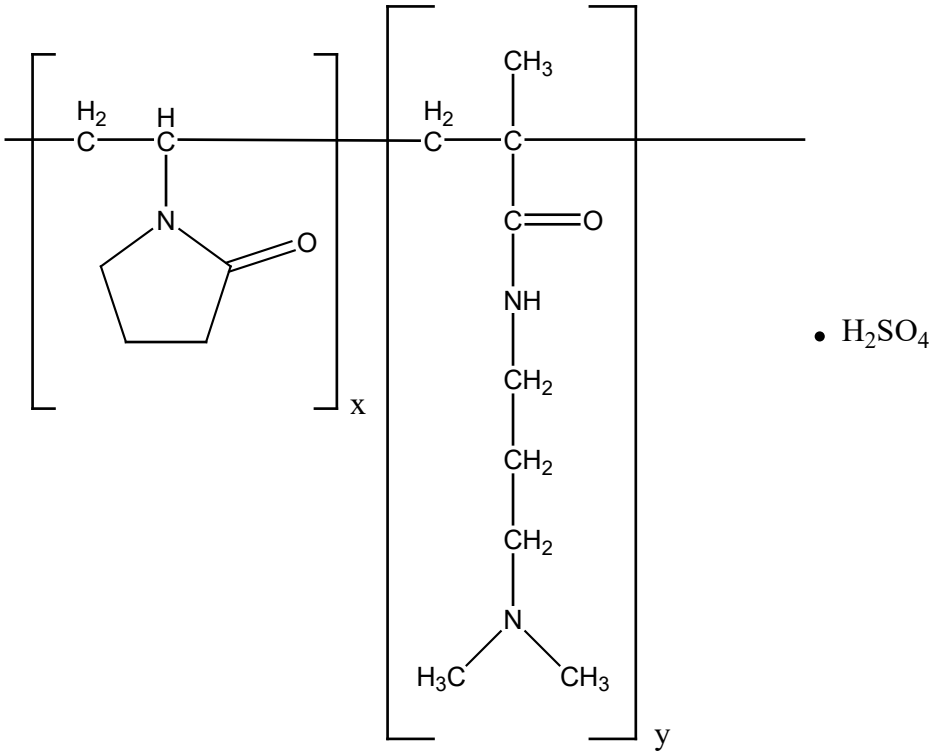
ISP (Australasia) Pty Ltd of 73-75 Derby Street SILVERWATER NSW 2128 has submitted a limited notification statement in support of their application for an assessment certificate for Polymer in Styleze CC - 10.

2. IDENTITY OF THE CHEMICAL

The notifier has not claimed any information to be exempted from publication in the Full Public Report.

Chemical Name:	2-propenamide, N-(3-dimethylamino)propyl-2-methyl-, polymer with 1-ethenyl-2-pyrrolidinone, sulphate
Chemical Abstracts Service (CAS) Registry No.:	175893-71-7
Other Names:	vinyl pyrrolidone dimethylaminopropylmethacrylamide copolymer
Marketing Name:	Styleze CC-10
Molecular Formula:	$(C_9H_{18}N_2O.C_6H_9NO)_X.XH_2SO_4$ (unspecified, see comments below)

Structural Formula:



Molecular Weight:

Number-Average Molecular Weight (NAMW): 2.131×10^6

Polydispersity: 1.957

Weight-Average Molecular Weight (WAMW): 4.170×10^6

Maximum Percentage of Low Molecular Weight Species: none detectable

Molecular Weight < 500:

Molecular Weight < 1 000:

Weight Percentage of Ingredients:

Chemical Name	*CAS No.*	*Weight %*
vinyl pyrrolidone	88-12-0	86
dimethylaminopropylmethacrylamide (DMAPMA)	not known	14

Method of Detection and Determination: infrared (IR) spectrum

Spectral Data: IR spectrum with major absorbance peaks at 1 292,

1 464, 1 660, 2 959 and 3 400 cm^{-1}

Comments on Chemical Identity

The GPC trace provided indicates a spread of molecular weights (polydispersity 1.957) with no low molecular weight species present.

Under the conditions of polymerisation, the molecular formula will remain unspecified although the notified chemical is a copolymer of vinyl pyrrolidone and DMAPMA.

3. PHYSICAL AND CHEMICAL PROPERTIES

The notified polymer will be imported as a 10% aqueous medium (Styleze CC-10). The physical and chemical properties for Styleze CC-10 are listed below unless otherwise stated.

Appearance at 20°C and 101.3 kPa:	clear to slight hazy viscous liquid
Boiling Point:	not determined
Specific Gravity:	1.02
Vapour Pressure:	3.166 kPa at 25°C
Water Solubility:	51 mg/L (parent base, see comments below)
Partition Co-efficient (n-octanol/water):	log P_{ow} = 4 (parent base, see comments below)
Hydrolysis as a Function of pH:	not expected to hydrolyse between pH 3.5 – 10 (functional amide group may undergo hydrolysis under extreme temperature and pH)
Adsorption/Desorption:	log K_{oc} = 3.6 (K_{oc} = 3 875, see comments below)
Dissociation Constant:	pK_a = 9.8 (tertiary amine functionality)
Flash Point:	notified polymer is present as an aqueous solution and is not expected to be flammable
Flammability Limits:	not flammable
Autoignition Temperature:	not determined
Explosive Properties:	not explosive
Reactivity/Stability:	stable under room conditions
Particle Size:	not applicable as product is a liquid

Comments on Physico-Chemical Properties

It should be noted that the values provided were either for the imported product (10% aqueous medium) or estimations for the parent base. The computer estimation model ACD (Advanced Chemistry Development Lab) was used to generate the above estimations based on the smallest repetitive unit (3:1).

From the ACD estimation for solubility of the parent base it can be presumed that the solubility of the notified polymer will be greater than 51 mg/L on the basis that the polymer is a salt. The presence of the potentially hydrophilic [-$N(CH_3)_2$] groups and the cationic nature are likely to confer greater solubility. The notified polymer would therefore be expected to be moderately soluble.

The notifier has indicated that the estimated log P_{ow} for the parent base is 4. The notified polymer is likely to have a log P_{ow} less than 4 because of the potentially hydrophilic protonated [-$N(CH_3)_2$] groups. While this suggests that the notified polymer is somewhat hydrophobic, it does not indicate strong partitioning to the oil phase or organic matter. This is supported by the expected moderate water solubility of the notified polymer.

The ACD estimation of K_{oc} for the parent base is 3 875. Since the notified polymer is a salt, it may have a lower K_{oc}. The K_{oc} is expected to be further reduced due to the incorporation of positively charged [-$N(CH_3)_2$]+ groups which may increase water solubility. Whilst these features may increase mobility in soil, the high molecular weight and electrostatic attraction between the polymer an soil colloidal material may mitigate mobility".

The pK_a is based on trimethylamine. Based on this estimate the polymers should remain in the cationic form in the aquatic environment.

4. PURITY OF THE CHEMICAL

Degree of Purity: > 99%

Hazardous Impurities (monomers):

Chemical name:	vinyl pyrrolidone
CAS No.:	88-12-0
Weight percentage:	< 0.01%
Toxic properties:	oral rat LD_{50} = 1 470 mg/kg confirmed carcinogen; moderately toxic by ingestion; a severe eye irritant (Sax & Lewis, 1996)

Non-hazardous Impurities (> 1% by weight): none

Additives/Adjuvants;

Chemical name:	benzalkonium chloride
CAS No.:	68391-01-5
Weight percentage:	approximately 0.09%
Toxic properties:	none

5. USE, VOLUME AND FORMULATION

The notified polymer will be used as a component in hair care products such as gels, mousses, styling lotions and shampoos to improve the holding ability, condition, shine and manageability of hair. The concentration of the notified polymer in the currently identified finished products is 1% (w/v) in aluminium aerosol canisters (200 g – 375 g in capsules), PVC bottles and tubes.

The polymer will not be manufactured in Australia. The notifier estimates that the import volume will eventually be 500 kg per year. The polymer will be imported as a 10% aqueous medium (Styleze CC-10) and mixed with other ingredients at 5 formulation sites to produce the finished hair care products.

6. OCCUPATIONAL EXPOSURE

Routes of Exposure
The notified polymer is a viscous liquid of moderate solubility. Direct dermal contact may occur, however substantial dermal absorption is not expected due to the high molecular weight of the polymer. Considering the low volatility and enclosed nature of the processes inhalation exposure is not expected to be significant.

Transport and Storage
The notified polymer will be imported in 200 kg drums. The notifier states that the number of waterside, transport and warehousing personnel who will be involved in handling the polymer will be small (< 4). Workers will handle the drums infrequently for short periods (2-4 hours/day, 2–4 days/year) during loading, unloading and storage (notifier's site). It is unlikely that any substantial exposure will occur except in the case of an accident involving a breach of packaging.

Warehouse workers at the customer site will also be involved in unloading the notified polymer from delivery trucks. The drums are handled occasionally for a short period of time (30 minutes/day, 3 days/year), and exposure is unlikely unless packaging is breached.

Formulation, Quality Control and Packaging and Retailing
Reformulation of Styleze CC-10 with other ingredients to form the end-use product is a batch process. The number of batches mixed per annum is not provided, however it is anticipated to occur for only 6 days/year. The product containing the notified polymer is manually decanted from the import drums into the mixing vessel (10 000 L capacity). The compounding process is carried out in an enclosed automated system. As each batch is

mixed, QA samples are obtained, and the mixture pumped via an automatic filling line and transferred to final packaging. If spillage occurs at this point, skin contamination may occur. Workers wear long sleeved overalls, head covering, safety glasses, boots and impervious gloves.

The filling process is automated, however if overfilling and spillage occurs, skin contamination with the enduse products containing the notified polymer (1%) may occur. Filling line workers operate and clean the filling equipment for 8 hours/day, 6 days/year and wear disposable latex gloves, safety glasses, uniforms and safety shoes.

Laboratory personnel are expected to be involved in QA activities 30 minutes/day, 6 days/year. Spillage can be result in dermal exposure but quantities handled are small and staff wear long sleeved laboratory coats, facemasks, safety glasses and impervious gloves.

The notifier states sampling, dispensing and compounding operations carried out under enclosed and automated conditions would minimise generation of aerosols, hence inhalation exposure during these activities will not be substantial.

Packaging workers pack product containers into cartons for 6 hours/day for 6 days/year. They wear long sleeved overalls, a head covering, safety glasses, safety boots and impervious gloves. Worker exposure will only occur during equipment malfunction.

Retail workers at supermarkets and at other retail outlets unloading hare care products from cartons and packing on shelves will handle the packed product frequently (200 days/year) for very short periods at a time (0.02 hours/day). Exposure is only likely in the event of an accident.

7. PUBLIC EXPOSURE

Styleze CC-10 will be included in hair care products up to 10% containing the notified polymer up to a concentration of 1%. No details of the frequency of exposure to products containing the notified polymer have been provided. However as it is to be incorporated in hair gels, mousses, styling lotions and shampoos, public exposure is likely to be frequent and extensive but, on the assumption that the products are washed off after application, of short duration.

In the event of a transport accident public exposure to the notified polymer is unlikely to be significant. Spilt material may be recovered by sand adsorption or by other means and transferred into waste receptacles for subsequent disposal according to local government regulations.

As the notified polymer is not volatile, the manufacture of products containing it is unlikely to lead to public exposure other that in those who purchase the products for their own use.

8. ENVIRONMENTAL EXPOSURE

Release

It has been estimated that spills will account for the loss of 1% per year of the notified polymer.

An estimated 1% (5 kg per year) of the contents of the import container will remain as residue after the container is emptied. The import containers, with the residue, will be disposed of to landfill.

All reformulation process equipment will be washed with the resultant washwater going to an on-site wasterwater treatment plant. An estimated 0.5% (2.5 kg per year) of the final product will be lost in watewater.

The formulation site wastewater treatment plant consists of a 30 000 L averaging tank, a solids separator, a grease remover, automatic pH adjustment system and a dissolved air flotation tank (DAF) with the supernatant from the DAF going to sewer. The notifier has not quantified the amount of notified polymer removed in the on-site treatment plant but has indicated that at least 80% should be removed. The estimated log P_{ow} indicates that the quantified polymer would have an affinity for organic matter. This, plus the ACD K_{oc} estimation and the possible presence of N^+, support the expectation that the majority of the polymer will be removed during treatment.

The notifier has estimated that there will be approximately 2% of the final product left as residue in the empty end use container. The container and residue will be disposed of in the domestic rubbish and go to landfill.

The product is applied to hair to improve hair manageability. The notifier has not indicated the amount of uptake of the polymer by hair, but ultimately it will all be removed in hair washing, and flow to the sewer.

Fate

The majority of the imported volume will end up in the sewer , while the remainder will end up in landfill.

A summary of the estimated annual amounts and likely disposal sites of waste notified polymer from the reformulation process is :

spills	1%	5 kg	on-site treatment plant/sewer
import container residues	1%	5 kg	landfill
reformulation washwater	(0.5% at 1% conc.)	2.5 kg	on-site treatment plant/sewer
end use container residue	(2%)	10 kg	landfill

Approximately 15 kg (3%) of the imported notified polymer will go to landfill. Because of its positive charge, likely K_{oc} and Log Pow values and large molecular weight, the polymer is not expected rapidly leach out of the landfill.

Approximately 1.5% (7.5 kg) of the polymer will enter the on-site treatment plant via spills and process equipment washing. The likely K_{oc} of the polymer suggests it will adsorb to the sludge in the treatment plant. If it is presumed that 80% of the polymer is removed in the treatment plant, 1.4 kg would enter the sewer in the effluent from the treatment plant.

An high proportion 95.5% (277.5 kg) of the polymer may end up in the sewer via home use. It is likely that the polymer will be removed in the metropolitan sewage treatment plant. If it is presumed that 80% of the polymer is removed in the sewage treatment plant, 91 kg may reach the aquatic environment.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of Styleze CC-10

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	Rat	LD50>5000mg/kg	Cerven, 1994a
skin irritation	rabbit	minimal irritant	Kieffer, 1994
eye irritation	Rabbit	minimal irritant	Cerven, 1994b

9.1.1 Oral Toxicity (Cerven, 1994a)

Species/strain:	rat/Wistar Albino
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	gavage; 5000 mg/kg
Test method:	EPA/TSCA Health Effects Testing Guidelines, 40 CFR – Part 792
Mortality:	no deaths occurred during the observation period
Clinical observations:	body weight gains were normal
Morphological findings:	Necropsy results were normal
LD_{50}:	> 5000 mg/kg
Result:	the notified chemical was of very low acute oral toxicity in rats

9.1.2 Dermal Toxicity

A dermal toxicity study was not provided

9.1.3 Inhalation Toxicity

An inhalation study was not provided.

9.1.4 Skin Irritation (Kieffer, 1994)

Species/strain:	rabbit/New Zealand white
Number/sex of animals:	2 males, 4 females
Observation period:	3 days
Method of administration:	the test substance was applied as received and dosed by a volume of 0.5 mL/site (concentration not stated) as a semi-occlusive dressing after 4 hours any residual material was rinsed off with distilled water
Test method:	EPA/TSCA CFR – Part 798.4470
Comment:	Erythema and oedema, absent to slight at 30-60 minutes after patch removal, was absent at 24, 48 and 72 hours; no abnormalities were noted over the observation period
Result:	Based on the reactions occurring 30-60 minutes after removal of the semi-occlusive dressing, and their disappearance shortly thereafter, the notified chemical was considered to be a minimal irritant to the skin of rabbits

9.1.5 Eye Irritation (Cerven, 1994b)

Species/strain:	rabbit/New Zealand white
Number/sex of animals:	6 males
Observation period:	3 days
Method of administration:	a dose of 1 mL (concentration not stated) was placed into the conjunctival sac of each eye and the lids were held together for approximately 1 second; the contralateral eye served as control
Test method:	EPA/TSCA 40 CFR – Part 798.4500

Draize scores of unirrigated eyes:

Cornea: all individual scores were zero

Iris: all individual scores were zero

Conjunctiva	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***
1	1	0	2	0	0	1	0	0	0	0	0	0
2	2	2	2	1	1	1	0	0	0	0	0	0
3	1	0	2	0	0	1	0	0	0	0	0	0
4	1	1	2	0	0	1	0	0	0	0	0	0
5	1	0	2	1	0	1	0	0	0	0	0	0
6	1	0	2	0	0	1	0	0	0	0	0	0

[1] see Attachment 1 for Draize scales Draize (1959)
o = opacity a = area r = redness c = chemosis d = discharge

Comment:

mean scores (24, 48, 72 hours):
corneal opacity: 0
irideal lesions: 0
conjunctival redness: 0.11
conjunctival chemosis: 0.055

there were no corneal opacities or irideal lesions noted at any observation period

conjunctival irritation, noted in 6/6 eyes, cleared by day 2

no abnormal physical signs were noted during the observation period

Result:

the notified chemical was considerd to be minimally irritating to the eyes of rabbits

9.2.1 Phototoxic and Photoallergy Potential (Kanengiser, 1997)

A total of 25 female and male panelists ranging in age from 20-64 years were selected for the study, on the condition they had no history of acute or chronic dermatological, medical and/or physical conditions which could influence the outcome of the test.

Photoallergy Evaluation

Induction phase:
Approximately 0.2 mL of test material was applied to duplicate sites on the back under semi-occlusive conditions. About 24 hours later, the patches were removed and one site was irradiated with two times the panelist's Minimal Erythemal Dose. The remaining site served as the non-irradiated control. This procedure was carried out twice weekly for a total of six

applications. Test and control sites were examined at 24 hours following irradiation of the test sites.

Challenge phase:
Approximately 2 weeks following the last application, duplicate patches were applied to sites previously unexposed to the test material. Twenty-four hours later, the patches were removed, and one test site was irradiated with a non-erythrogenic dose of UVA radiation equivalent to 10 J/cm^2. The second test site served as a test material treated, non-irradiated control site. An additional untreated test site was also exposed to radiation. The challenge sites were graded at 24, 48 and 72 hours following irradiation.

Photoxicity Evaluation
A sub-group of 10 panelists had a third patch applied during the photoallergy induction phase. After 24 hours, the patches were removed and the test sites were irradiated with long wave (UVA) radiation (equivalent to approximately 10 J/cm^2). An adjacent, untreated test site was also irradiated (control site). Treated and control sites were examined at 24, 48 and 72 hours post-irradiation.

Results:

Photoallergic Potential
A total of 25 panelists completed the study. The challenge post-irradiation phase showed no visible skin reactions (that is, eczematous, urticarial, lichen planus-like, or sunburn-like reactions) for the test material.

Phototoxic Potential
A total of 10 panelists completed the study. No visible skin reactions (that is, severe sunburn) were observed on the non-irradiated (treated) test site. One panelist had a minimal erythemal response on both the control (irradiated, non-treated) and irradiated (treated) test sites at the 24 and 48 hour readings.

Conclusion
The clinical evaluation of the test material did not exhibit any evidence of phototoxic or photoallergic potential.

9.2.2 Repeated Insult Patch Test (Kanengiser, 1997)

Panelists were selected for the study on the condition they had no history of acute or chronic dermatological, medical and/or physical conditions which could influence the outcome of the test.

Test method
Prior to the application of the patch, the test area was wiped with 70% isopropyl alcohol and allowed to dry. The test material, (0.2 mL Styleze CC-10, 10.9% solids) applied under an occlusive patch to the upper back (between the scapula) and allowed to remain in direct skin contact for a period of 24 hours. Patches were applied to the same site on Monday, Wednesday and Friday for a 3 week induction period. The sites were graded for dermal irritation and sensitisation 24 hours after removal of the patches by the subjects on Tuesday and Thursday, and 48 hours after removal of the patches on Saturday. Following a 2 week rest period, the challenge patches were applied to previously untreated test sites on the back.

After 24 hours, the patches were removed and the test sites were evaluated for dermal reactions. The test sites were again evaluated at 48 and 72 hours.

Results:

Induction phase
A total of 104 panelists completed the study. During the induction phase, one subject exhibited a 4+ level reaction (erythema and oedema with vesiculation) at the second reading. This subject was judged to be presensitised to the test material and was not challenged. Two subjects exhibited 3+ level reactions (erythema and oedema). One subject exhibited the reaction at the second reading and also was not challenged. The other subject exhibited the reaction at the fifth reading. This site was changed to a virgin site, where a ± level reaction (barely perceptible erythema) was evident at the ninth reading. Four subjects exhibited 2+ level reactions (well defined erythema) with oedema. Two subjects exhibited 2+ level reactions. Seventeen subjects exhibited 1+ level reactions (mild erythema), four subjects with oedema. Twenty-eight subjects exhibited ± level reactions.

Challenge phase
During the challenge phase, 3 subjects exhibited 1+ level reactions, one subject with oedema. These reactiosn diminished to ± level or zero at the 48 hour and/or 72 hour readings. Eight subjects exhibited ± level reactions.

Conclusion
Based on the test population of 104 subjects, and under the conditions of the study, there was inadequate evidence to determine that the polymer solution (Styleze CC-10) was a skin sensitiser at a concentration of 10%.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (Xu, 1994)

Strains: *Salmonella typhimurium*: TA98, TA100, TA1535, TA1537 and TA1538

Concentration range: with S9: 0.5, 1.0, 5.0, 10 and 50 μL/plate
without S9: 1.0, 5.0, 10, 50 and 100 μL/plate

all test solutions were prepared in water

Metabolic activation: 10% rat liver S9 fraction (Aroclor 1254-induced) in standard cofactors

Positive controls:

Strain	S9	Chemical	Concentration (μg/plate)
TA98	-	2-nitrofluorene	5.0
TA98	+	2-aminoanthracene	1.25
TA100	-	sodium azide	1.0

TA100	+	2-aminoanthracene	1.25
TA1535	-	sodium azide	1.0
TA1535	+	2-aminoanthracene	1.25
TA1537	-	9-aminoacridine	50
TA1537	+	2-aminoanthracene	1.25
TA1538	-	2-nitrofluorene	5.0
TA1538	+	2-aminoanthracene	1.25

Test method: US EPA Title 40 Code of Federal Regulations Parts 160 and 792

Comment: all experiments were repeated and all dose determinations were performed in triplicate

the mean reversion frequency of the solvent control plates for TA98 in the first mutation assay in the presence of S9 was 45, compared with 20 as indicated in the protocol; this was not considered to have any adverse effect on the interpretation of the test results

no significant increases in the frequency of revertants were recorded for any of the strains, at any dose level either with or without S9; all positive controls responded appropriately

Result: the notified chemical was considered to be non-mutagenic under the conditions of the assay

9.4 Overall Assessment of Toxicological Data

The Polymer in Styleze CC-10 has very low oral toxicity in rats, with an LD_{50}>5000 mg/kg. It has minimal capacity as a skin irritant in the rabbit, because the slight erythema and oedema present at 30-60 minutes after patch removal had disappeared by the first day of the observation period. In an eye irritation study, the notified chemical produced conjunctival irritation in all six test animals up to the first day of observation, and had resolved by day 2.

The phototoxic and photoallergy evaluation and a repeated insult patch test, were performed with the notified chemical with human volunteers. There was no evidence that the notified polymer had potential to elicit positive responses as a phototoxic or photoallergic compound. Based on the results of the repeated insult patch test a 10% solution of Styleze CC-10 could not be determined to be skin sensitiser. However, due to deficiencies in the study design and skin reactions in a few study subjects, the skin sensitisation potential of the test material could not be fully evaluated.

Hazard Classifiction

The notified Polymer in Styleze CC-10, does not meet any of the classification criteria for toxicological end points assessed as described in the NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1999) and is considered to be non-hazardous.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicological data were provided. Ecological data are not required for polymers of NAMW > 1 000 according to the Act. It is likely that the notified polymer will exist in the aquatic environment in the quaternized (cationic) form. Boethling and Nabholz (1997) consider cationic polymers with molecular weights greater than 1000K but less than 2500K to be moderately to highly toxic to aquatic organisms, with LC_{50}/EC_{50} between 0.3 and 2.3 mg/L.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

This assessment assumes that all of the notified polymer in the final product ultimately enters the sewer, to be released in very low concentrations and in a very diffuse manner all over Australia.

If it is presumed that there is no removal in the sewage treatment plant, the resultant Predicted Environmental Concentrations (PEC) in receiving waters would be:

Amount released to sewer	477.5 kg
Population	18 million
Volume of water per person	150 L
Dilution factor in receiving water	1:10
PEC receiving water	0.018 mg/L

A worst case scenario would be if a full reformulation batch was released to sewer. The resultant receiving waters PEC would be :

Amount of notified polymer entering sewer	100 kg
Volume of water being handled in metropolitan STP	250 ML/day
Dilution in receiving waters	1:10
PEC	0.04 mg/L

Under optimal conditions, which includes 80% removal in all treatment plants, the PEC would be further reduced to 0.0036mg/L and 0.008 mg/L, respectively. Without any ecotoxicological data it is difficult to determine the actual environmental hazard posed by the polymer. Boethling and Nabholz (1997) indicate that this type of polymer may have a moderate to high toxicity to aquatic organisms with an LC_{50}/EC_{50} between 0.3 and 2.3 mg/L. Taking into account adsorption, the likely PEC is at least 2 orders of magnitude below the calculated values and the polymer is expected to pose a low hazard to the environment.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Based on the toxicological data provided the notified polymer is not expected to exhibit acute oral toxicity. However, it is a slight skin and eye irritant. Repeated patch testing on human volunteers was inadequate to determine its sensitisation potential. The notified polymer would not penetrate the skin at a NAMW of 2.131×10^6. Phototoxic and photoallergic potential was not demonstrated in human volunteers. The notified chemical is not determined to be a hazardous substance, according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

Occupational Health and Safety

Waterside, warehouse and transport workers will be exposed to the polymer only in the event of an accident or damaged to packaging. The occupational health risk to these workers is negligible, particularly considering the low frequency of exposure and the low hazard presented by the polymer present at 10% in Styleze CC-10.

Dermal contact due to spillage could occur during manual decanting and filling. Due to the mechanised and closed nature of the compounding process it is unlikely that these workers will come into contact with the notified polymer. However all workers are expected to wear personal protective equipment. Enclosed conditions and exhaust ventilation will minimise inhalation exposure. Therefore the risk of adverse health effects is minimal.

Considering the short duration and low frequency of exposure, small volumes of product handled and low concentration of notified polymer in the enduse products, quality control workers are not expected to come into substantial contact with the notified polymer under normal circumstances.

Similarly, a low occupational health risk exists for packaging and retail workers, who are likely to be dermally or inhalationally exposed to low concentrations of the notified polymer in the event of an accident.

Public Health

The primary hazard associated with the notified polymer is the potential for skin reactions. Due to deficiencies in the design of the Human Repeat Insult Patch Test, the observation of severe reactions in a small number of subjects and equivocal skin sensitisation reactions in a few other subjects, a potential for skin sensitisation or other skin reactions cannot be ruled out. As the potential for both skin irritation and skin sensitisation are dose related and the effects observed were either limited to few subjects or weak in magnitude with a 10% preparation of the notified polymer left in contact with the skin for 24 hours under occlusion, the use of the notified polymer at 1% in rinse off chemicals is unlikely to present a significant hazard. At higher concentrations, particularly in products intended to be left on the skin for periods of a day or longer, the inclusion of a cautionary statement on the label would be appropriate.

13. RECOMMENDATIONS

To minimise occupational exposure to Polymer in Styleze CC-10 the following guidelines and precautions should be observed:

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (Standards Australia, 1994) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand, 1992);
- Industrial clothing should conform to the specifications detailed in AS 2919 (Standards Australia, 1987) and AS 3765.2 (Standards Australia, 1990);
- Impermeable gloves should conform to AS/NZS 2161.2 (Standards Australia/Standards New Zealand, 1998);
- All occupational footwear should conform to AS/NZS 2210 (Standards Australia/ Standards New Zealand, 1994);
- Spillage of the notified chemical should be avoided. Spillages should be cleaned up promptly with absorbents which should be put into containers for disposal;
- Good personal hygiene should be practised to minimise the potential for ingestion; and
- A copy of the MSDS should be easily accessible to employees.

To ensure that consumers are alerted to the potential for skin reactions the following cautionary statement should be included in the label for products containing > 1% of Styleze CC-10:

- This preparation may cause skin reactions in sensitive persons. If a skin reaction develops stop using product.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994).

This MSDS was provided by the applicant as part of the notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under subsection 64(2) of the Act, secondary notification of the notified chemical shall be required if any of the circumstances stipulated occur.

Under subsection 64(1) secondary notification of the notified chemical shall be required if the method of use changes in such a way as to greatly increase the environmental exposure of the notified polymer, particularly to natural waters.

If the import volume increases to over 1000 kg aquatic toxicity data will have to be provided.

If the notified polymer is used at concentrations ≥ 1%, greater exposure of the public to the notified polymer will occur. Under such circumstances, further information shall be required in order to assess the risks to public health.

16. REFERENCES

Boethling SB and Nabholz JV (1997) Environmental Assessment of Polymers under the US Toxic Substances Control Act. In Hamilton JD and Sutcliffe R (eds), Ecological Assessment of Polymers, pages 213 –217 and 222. Van Nostrand Reinhold, USA.

Cerven DR (1994a) Acute Oral Toxicity (Limit Test) in the Rat, Project No. MB 94-3731 A, MB Research Laboratories Inc, PA USA.

Cerven DR (1994b) Eye Irritation to the Rabbit, Project No. MB 94-3731 D, MB Research Laboratories Inc, PA USA.

Draize JH (1959) Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics. Association of Food and Drug Officials of the US, **49**: 2-56.

Kieffer L (1994) Skin Irritation to the Rabbit, Project No. MB 94/3731 C, MB Research Laboratories Inc, PA USA.

Kanengiser BE (1997) Repeated Insult Patch Test, Project No. CRL43697, Clinical Research Laboratories Inc, NJ, USA.

Kanengiser BE (1997) Phototoxic and Photoallergy Potential, Project No. CRL38597, Clinical Research Laboratories Inc, NJ, USA.

Lewis RJ (1996) Sax's Dangerous Properties of Industrial Materials, 9th Edition, Van Nostrand Reinhold, New York, USA.

National Occupational Health and Safety Commission (1994) National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)]. Australian Government Publishing Service, Canberra.

National Occupational Health and Safety Commission 1999, Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1999)], Australian Government Publishing Service, Canberra.

Standards Australia (1987) Australian Standard 2919-1987, Industrial Clothing. Standards Association of Australia, Sydney.

Standards Australia (1990) Australian Standard 3765.2-1990, Clothing for Protection against Hazardous Chemicals Part 2 Limited protection against specific chemicals. Standards Association of Australia, Sydney.

Standards Australia (1994) Australian Standard 1336-1994, Eye protection in the Industrial Environment. Standards Association of Australia, Sydney.

Standards Australia/Standards New Zealand (1992) Australian/New Zealand Standard 1337-1992, Eye Protectors for Industrial Applications. Standards Association of Australia/Standards Association of New Zealand, Sydney/Wellington.

Standards Australia/Standards New Zealand (1994) Australian/New Zealand Standard 2210-1994, Occupational Protective Footwear. Standards Association of Australia/Standards Association of New Zealand, Sydney/Wellington.

Standards Australia/Standards New Zealand (1998) Australian/New Zealand Standard 2161.2-1998, Occupational protective gloves, Part 2: General requirements. Standards Association of Australia, Sydney.

Xu J (1994) Reverse mutation assay "Ames Test" using Salmonella typhimurium Project No. 0284-2110, SITEK Research Laboratories, MA, USA.

Attachment 1

The Draize Scale for evaluation of skin reactions is as follows:

Erythema Formation	*Rating*	*Oedema Formation*	*Rating*
No erythema	0	No oedema	0
Very slight erythema (barely perceptible)	1	Very slight oedema (barely perceptible)	1
Well-defined erythema	2	Slight oedema (edges of area well-defined by definite raising	2
Moderate to severe erythema	3	Moderate oedema (raised approx. 1 mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4

The Draize scale for evaluation of eye reactions is as follows:

CORNEA

Opacity	*Rating*	*Area of Cornea involved*	*Rating*
No opacity	0 none	25% or less (not zero)	1
Diffuse area, details of iris clearly visible	1 slight	25% to 50%	2
Easily visible translucent areas, details of iris slightly obscure	2 mild	50% to 75%	3
Opalescent areas, no details of iris visible, size of pupil barely discernible	3 moderate	Greater than 75%	4
Opaque, iris invisible	4 severe		

CONJUNCTIVAE

Redness	*Rating*	*Chemosis*	*Rating*	*Discharge*	*Rating*
Vessels normal	0 none	No swelling	0 none	No discharge	0 none
Vessels definitely injected above normal	1 slight	Any swelling above normal	1 slight	Any amount different from normal	1 slight
More diffuse, deeper crimson red with individual vessels not easily discernible	2 mod.	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
Diffuse beefy red	3 severe	Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
		Swelling with lids half-closed to completely closed	4 severe		

IRIS

Values	*Rating*
Normal	0 none
Folds above normal, congestion, swelling, circumcorneal injection, iris reacts to light	1 slight
No reaction to light, haemorrhage, gross destruction	2 severe

MSDS