File No: NA/900

July 2001

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Precis 900

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Director
Chemicals Notification and Assessment

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Precis 900

1. APPLICANT

Nuplex Industries Pty Ltd (ABN 25 000 045 572) of 49-61 Stephen Road, Botany NSW, 2019 has submitted a standard notification statement in support of their application for an assessment certificate for Precis 900.

2. IDENTITY OF THE CHEMICAL

Marketing Names: Precis, Precis 900

The chemical name, CAS number, molecular and structural formulae, molecular weight, spectral data, details of the chemical composition and details of exact import volume and customers have been exempted from publication in the Full Public Report and the Summary Report.

3. PHYSICAL AND CHEMICAL PROPERTIES

The physico-chemical properties tabulated and discussed below were determined for a material known as Precis 800 (Butterworth Laboratories, 1999a). The difference between Precis 800 and Precis 900 is primarily in the alkyl and alkenyl R and R' groups of the starting materials.

Appearance at 20 °C & 101.3 kPa:	viscous light brown liquid
Boiling Point:	> 300°C
Specific Gravity:	< 1
Vapour Pressure:	no data provided – see comments below.
Water Solubility:	5.5 mg/L (pH 3.5)
Particle Size:	not applicable as the notified chemical is a liquid
Partition Co-efficient (n-octanol/water):	log Kow > 6.3 – see comments below.
Hydrolysis as a Function of pH:	test not performed due to poor solubility.

Adsorption/Desorption:	log Koc > 4.5 – see comments below.
Dissociation Constant:	no data provided – see comments below.
Flash Point:	> 60.5 °C
Reactivity/Stability:	no reactivity anticipated under normal environmental conditions

3.1 Comments on Physico-Chemical Properties

No vapour pressure data was provided, but due to its high molecular weight the notified chemical is expected to have a very low vapour pressure.

The solubility of the chemical in double distilled water was determined using a modified shake flask method based on the procedures of OECD TG 105. The water solubility was first roughly established as being around 5 mg/L. In the definitive test an excess of test material (*ca*. 1 gram) was added to each of six flasks containing water, stirred in a water bath at 30ºC for 1, 2 and 3 days (two flasks for each time period), and transferred to a 20ºC water bath to equilibrate for at least 24 hours. Following equilibration a sample of each of the aqueous suspensions was removed, centrifuged and analysed for notified chemical using High Performance Liquid Chromatography (HPLC). Even after centrifugation the samples exhibited turbidity and this was attributed to emulsion formation. By extending the equilibration time at 20ºC it was possible to obtain six samples (one from each flask) considered suitable for HPLC analysis and these provided values for the water solubility of 5.308, 1.184, 9.203, 6.139, 4.210 and 6.210 mg/L. The two outliers of 1.184 and 9.203 mg/L were ignored and water solubility of the test material was taken as the mean of the remaining 4 samples and determined as 5.467 ± 0.933 mg/L. It was also noted that the pH of the water extracts was typically 3.52, presumably due to the residual aliphatic carboxylic acids present as impurities in the chemical.

No hydrolysis data was provided since it was considered that the low water solubility would have precluded ready and accurate determination of concentration of the notified chemical or the degradation products. However, the notified chemical contains functional groups which could be unstable under basic conditions.

The *n*-octanol/water partition coefficient (Kow) for the analogue Precis 800 was determined using a variation of the HPLC procedure of OECD TG 107. The retention time of the analogue chemical on a C18 HPLC column eluted with a suitable solvent is compared with the retention time of DDT (log Kow = 6.3) on the same column, and using the same elution solvent. In the present test while the elution peak of DDT eluted with a methanol/water solution (9:1) was observed at 5.66 minutes, no peak corresponding to that of the test material was observed even after 30 minutes. Consequently the value of log Kow for the Precis 800 was taken as > 6.3. A high value for log Kow is expected as the notified chemical contains a high proportion of saturated and unsaturated hydrocarbon.

The soil adsorption/desorption coefficient (Koc) for the analogue Precis 800 was also estimated using an HPLC method similar to that used for estimation of Kow and conformed to the draft OECD Guideline (1997) titled “Estimation of the Adsorption Coefficient (Koc) on Soil and on Sewage Sludge using High Performance Liquid Chromatography”. The

elution time of the analogue chemical on a suitable HPLC column is compared with those for a series of reference chemicals with known values of log Koc. In the present case the analogue chemical eluted at a longer time than sulprofos (log Koc = 4.46), the reference with the largest retention time, so the value of log Koc for Precis 800 was determined as being > 4.46. This indicates that the notified chemical would have a high affinity for organic matter in soils.

Although the notified chemical contains no acidic or basic functional groups, it does contain > 1 % non-hazardous impurities, which are weak acids with pKa typically 3.5-4, so Precis 900 may be slightly acidic in water. The solutions prepared during the determination of the water solubility were slightly acidic with pH 3.52.

4. PURITY OF THE CHEMICAL

Degree of Purity: high

Hazardous Impurities: None stated.

Non-hazardous Impurities (> 1% by weight): confidential

Additives/Adjuvants: None.

5. USE, VOLUME AND FORMULATION

Precis 900 will be used as a sizing agent in the paper making industry and acts by increasing the ability of the paper to repel water and thereby reduce ink running. The notified chemical will be imported as neat liquid in 1000 kg Schutz containers within shipping containers and is re-formulated into a 26 % aqueous emulsion. Precis 900 will comprise < 0.2 % by weight of the finished paper. The volume intended for importation will exceed 100 tonnes per annum for five years.

6. OCCUPATIONAL EXPOSURE

Workers potentially exposed to the notified chemical are involved in importation and transport, formulation and paper manufacturing processes.

Importation/Transport (up to four workers)
The notified chemical will be imported as a liquid in 1000 kg Schutz containers. In the event of spillage dock and transport workers may be exposed to the chemical. The notified chemical is transported by road to the notifier's formulation site in Victoria, and the reformulated product (*ca* 25 % notified chemical) is transported by road to two paper mills.

Formulation Process (4 days/week; 20 workers)
The formulation process is fully automated, where the notified chemical is pumped into a vented, fully enclosed mixing tank. Once the remaining constituents are added, the mixture (containing *ca*. 25 % notified chemical) is automatically pumped to fully enclosed 40000 L

tanks. Dermal exposure to the notified chemical may occur when transfer hoses are connected to the product containing *ca* 25 % notified chemical may occur on connection or disconnection at transfer hoses when road carriers are filled for transfer to the end sites.

Formulation workers are required to wear gloves, safety glasses and coveralls. Clean-up procedures for spillage should be carried out with additional personal protective equipment (PPE). Eye wash/shower stations are accessible thoughout the manufacturing areas. Spillages are contained in bunded areas, collected and disposed of to land-fill. Equipment servicing is carried out routinely by trained personnel. Quality control testing of the pre-product mixture is performed in a fume cupboard. Up to twenty workers are involved in the emulsion/manufacturing process.

Paper Manufacturing Process (up to six workers)
On a weekly basis, Precis 900 emulsion is pumped into road carriers for transport to the end use customer site. The emulsion is pumped into bulk storage tanks until required in the fully automated and enclosed paper making process. Dermal exposure to the product containing *ca.* 25 % notified chemical may occur during connection or disconnection of transfer hoses during transfer from the road carriers. The notified chemical is permanently adhered to the cellulose fibres at a concentration of < 0.2 %. The paper pulp is heated and residual water and effluent is fed back into the water carrier line. The paper is then boxed and sold to the domestic market. There is no worker exposure in this process.

Handling of Treated Paper
The notified chemical is reportedly irreversibly bound to the paper, so there is no exposure for workers handling treated paper.

7. PUBLIC EXPOSURE

Public exposure to the notified chemical is expected to be high, as paper containing the notified chemical will be sold to the domestic market. However, during the paper making process, the notified chemical is irreversibly bound to the paper matrix. Therefore, public contact with the notified chemical in paper products will be negligible.

8. ENVIRONMENTAL EXPOSURE

8.1 Release
Very little release of the notified chemical is expected during formulation of the 25 % emulsion. The notifier indicated that a maximum of 50 kg of the chemical would be lost as a result of spills or equipment leaks, contained within bunding, collected and placed into landfill by a licensed waste operator. Some Precis 900 would remain as residues in the emptied Schutz containers, but the notifier indicated that this was likely to amount to a maximum of 100 kg per annum, and recovered into a waste sludge during washing and refurbishment of the containers. This sludge would be incinerated or placed into landfill. Overall, the notifier anticipates losses of approximately 150 kg per annum of the notified chemical resulting from reformulation into emulsion, and this is likely to be placed into landfill.

Small quantities of the 25 % emulsion may be lost as a result of spills or leaks during transfer of the emulsion to the paper machines, and the notifier indicated that total annual losses would be a maximum of 50 kg per annum. These losses would presumably be absorbed onto sawdust or other suitable materials and be disposed of into landfill. Since the manufacture of the paper is a fully enclosed process with all excess water returned to the process, no release of Precis 900 is expected.

The notifier indicated that approximately 100 kg of Precis 900 may remain in the storage tanks. Periodically these would be drained and the waste pumped to the plant effluent treatment facility where it is likely that the Precis 900 would react with waste cellulose (eg. paper pulp), eventually associate with sludge, and be either incinerated or placed into landfill.

The notified chemical is chemically bound to the cellulose fibres in the paper and no release is expected through handling of the paper, or through its use as a packing material.

8.2 Fate

Most of the notified chemical will become incorporated into paper at a maximum level of 0.2 % through chemical binding to the cellulose fibres. Consequently, the fate of most of the notified chemical will be that of the paper. Waste paper will be burnt, placed into landfill, or repulped and used in the production of recycled paper. No indication of the amount of paper likely to be recycled was given in the notification.

A small quantity of the notified chemical (*ca.* 300 kg per annum) may be released during reformulation and use during manufacture of water repellent paper. The majority of this is likely to be placed into landfill although some may be incinerated.

No data on the biodegradation of Precis 900 was provided, although the notifier provided a report (Butterworth Laboratories, 1999b) on the biodegradation of the very similar chemical Precis 800. This differs from the notified chemical only in having slightly different fatty acid starting materials. Precis 800 was found to be not readily biodegradable, and in a CO_2 evolution test (OECD TG 301 B) only 13 % degradation was observed after 28 days incubation of suspensions of the test material with sewage sludge. This test was performed in duplicate using suspensions containing nominally 18.7 mg/L of Precis 800 (equivalent to 15 mg/L of organic carbon) in the sewage inoculum, with the volume of evolved CO_2 determined periodically over the 28 day test period. In contrast the reference material sodium benzoate was more than 80 % degraded over the 28 day test period, which established the viability of the sewage bacteria used in the test. Although Precis 800 was not readily biodegradable under the stringent conditions of this test, it can be considered to be ultimately biodegradable, and it is likely that the notified chemical (Precis 900) would exhibit similar behaviour.

It is also to be noted that in the above test using a mixture of Precis 800 and sodium benzoate as substrate, the rate of CO_2 evolution was close to the sum of that from sodium benzoate and Precis 800 alone, indicating that the notified chemical is not inhibitory to the bacterial action.

Incineration would destroy the notified chemical with evolution of water vapour and oxides of carbon. The notified chemical is likely to be ultimately degradable, and in a landfill would be slowly mineralised to water and carbon dioxide through slow biological and abiotic processes. The high log Koc suggests that if the notified chemical were liberated from the degrading cellulose prior to being attacked by bacteria, it would associate with organic matter

in soils and sediments and immobilise with little likelihood of leaching into the wider water compartment.

The low water solubility (5.5 mg/L), high log Kow (>6.3) and modest molecular weight indicate that the notified chemical may have a high potential for bioconcentration (Connell, 1990). However, since very little of the notified chemical is expected to reach the water compartment, bioaccumulation is unlikely. Despite the possibility for bioconcentration, slow biodegradation of the notified chemical is expected to preclude bioaccumulation.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

There is no data available for the notified chemical, however some acute toxicology data has been provided for the analogue Precis 800.

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 2000 mg/kg	Covance, 1999a
acute dermal toxicity	rat	LD_{50} > 2000 mg/kg	Covance, 1999b
eye irritation	rabbit	slight irritant	Covance, 1999c

9.1.1 Oral Toxicity (Covance, 1999a)

Species/strain:	Crl:WI(Glx/BRL/Han)BR; Charles River
Number/sex of animals:	5/sex
Observation period:	15 days
Method of administration:	Oral gavage at 2000 mg/kg in corn oil (10 mL/kg). Preliminary doses of 5, 50, 500 and 2000 mg/kg were used to determine the highest non-lethal threshold.
Test method:	OECD TG 420
Mortality:	No animals died during the experimental time.
Clinical observations:	No observable clinical signs. All rats recorded weight gains during the observation period.
Morphological findings:	No macroscopic changes were observed following necropsy.
LD_{50}:	The minimum lethal dose was greater than 2000 mg/kg.
Result:	The notified chemical was of very low acute oral toxicity in rats under the stated conditions.

9.1.2 Dermal Toxicity (Covance, 1999b)

Species/strain:	Crl:WI(Glx/BRL/Han)BR; Charles River
Number/sex of animals:	5/sex
Observation period:	8 days
Method of administration:	Applied undiluted to the clipped dorsum on day 1 at 2000 mg/kg and covered by a semi-occlusive dressing for 24 hours
Test method:	OECD TG 402
Mortality:	No animal died during the observation period.
Clinical observations:	Two male and two female rats showed staining of the snout, anogenital soiling (one male and one female observed at up to day 3); there was one case of chromodacryorrhoea or reddish conjunctival exudate. Changes were apparent from 30 minutes after treatment. All animals were normal 3 days after treatment. The majority of rats achieved body weight gains in both weeks of the study. All animals scored 0 for erythema or oedema on the Draize scoring method.
Morphological findings:	No macroscopic changes were apparent during necropsy, except distension of the jejunum and rectum in one female and uterine distension in another female.
Comment:	A preliminary study using two females and a dose level of 2000 mg/kg was conducted. The observable dermal reactions were limited to snout and/or anogenital soiling on day 2 (only). No other test dose was used.
LD_{50}:	Acute LD_{50} was greater than 2000 mg/kg.
Result:	the notified chemical was of low dermal toxicity in rats under the stated conditions.

9.1.3 Eye Irritation (Covance, 1999c)

Species/strain:	Albino Rabbit / New Zealand White
Number/sex of animals:	3/female
Observation period:	72 hours

Method of administration: Single ocular instillation into the conjunctival sac (100 µL of neat notified chemical)

Test method: OECD TG 405[1,2]

Draize scores of unirrigated eyes:

Time after instillation

Animal	***1 day***			***2 days***			***3 days***		
Cornea	All Draize scores were zero								
Iris	All Draize scores were zero								
Conjunctiva	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***
1	1*	0	2*	0	0	0	0	0	0
2	1*	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0

[1] see Attachment 1 for Draize scales
r = redness c = chemosis d = discharge * = 4 hours after instillation

Irrigated eyes: No data reported.

Comment: Single ocular instillation of the notified chemical into the rabbit eye caused no corneal opacity or iridial inflammation. Conjunctival irritation was limited to incidences of hyperaemia and discharge that moistened the eyelids and hairs adjacent to the eye. All reactions had resolved by 24 hours post instillation. Group mean values for ocular reactions were 0, with the exception of conjunctival redness (0.7 at 1 and 4 hours after instillation). There was no initial instillation sting response caused by the notified chemical.

Result: the notified chemical was a slight irritant to the eyes of rabbits

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (Covance, 1999d)

Strains: TA 98, TA 100, TA 1535, TA 1537 and TA 102

Metabolic activation: 10 % S9 fraction from rats pre-treated with Arochlor 1254.

Concentration range: 40, 200, 312, 625, 1000, 1250, 2500, 5000 μg/plate in acetone.

Test method: OECD TG 471 (plate incorporation and preincubation methods)

Comment: Precipitation was noted at concentrations above 1000 μg/plate. Acetone was used as the negative solvent control, while positive controls were 2-nitrofluorene (DMSO), NaN_3 (water), 9-aminoacridine (DMSO), Glutaraldehyde (water) and 2-aminoanthracene (DMSO). There was no statistically significant increase in the number of revertant colonies in any of the tester strains. There was a noted decrease in revertant colonies of TA 102 in the absence of S9, possibly due to toxicity of the notified chemical. This trend was less pronounded in the TA 102 system with S9. Control plates behaved according to historical controls.

Result: The notified chemical was non mutagenic under the conditions of the test.

9.3.2 Chromosomal Aberration Assay in Precis 800 (Covance, 1999e)

Cells: Cultured human peripheral blood lymphocytes

Metabolic activation system: 2 % S9 fraction from rats pre-treated with phenobarbitone and β-naphthoflavone

Dosing schedule: 2450, 3500 and 5000* μg/mL.

Metabolic Activation	Experiment Number	Treatment Time	Controls
-S9	1	treatment time = 3 hours	Positive: NQO
	2	treatment time = 20 hours	Negative: acetone and culture medium
+S9	1	treatment time = 3 hours	Positive: CP
	2	treatment time = 3 hours	Negative: acetone and culture medium

NQO- 4-Nitroquinoline-1-oxide DMSO – dimethylsulphoxide
CP - cyclophosphamide * - cultures selected for metaphase analysis

Test method: OECD TG 473

Comment: In Experiment 1, the notified chemical precipitated and formed an emulsion during the treatment period at concentrations between 70 and 100 μg/mL (-S-9) and below 50 μg/mL (+ S-9). There was no marked increase in osmolarity or pH upon addition of Precis 800.

Likewise, in Experiment 2, an emulsion was formed during the treatment period at *ca* 400 μg/mL (+S-9) and persisted through to the harvest time when treatment was extended to 20 hours.

There was no measurable mitotic inhibition in Experiment 1 for doses up to 1715 μg/mL (+/-S-9). Mitotic inhibition for 2450, 3500 and 5000 μg/mL (-S-9) was 10, 39 and 0 % respectively, while 18, 9, and 28 % mitotic inhibition was observed for these doses with S-9.

There was no measurable mitotic inhibition reported in Experiment 2 for doses up to 400 μg/mL (+/-S-9). Mitotic inhibition for 588, 840, 1200, 1715, 2450, 3500 and 5000 μg/mL (-S-9) was 13, 8, 0, 13, 28, 18 and 18 % respectively. The mitotic inhibition was reduced with the use of S-9 (0, 14, 0, 0, 0, 2 and 0 % respectively).

Small but statistically significant increases in structural aberrations were observed in several cultures, particularly for Experiment 2, -S9, at 1201 μg/mL (20 hr treatment), but these were not dose dependent or reproducible.

Result: The notified chemical was non clastogenic under the conditions of the test

9.4 Overall Assessment of Toxicological Data

Toxicological data were provided for a chemical with a close structural relationship to the notified chemical, Precis 800. This data is accepted as representing the toxicity of the notified chemical. The data showed that the surrogate chemical was of very low acute oral toxicity in the rat (LD_{50} > 2000 mg/kg). The acute dermal toxicity was low (LD_{50} > 2000 mg/kg). The analogue chemical was a slight irritant to the eyes of rabbits, with conjunctival effects seen on the day of dosing. Skin irritancy tests were not conducted, with the following given as justification; (i) no skin irritancy was observed in the dermal limit test (ii) impurities in Precis 900 are mild to moderate human skin irritants (Lewis, 1996). The impurities are present at below standard cut-off for a skin irritant is 20 % according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (Approved Criteria) (NOHSC, 1999).

In genotoxicity studies, the analogue Precis 800 tested negative in the Ames *Salmonella typhimurium* test and was not clastogenic in the chromosomal aberration assay.

Based on the analogue studies provided, the notified chemical is not classified as a hazardous substance in accordance with the Approved Criteria.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No experimental data on the toxic effects of the notified chemical was provided in the dossier, although the notifier stated that experiments had shown that the LC_{50} for Precis 800 against both trout (presumably juvenile rainbow trout – *Onchyrinkus mykiss*) and daphnia (presumably *Daphnia magna*) were > 10000 mg/L. The original test reports documenting these tests could not be obtained by the notifier.

However it is possible to estimate toxic end points through use of appropriate Quantitative Structure Activity Relationships (QSARs), and the notifier provided a copy of a paper describing such a method (Van Leeuwen *et al*, 1992). Using the experimental value for log Kow > 6.3 and taking 476 g/mol as a representative molecular weight for the notified chemical, the following end points were calculated using the methods and equations described in this paper.

Species	Result (QSAR)
Fish, fathead minnow (*Pimephales promelas*)	LC_{50} (96 h) < 0.082 mg/L
Daphnia magna	EC_{50} (48 h) < 0.032 mg/L
Algae (*Skeletonema costatum*)	EC_{50} (96 h) < 1.58 mg/L

These QSAR estimate very high to high toxicity to aquatic species at levels well below the measured water solubility of the notified chemical (5.5 mg/L). It is to be noted that QSAR estimates for toxicity have been shown to be very questionable unless strong structural similarity exists between the test chemical and those from which the QSAR was derived, and this is particularly relevant for chemicals having values for log Kow in excess of 6. Consequently, while the QSAR estimates indicate possible toxicity to aquatic species, the true toxicity of the notified chemical is unlikely to be as high as the results in the table above suggest.

It is also to be noted that in the biodegradation test (Butterworth Laboratories, 1999b), Precis 800 was found non-toxic to sewage sludge bacteria.

Despite the possible toxicity of the notified chemical to aquatic organisms, due to low release rates and the high affinity for the organic component of soils and sediments the notified chemical is unlikely to reach the water compartment at concentrations likely to cause significant toxic effects.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Very little release of the notified chemical is anticipated during either reformulation into the aqueous emulsion or during the final use of the emulsion in the manufacture of water repellent paper. The notifier indicated a maximum annual release in association with waste sludge from water treatment facilities at the reformulation plant or the paper mills of around 300 kg for these activities. Most of the released chemical would be either incinerated or be placed into landfill. The fate of most of the chemical will be the same as that of the paper, namely incineration, landfill or paper recycling. Incineration of the chemical will destroy it

with production of water and oxides of carbon. Although not classified as being readily biodegradable, the notified chemical in landfill is expected to undergo slow decomposition and mineralisation to water and carbon dioxide through slow biological and abiotic processes.

The notified chemical has a high affinity for the organic component of soils and sediments and very little is expected to reach the water compartment. Although it has potential for bioconcentration, this is not considered to be a hazard since very little is likely to reach the water compartment. There is little potential for bioaccumulation due to the expected low potential for bioconcentration and the demonstrated slow but definite biodegradation.

No reports on the aquatic toxicity of the notified chemical were provided although the notifier stated that experiments had shown that the LC_{50} against both trout and daphnia were > 10000 mg/L. No toxicity of Precis 800 to sewage bacteria was observed in the test on biodegradation. However, QSAR estimates indicate the possibility for toxicity of the notified chemical against aquatic species, although these estimates should be treated with caution.

Despite the possibility for toxicity, due to the low expected release rate and the high affinity of the notified chemical for the organic component of soils and sediments it is unlikely that the notified chemical would reach the water compartment in sufficient concentration to cause significant damage.

When used in the manner indicated as a sizing to impart water repellency to paper, the notified chemical is not considered hazardous to the environment.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Hazard Summary

Toxicological data were provided for a chemical with a close structural relationship to the notified chemical, Precis 800. The data suggest that the notified chemical will be of very low acute oral toxicity and low acute dermal toxicity in the rat, a slight irritant to the eyes of rabbits, non-mutagenic and non-clastogenic.

Based on the studies provided, the notified chemical is not classified as a hazardous substance in accordance with the Approved Criteria.

Occupational Health and Safety Risk Assessment

Only in the event of spillage would dock and transport workers be exposed to the chemical. Precis 900 is viscous and has negligible vapour pressure. Consequently, inhalation is not considered a significant route of exposure under normal use conditions.

The formulation process is fully automated and workers are required to wear gloves, safety glasses and coveralls. The notified chemical is diluted from neat to *ca* 25 %. Worker exposure is expected to be negligible except in the event of spillage, when additional PPE is recommended. Dermal exposure to the neat or 25 % notified chemical may occur when transfer hoses are connected or disconnected when filling storage tanks or road tankers. Given the anticipated low toxicity of the notified chemical, the health risk to workers is low.

During paper manufacturing, the emulsion is pumped into bulk storage tanks then

automatically fed into the papermaking machine. There is no worker exposure in this process. The notified chemical is permanently adhered to the cellulose fibres at a concentration of < 0.2 %.

There is negligible risk to workers handling treated paper.

Public Health
Public exposure to the notified chemical is expected to be high, as paper containing the notified chemical will be sold to the domestic market. However, as the notified chemical is irreversibly bound to the paper matrix, public contact with the notified chemical in paper products will be negligible. The notified chemical is of low toxicity, consequently the public risk from the notified polymer through all phases of its life-cycle is considered to be low.

13. RECOMMENDATIONS

To minimise occupational exposure to Precis 900, the following guidelines and precautions should be observed:

- Safety goggles, chemical resistant industrial clothing and footwear and impermeable gloves should be used while handling the notified chemical;
- Spillage of the notified chemical should be avoided. Spillages should be cleaned up promptly with absorbents which should be put into containers for disposal;
- A copy of the MSDS should be easily accessible to employees.

If products containing the notified chemical are hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999), workplace practices and control procedures consistent with State and Territory hazardous substances regulations must be in operation.

Guidance in selection of goggles may be obtained from Australian Standard (AS) 1336 (Standards Australia, 1994) and Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand, 1992); for industrial clothing, guidance may be found in AS 2919 (Standards Australia, 1987) and AS 3765.2 (Standards Australia, 1990); for impermeable gloves or mittens, in AS 2161 (Standards Australia/ Standards New Zealand, 1998); for occupational footwear, in AS/NZS 2210 (Standards Australia/ Standards New Zealand, 1994a).

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 the Act, the director must be informed if any of the circumstances stipulated under subsection 64(2) of the Act arise, and secondary notification of the notified chemical may be required. No other specific conditions are prescribed.

16. REFERENCES

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Covance (1999b) Precis 800: Acute Dermal Toxicity Study in the Rat, Study No. 664/4 Covance, Harrowgate, England, 1999 (unpublished report)

Covance (1999c) Precis 800, Eye Irritation Study in the Rabbit, Study No. 664/6 Covance, Harrowgate, England, 1999 (unpublished report)

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Attachment 1

The Draize Scale (Draize, 1959) 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 (Draize *et al*., 1944) 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.
		Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
Diffuse beefy red	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

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