File No: NA/982

March 2002

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

INTERSEPT

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Director
Chemicals Notification and Assessment

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INTERSEPT

1. APPLICANT

Interface Australia Pty Ltd (ABN 39 000 692 026) of 4 Henry St PICTON NSW 2571 has submitted a standard notification statement in support of their application for an assessment certificate for INTERSEPT.

2. IDENTITY OF THE CHEMICAL

The chemical name, CAS number, molecular and structural formulae and composition have been exempted from publication in the Full Public Report and the Summary Report.

Other Names:	Carpet treatment, DO4816
Marketing Name:	INTERSEPT
Molecular Weight:	The notified chemical consists of three components with molecular weights of 595.9, 483.7 and 210.2.
Method of Detection and Determination:	High Performance Liquid Chromatography – Mass Spectrometry (HPLC – MS).
Spectral Data:	HPLC – MS data were provided.

3. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa	Light yellow viscous liquid with amine odour.
BOILING POINT	No Data.

METHOD OECD TG 103.
TEST FACILITY SEPC (1990).
Remarks Test not completed as compound decomposed without boiling above 250°C.

FREEZING POINT -39°C

METHOD OECD TG 102.
TEST FACILITY SEPC (1990).

DENSITY	$D_4^{20} = 0.99$

METHOD OECD TG 109.
TEST FACILITY SEPC (1990).
Remarks The test was performed at 22.5°C, and some microbubbles of air could not be removed from the pycnometer. However, these minor differences from the test protocol were not considered significantly large to greatly affect the final result.

VAPOUR PRESSURE	No data.

METHOD OECD TG 104.
TEST FACILITY SEPC (1990).
Remarks Although an attempt to determine the vapour pressure was made, variations in the measured data with time precluded definitive analysis of the results. Accordingly no quantitative data on this property are available, but the relatively high molecular weights and polar natures of the three principal components indicate that the vapour pressure at ambient temperature will be low.

WATER SOLUBILITY	1.68 mg/L of P at 20°C. This equates to approximately 300 mg/L of the notified chemical.

METHOD OECD TG 105.
TEST FACILITY SEPC (1990).
Remarks The test was performed using the column elution method, with the concentration of the test material in the equilibrated solution determined for contained phosphorus by spectrophotometry. The pH of the eluate was approximately 6 (as determined by pH paper). Although two of the compounds present in the new substance are ions, the large aliphatic hydrocarbon component of each of these apparently preclude measurement of true water solubility.

HYDROLYSIS AS A FUNCTION OF PH	No data provided.

Remarks All three major components of the new substance contain phosphate ester groups, and while these may hydrolyse under extreme pH conditions hydrolytic degradation is unlikely in the usual environmental pH region between 4 and 9.

PARTITION COEFFICIENT (N-OCTANOL/WATER)	No data provided.

Remarks The various ions comprising the new chemical are surface active (see remarks on surface tension measurements below) and consequently the n-octanol/water partition coefficient may have little relevance for this mixture of compounds. However, the compound is completely soluble in n-octanol and in standard fat in all proportions (see below) indicating that

it has high affinity for organic phases.

ADSORPTION/DESORPTION No data provided.

Remarks The high affinity of the compound for n-octanol and fat indicates a high affinity for organic matter, and if released to the soil the notified chemical is expected to become associated with the organic components of soil and sediments.

DISSOCIATION CONSTANT No data provided.

Remarks The notified material contains 17.7% of phosphoric acid, mono (2-ethylhexyl) ester which is expected to be acidic with pKa1 expected to be 2-3 and pKa2 expected to be 6-8. The acid number of the material is quoted as 185 (SEPC, 1990) which indicates the presence of dissociable acidic groups.

FLASH POINT 167.5°C

METHOD EEC Directive 84/449 – Annex V – method A9.
TEST FACILITY SEPC (1990).
Remarks Correction of the observed flash point was made to a pressure of 101.3 kPa and the mean of the corrected flash points was rounded to the next 0.5°C.

FLAMMABILITY Not flammable.

METHOD EEC Directive 84/449 – Annex V – method A13.
TEST FACILITY SEPC (1990).
Remarks No ignition was observed at 24.5°C.

AUTOFLAMMABILITY (LIQUIDS) 382°C

METHOD EEC Directive 84/449 – Annex V – method A15.
TEST FACILITY SEPC (1990).
Remarks Owing to the viscosity of the test substance, it was not possible to determine exactly the volume or the quantity used. Each assay was performed with one drop of the test substance from the hypodermic syringe.

EXPLOSIVE PROPERTIES Not explosive.

METHOD EEC Directive 84/449 – Annex V – method A14.
TEST FACILITY SEPC (1990).
Remarks Only heat and mechanical sensitivity (shock) tests were performed. The study of mechanical sensitivity (friction) was not performed as the material is a liquid.

ADDITIONAL TESTS

N-OCTANOL SOLUBILITY	Miscible in all proportions with n-octanol.

METHOD	EEC Directive 84/449 Method A8.
TEST FACILITY	SEPC (1990).
Remarks	The notified substance was found to be miscible in all proportions with n-octanol, and this is in accord with the high alkyl group content of the substance. This result indicates that the compound will have high affinity for lipid and other organic environments.

FAT (OR N-OCTANOL) SOLUBILITY	Miscible in all proportions with standard fat

METHOD	OECD TG 116.
TEST FACILITY	SEPC (1990).
Remarks	As with the solubility in n-octanol, the full miscibility with fat is in accord with the high alkyl group content of the new chemical.

SURFACE TENSION	37.2 mN/m at 20ºC.

METHOD	OECD TG 115 Surface Tension of Aqueous Solutions.
TEST FACILITY	SEPC (1990).
Remarks	Reference to the chemical structure of the three principal components of the notified chemical indicates that the organic ions should have surfactant properties – ie. a large aliphatic hydrocarbon moiety bonded to a polar "head" group. This is confirmed by the measurements (SEPC 1990) which indicate significant surface activity for the notified chemical.

4. PURITY OF THE CHEMICAL

Degree of Purity:	The notified chemical comprises three components. The toxicological data tabulated in section 9 were derived using this mixture. These components comprise 100% of the notified chemical.
Additives/Adjuvants:	The notified chemical is blended with ammonium hydroxide prior to carpet manufacture.

5. USE, VOLUME AND FORMULATION

The notified chemical is used as a bacteriocide/fungicide in the manufacture of carpets. It is first neutralised with ammonium hydroxide then incorporated into a precoat which attaches the carpet fibers to a backing material. It will be imported neat at 9 tonnes per year for the first five years in 205 L plastic lined steel drums.

6. OCCUPATIONAL EXPOSURE

Unloading the imported drums at the wharf and their transportation to the warehouse is accomplished by 4 workers each working 4 hours per day, 4 days per year. Exposure to the notified chemical is unlikely except in the event of drum rupture via a transport or warehouse accident.

The notified chemical is neutralised with ammonium hydroxide solution in a mixing vat to a concentration of 74%. Two workers (drum handlers, process workers, container recyclers and storage tank workers) work 1 hour per day, 4 days per year. The drum contents are poured into the mixing vat using a mechanical drum lifter. Ammonium hydroxide solution is added to the open mixing and the contents are mixed at a moderate speed. The viscosity of the notified chemical precludes inhalation exposure and aerosols are not produced during any of the mixing operations according to the notifier. Initially the plastic liners from the drums, containing approximately 100 – 150 mL of the notified chemical will be removed and sent to landfill. At a later date they will be used as feedstock for the manufacture of the bitumus backing for carpets. There appears to be some potential for dermal and ocular exposure to small amounts of the notified chemical during handling of the drums and of the plastic lining. The notifier has indicated that workers are required to wear personal protective equipment (PPE) such as gloves, goggles, respirator, overalls and safety shoes to prevent exposure.

Following mixing, the solution of notified chemical and ammonium hydroxide is pumped via gravity feed to a 1000 L storage container using a sealed transfer line. Prior to this small samples are removed for testing and dermal and ocular exposure of laboratory workers may be possible.

The notified chemical solution is pumped via a fully enclosed system to the precoat mixing tank where mixing into the precoat occurs using a screw mixer or ribbon blender prior to pumped via fully enclosed system to bulk tankers. The final concentration of notified chemical in the precoat is 1.5%. Minimal worker exposure is expected during these operations and is further precluded by the use of personal protective equipment. The notifier states that at the site of mixing the notified chemical with ammonium hydroxide solution and then into the precoat, dedicated equipment is to be used, decontamination of the equipment is not necessary and all rinse water is recycled. Therefore, worker exposure from equipment cleaning is likely to be low.

For preparation of the precoat two workers (1 hour per day, 17 days per year) will be involved in each of the following operations: handling of the 1000 L containers, performing the process, transfer of the precoat to tankers and transport of the precoat to the carpet manufacturing site.

Two workers (1 hour per day, 17 days per year) are responsible for pumping precoat from the bulk tankers to the application system by fully enclosed transfer. Two workers each (8 hours per day, 220 days per year) are responsible for process work, container recycling or carpet storage. In the precoat application system a roller is used to apply the precoat and a blade removes excess to the application tank. Following application, the precoat is dried and hardened in a heated drying oven with air circulation and extraction. Exposure during these operations should be low.

Exposure of workers to the notified chemical in the finished carpet should be minimal as the notified chemical in encapsulated.

7. PUBLIC EXPOSURE

Exposure of the public as a result of transport and disposal of products containing the notified chemical is assessed as being negligible.

Public exposure to the notified chemical will be widespread and will occur primarily as a result of dermal contact with treated carpet products. Inhalation exposure to INTERSEPT as a result of out-gassing from treated carpets is considered to be unlikely since the notified chemical has a relatively low volatility and is unlikely to become airborne after inclusion in the polymer matrices of pre-coat materials. However, as carpets wear and backing materials and/or fibres are broken from treated carpets small particles may become a part of dust and could be inhaled. Ingestion exposure is also possible, especially in young children, as a consequence of dermal contact with treated carpet and transfer of material from the hands to the mouth.

INTERSEPT treated carpets will be used in domestic, industrial and commercial buildings. The notifier considered the potential exposure of adults in a workplace (office) environment, elderly people in a nursing home environment, pregnant women in a hospital and children in a day-care environment. The notifier did not consider exposure to treated carpets used in a domestic environment.

Dermal exposure scenarios

The notifier's risk assessment assumed, as a worst case, that the skin surface area potentially exposed to treated carpets was limited to the forearms and hands for adults in a workplace (2000 cm^2), the forearms, hands and feet of pregnant women in a hospital and residents of nursing homes (3100 cm^2) and the head, hands, legs, neck and arms (approximately 25% of the total body surface area or 1830 cm^2) for a child of about 2-6 years of age. However, it was considered that the hands, feet, lower legs, forearms, head and neck may potentially be exposed in all adults. In addition a small child (<2 years old) may potentially have almost all of its skin surface exposed to treated carpet since small children may often be naked when placed and/or playing on carpets. Both of these exposure scenarios may be equally applicable to adults or small children in a domestic environment.

Using the same source of information on body surface areas as used by the notifier, body surface areas exposed in adults is assumed to be 6350 cm^2 and for a child it was assumed to be 4600 cm^2 (MIMS, 2001). Body weights were assumed to be 70 kg for adults, 58 kg for a pregnant women, and 10 kg for a child of approximately 1 year of age.

The amount of INTERSEPT potentially transferred to the skin was estimated from data from wipe sampling and hot water extraction experiments (details of which were not provided). Wipe sampling revealed no detectable INTERSEPT, therefore the dislodgeable residue of INTERSEPT was assumed to be half of the limit of detection (1ppm) and the amount transferred to the skin was calculated using the formula:

Daily amount on skin = skin surface area in contact with carpet x carpet depth (0.1cm) x fibre density (1g/cm^3) x dislodgeable residue

The daily external dose was calculated as: *Daily amount on skin/ body weight.*

The notifier assumed that only the 2 ethyl hexyl phosphoric acid ester portion of INTERSEPT would penetrate through the skin and that 100% of this portion would be absorbed and calculated the daily internal dose as:

Daily internal dose = daily external dose x penetrable portion.

However, as an absolute worst case, it was considered that all portions of the INTERSEPT mixture would be 100% absorbed and therefore the daily internal dose would equal the daily external dose. The scenario specific internal dose was then calculated as:

$$\textit{Scenario specific daily internal dose} = \frac{\textit{Daily internal dose x frequency x duration}}{\textit{Averaging time}}$$

with the averaging time assumed to be equivalent to the exposure duration and the following frequencies and durations of exposure for each specific scenario:

250 8 hour days/year over 25 years for a working adult;
365 days 24 hours/day for 30 years for a nursing home resident;
180 days/year 24 hours/day for 6 months for a pregnant woman;
250 10 hour days/year for 5 years for a child in day care

The dislodgeable residue of INTERSEPT was also calculated using data from a hot water extraction experiment (details not supplied). New carpet samples and old carpet samples (129cm^2) yielded 12 and 11 ppm INTERSEPT respectively after hot water extraction or approximately 0.9 μg of INTERSEPT/cm^2 of carpet. The daily amount transferred to the skin was then calculated as:

Daily amount on skin = skin surface area x dislodgeable residue

and the daily external and internal doses and scenario specific doses were calculated according to the equations above using the same frequencies and durations of exposure.

Ingestion exposure scenario

For an assessment of ingestion exposure by a small child, it was assumed that a child would lick or otherwise put into his/her mouth four times/day the amount of material deposited onto the palm of the hands, which was assumed to be approximately half of the surface area of the hand or 100cm^2. The daily amount on the skin and the daily external dose were calculated using the equations above and the daily internal dose was identical to the daily external dose, assuming 100% absorption. The daily ingested dose was calculated as:

$$\textit{Daily ingested dose} = \frac{\textit{daily internal dose x no. events/day x frequency x duration}}{\textit{Averaging time}}$$

As for dermal exposures, ingestion exposures were calculated using data from both wipe sampling and hot water extraction experiments.

Irritation and sensitisation

For skin irritation it was assumed that the concentration on the skin would be the same as the concentration of INTERSEPT available from the carpet and was calculated using carpet thickness, fibre density and dislodgeable residue (by wipe sampling) as given above. The dose for skin sensitisation is assumed to be the same dose as for potential skin irritation. For eye irritation it was assumed that 10% of the dermal dose could be transferred to the eye. The notifier assessed the potential for pulmonary sensitisation to INTERSEPT (results shown below) however, it was considered that inhalation exposure was unlikely and therefore no independent assessment of potential for pulmonary sensitisation was conducted.

Dermal and systemic exposure using wipe sample data

Scenario	Dermal contact area (cm^2)	Daily amount on skin (mg/day)	Daily external dose (mg/kg/day)	Daily internal dose (µg/kg/day)	Scenario specific internal dose (µg/kg/day)
Adult in work environment	6350	0.32	4.5×10^{-3}	4.5	3.1
Adult in nursing home	6350	0.32	4.5×10^{-3}	4.5	4.5
Pregnant women in hospital	6350	0.32	5.5×10^{-3}	4.5	2.3
child	4600	0.23	2.3×10^{-2}	2.3	15.6

Dermal and systemic exposure using hot water extraction data

Scenario	Dermal contact area (cm^2)	Daily amount on skin (mg/day)	Daily external dose (mg/kg/day)	Daily internal dose (µg/kg/day)	Scenario specific internal dose (µg/kg/day)
Adult in work environment	6350	5.7	8.2×10^{-2}	82	55.8
Adult in nursing home	6350	5.7	8.2×10^{-2}	82	82
Pregnant women in hospital	6350	5.7	9.8×10^{-2}	98	48
child	4600	4.1	4.1×10^{-1}	410	279

Ingestion exposure for a small child

Data source	Dermal contact area (cm^2)	Daily amount on skin (mg/day)	Daily external dose (mg/kg/day)	Daily internal dose (µg/kg/day)	Scenario specific internal dose (µg/kg/day)
Wipe sample	100	0.005	5×10^{-4}	0.5	1.3
Hot water extraction	100	0.09	9×10^{-3}	9	24.6

8. ENVIRONMENTAL EXPOSURE

8.1 Release

RELEASE OF CHEMICAL AT SITE

1. ***Conversion of Intersept***

No information on the release of INTERSEPT from its neutralisation with ammonia was provided, but this is not expected to be large. However, some will be lost as a result of spills and leaks and as a worst case up to 1% (200 kg per annum) may be released in this manner. Due to the viscous nature of the chemical such spills are expected to be soaked up with vermiculite or other absorbent material and would then be placed into landfill or may possibly be incinerated.

2. ***Precoat Formulation***

No information on the release of INTERSEPT from its incorporation into the precoat was provided, but again this is not expected to be large, with any releases associated with spills and leaks. As a worst case up to 1% (200 kg per annum) may be released in this manner, and as above these spills are expected to be soaked up with absorbent material and either placed into landfill or incinerated.

3. ***Precoat Application***

Little release of precoat (or of the contained INTERSEPT) is anticipated during application to the carpet and in subsequent curing. However, it is likely that some precoat will remain unused at the end of each carpet manufacturing run, and this is also likely to be either incinerated or be placed into landfill. No estimates of the amount of waste precoat which remains unused was provided in the application, but again this is not expected to be large, with any releases associated with spills and leaks. As a worst case up to 5% (450 kg per annum) may be released in this manner, and as above these spills are expected to be soaked up with absorbent material and either placed into landfill or incinerated.

RELEASE OF CHEMICAL FROM USE

Very little of the chemical will be released from the carpet during its service life since it is incorporated into a cured polymer matrix between the carpet and its backing material. However, after the carpet has become worn it would be placed into landfill, and consequently the majority of the imported chemical will end up in landfill in this manner.

8.2 Fate

8.2.1. Ready biodegradability

TEST SUBSTANCE	INTERSEPT
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution

	Test (Modified Sturm Test) – CAA Bioremediation Systems, 1989.
Inoculum	Sewage bacteria.
Exposure Period	28 days
Auxiliary Solvent	None.
Analytical Monitoring	CO_2 absorption by 0.025M $Ba(OH)_2$ solution, followed by titration of residual $Ba(OH)_2$ with standardised HCl solution.
Remarks - Method	The degree of biodegradation was calculated from comparison of the measured quantity of CO_2 evolved with the theoretical maximum amount estimated from the total carbon content of the test material (Cambridge Analytical Associates Bioremediation Systems, 1989).

Results

Test substance (20 mg/L)		Sodium acetate Reference (20 mg/L)	
Day	% degradation	Day	% degradation
1	0	1	12
5	25	5	65
16	61	16	86
28	75	28	86

Remarks - Results	Another test using 10 mg/L of the test compound was also run, and the % degradation was at least as good on all days as for the 20 mg/L test.
CONCLUSION	On the basis of these results the test compound is classified as being readily biodegradable since 60% degradation was achieved within 10 days of having reached 10% degradation.
TEST FACILITY	Cambridge Analytical Associates Bioremediation Systems (1989).

8.1.2. Bioaccumulation

Remarks - Method	No experimental data on the potential for bioaccumulation was provided, but the modest molecular weight and apparently high affinity for lipid (as demonstrated by the high solubility of the compound in n-octanol and fat) indicate the possibility for bioaccumulation. However, the water solubility appears to be appreciable (approximately 300 mg/L) and biodegradation is also quite rapid, and these factors will mitigate bioaccumulation (Connell, 1990). Also, the use pattern of the new chemical is such that very little exposure to the water compartment is anticipated.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Summary of Toxicological Investigations

Endpoint & Result	*Assessment Conclusion*
Rat, acute oral LD50 = 2300 mg/kg bw	low toxicity
Rabbit, acute dermal LD50>2000 mg/kg bw	low toxicity
Rat, acute inhalation LC50=1.48 mg/L/4 hour	harmful
Rabbit, skin irritation	corrosive
Rabbit, eye irritation	severely irritating
Guinea pig, skin sensitisation - adjuvant test	evidence of sensitisation.
Rat, dietary Repeated Dose Toxicity-90 Days.	NOEL = 62.5 mg/kg/day (male), NOEL = 37.5 mg/kg/day (female)
Genotoxicity - bacterial reverse mutation	Non mutagenic
Genotoxicity – in vitro sister chromatid exchange	Non genotoxic
Genotoxicity – in vitro chromosomal aberration	Non genotoxic
Genotoxicity – in vitro mouse lymphoma mutation	Non genotoxic
Developmental & Reproductive Effects	NOAEL=125 mg/kg/day

9.2 Acute Toxicity

9.2.1 Acute Oral Toxicity

TEST SUBSTANCE — Carpet treatment, DO4816 (INTERSEPT)

METHOD
- Species/Strain: Rat/Sprague Dawley.
- Vehicle: None.
- Remarks - Method: Appears similar to OECD TG 401.

RESULTS

Group	*Number & Sex of Animals*	*Dose mg/kg bw*	*Mortality*	
			males	*females*
1	10/sex	800	0/10	0/10
2	"	1300	0/10	1/10
3	"	2000	0/10	5/10
4	"	2600	6/10	10/10

5	"	3200	8/10	10/10
6	"	4000	8/10	10/10

LD50	2300 mg/kg bw (combined).
Signs of Toxicity	Hypoactivity, diarrhoea, piloerection and bloody nasal discharge recorded in 2000 mg/kg animals. At necropsy external signs of diarrhoea were noted amongst females from a dose level of 2000 mg/kg and in males from 3200 mg/kg. Nasal and ocular discharge were seen at the two highest doses.
Effects in Organs	Enlarged adrenals for 2600 mg/kg females but not for other groups. Some thickening of the cardiac area of the stomach in 3200 and 4000 mg/kg males.
Remarks - Results	LD50: 2850 mg/kg bw (male), 1900 mg/kg bw (female).

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

TEST FACILITY — Raltech Scientific Services Inc (1979).

9.2.2 Acute Dermal Toxicity

TEST SUBSTANCE — Carpet treatment, DO4816 (INTERSEPT)

METHOD

Species/Strain	Rabbit/New Zealand White.
Vehicle	None.
Type of dressing	Occlusive.
Remarks - Method	24-hour treatment. Abraded skin.

RESULTS

Group	*Number & Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	4/sex	2000	1 male.
2	2/sex	20000	All animals.

LD50	> 2000 mg/kg bw
Signs of Toxicity	
- Local	At 20000 mg/kg bw effects characterised as corrosive in 3 of 4 animals.
- Systemic	At 2000 mg/kg, diarrhea and respiratory congestion were observed in individual males, and most males and all females appeared normal.
Effects in Organs	At 2000 mg/kg, changes in the lung such as empyemic lung, multiple pinpoint red foci on the lung, and consolidated lung were observed.

Remarks - Results	No data of skin irritation effects for the animals at 2000 mg/kg. No clinical signs and necropsy results were provided in the report for animals at 20 000 mg/kg.
CONCLUSION	The notified chemical is of low toxicity via the dermal route.
TEST FACILITY	Raltech Scientific Services Inc (1979).

9.2.3 Acute Inhalation Toxicity

TEST SUBSTANCE	INTERSEPT
METHOD	OECD 403 Acute Inhalation Toxicity.
Species/Strain	Rat/albino.
Vehicle	Ethanol.
Method of Exposure	Whole-body exposure.
Exposure Period	4 hours
Physical Form	Liquid aerosol.
Particle Size	1.5 microns.
Remarks - Method	

RESULTS

Group	*Number & Sex of Animals*	*Concentration (mg/L) Actual*	*Mortality*	
			males	*females*
1	5/sex	1.27	2/5	3/5
2	"	2.32	4/5	2/5
3	"	2.82	5/5	3/5
4	"	4.75	5/5	5/5

LC50	1.48 mg/L/ 4 hours (combined).
Signs of Toxicity	Effects observed during the exposure or subsequently 14 day observation period were lacrimation, irregular breathing, damp fur, poor coat quality, lethargy, crusty nose, crusty eye, emaciation, gasping, crusty muzzle, squinting, yellow/brown staining fur and alopecia.
Effects in Organs	Mottling and foamy material in the lungs and tracheas of many animals, particularly at the high dose.
Remarks - Results	1.43 mg/L/4 hours (male), 1.53 mg/L/4 hours (females).
CONCLUSION	The notified chemcial is harmful via inhalation.
TEST FACILITY	American Biogenics Corp (1986)

9.2.4 Skin Irritation

TEST SUBSTANCE	Carpet Treatment, DO4816 (INTERSEPT)
METHOD	Not specified.
Species/Strain	Rabbit/New Zealand White
Number of Animals	6
Observation Period	72 hours
Vehicle	Not specified.
Type of Dressing	Taped gauze patch.
Remarks - Method	Abraded and unabraded sites used. Readings at 24 and 72 hours only.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Erythema/Eschar	"Corrosive"	4	72 hours	4
Oedema	"Corrosive"	4	72 hours	4

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

Remarks - Results	Abraded and unabraded sites gave same result.
CONCLUSION	The notified chemical is corrosive to skin.
TEST FACILITY	Raltech Scientific Services Inc (1979).

9.2.5 Eye Irritation

TEST SUBSTANCE	Carpet Treatment, DO4816 (INTERSEPT).
METHOD	Not specified.
Species/Strain	Rabbit/New Zealand White
Number of Animals	6 (eyes were unwashed), 3 (eyes were washed for 1 minute starting at 30 seconds after installation).
Observation Period	7 days
Remarks - Method	0.1 mL of test substance placed in 1 eye with the untreated eye serving as control.

RESULTS

Unwashed eyes

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	2	2	7 days	2
Conjunctiva: chemosis	2.1	3	"	3
Conjunctiva: discharge	1.8	3	"	3
Corneal opacity	2.0	4	"	4
Iridial inflammation	0.5	1	"	1

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

Washed eyes

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	*2*	*3*			
Conjunctiva: redness	2	2	2	2	7 days	2
Conjunctiva: chemosis	2.7	2.3	2	3	"	3
Conjunctiva: discharge	1.7	2	2	2	"	2
Corneal opacity	2	2	2	3	"	3
Iridial inflammation	0.7	0.3	0	1	"	1

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

Remarks - Results: For washed and unwashed eyes sloughing of 75 – 100% of the corneal epithelium was observed from 24 to 72 hours. At 7 days for unwashed eyes 3 animals exhibited 1 – 25% and 3 animals 50 – 74% sloughing of the corneal epithelium. For washed eyes 1 animal exhibited sloughing of 1 – 25% and a second animal sloughing of 26 – 49% of the corneal epithelium.

CONCLUSION: The notified chemical is severely irritating to the eye.

TEST FACILITY: Raltech Scientific Services Inc (1979).

9.2.6 Skin Sensitisation

TEST SUBSTANCE: INTERSEPT

METHOD: Magnusson and Kligman (1970)
Species/Strain: Guinea pig/Albino
PRELIMINARY STUDY: Maximum non-irritating concentration:

	intradermal: 0.25% v/v topical: 5% v/v
MAIN STUDY	
Number of Animals	Test Group: 20 Control Group: 20
INDUCTION PHASE	Induction Concentration intradermal: 0.25% v/v topical: 5% v/v
Signs of Irritation	Not reported.
CHALLENGE PHASE	
1st challenge	topical application: 2.5% v/v topical application: 1.25% v/v
2nd challenge	topical application: 2.5% v/v topical application: 1.25% v/v
Remarks - Method	The experimental procedure followed the US EPA Pesticide Assessment Guidelines.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*					
		1st challenge			*2nd challenge*		
		24 h	*48 h*	*72 h*	*24 h*	*48 h*	*72 h*
Test Group	2.5%				19	14	12
	1.25%				3	3	2
Control Group	2.5%				10	9	3
	1.25%				2	2	1

Remarks - Results	Animals with Draize score of 1 or higher were considered to have positive evidence of hypersensitisation after challenge. Results from first challenge were excluded as Whatman No 3 paper patches were used. The second challenge was made 2 days after the first challenge.
CONCLUSION	There was evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	Huntingdon Research Centre (1988)

9.3 Repeated Dose Toxicity

TEST SUBSTANCE	INTERSEPT
METHOD	Not specified.
Species/Strain	Rat/Cr1:CD(SD)BR
Route of Administration	Oral – diet.
Exposure Information	Total exposure days: 90 days.
Vehicle	Corn oil.

Remarks - Method	The dose level of the high dose males was reduced from 625 mg/kg/day to 375 mg/kg/day from the start of week 7 to increase the food consumption and body weight gain of the animals. The concentration of test article in the diet was adjusted weekly on the basis of the predicted mid-week group mean body weight and an estimate of the food consumption.

RESULTS

Group	*Number & Sex of Animals*	*Dose mg/kg bw/day*		*Mortality*
		males	*females*	
control	10/sex	0	0	None
low	"	62.5	37.5	None
mid	"	200	120	None
high	"	625	375	None

Clinical Observations

Piloerection progressing to rough hair coat in the mid and high dose groups. At the end of the study, these animals demonstrated rough coat and/or fur staining.

Body weight gain of high dose males was lower than controls by week 6 by 29% and the dose was therefore halved. Significant reductions in body weight gain were observed in high dose animals and mid dose males over the 13 weeks. This appeared to be correlated with reduced food consumption.

Laboratory Findings – Clinical Chemistry, Haematology

Mid and high dose males and high dose females exhibited a decrease in total bilirubin levels. High dose males exhibited lower aspartate aminotransferase (AST) alanine aminotransferase (ALT), phosphorus (also for the mid dose group) and creatinine. All treated females exhibited lower ALT and intermediate and high dose females exhibited decreased calcium and phosphorus.

Mid and high dose males exhibited lower decreased white cell counts and high dose females exhibited decreased haemoglobin, packed cell volume, mean cell volume and elevated platelet counts. High dose males also exhibited slightly higher red blood cell count. Individual values rarely fell outside the normal background range.

Effects in Organs

Elevated relative kidney weights were found in mid and high dose males and high dose females. Elevated relative liver weights were observed in mid and high dose females. Elevated relative liver weights were observed in all dosed males but the increases were not statistically significant. Mean relative adrenal weights in high dose animals were higher than that in the controls.

One male and two females from the high dose group had opaque eyes. Cataract was seen in the eye of three high dose male and seven out of ten high dose females.

Mid and high dose males exhibited forestomach lesions and thickening of the stomach was observed in 2 mid and 3 high dose males.

Histopathology

Lenticular degeneration (cataract) was observed in high dose animals. In addition, mid and high dose males had treatment related forestomach lesions.

Remarks – Results

Target organs were the eye, liver and kidney although microscopic effects were not seen in the latter two organs.

CONCLUSION:
The no observed effect level (NOEL) was 62.5 mg/kg/day for males and 37.5 mg/kg/day for females.

TEST FACILITY Hazelton (1989a)

9.4 Genotoxicity

9.4.1 Genotoxicity-Bacteria

TEST SUBSTANCE	INTERSEPT
METHOD	Ames *et al.* (1975)
Species/Strain	*S. typhimurium*: TA1538, TA1535, TA1537, TA98, TA100
Metabolic Activation System	Rat liver S9.
Concentration Range in Main Test	a) With metabolic activation: 0.005, 0.01, 0.05, 0.1, 0.5 µl/plate. b) Without metabolic activation:0.005, 0.01, 0.05, 0.1, 0.5 µl/plate.
Vehicle	dimethylsulfoxide
Remarks - Method	Positive controls: S9 absent: MNNG (TA 1535, TA 100),

9-AA (TA 1537),
2-nitrofluorene (TA 1538, TA 98)

S9 present:
2-aminoanthracene (all strains)

RESULTS

Metabolic Activation	*Test Substance Concentration (μg/plate) Resulting in:*			
	Cytotoxicity in PreliminaryTest	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Present				
Test 1		No	-	No
Absent	1.0		100	
Test 1		No	-	No

Remarks - Results: The notified chemical is considered negative for inducing mutation in bacteria in the presence or absence of metabolic activation.

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

TEST FACILITY: Hilltop Research (1986).

9.4.2 Genotoxicity-In Vitro

9.4.2.1 Sister Chromatid Exchange

TEST SUBSTANCE: INTERSEPT

METHOD: Not specified.
Cell Line: Chinese Hamster Ovary (CHO)
Metabolic Activation System: Rat liver S9 fraction.
Vehicle: dimethylsulfoxide
Remarks - Method: Positive controls:
mitomycin C (0.005 μg/mL) without S9, and
cyclophosphamide (1.5 μg/mL) with S9.

Metabolic Activation	*Test Substance Concentration (μg/mL)*	*Exposure Period*
Present		
Test 1	1.0, 3.33, 10 and 33.3 microgram/mL	25 hours
Absent		
Test 1	0.333, 1.0, 3.33 and 10 microgram/mL	25 hours

RESULTS

Metabolic Activation	*Test Substance Concentration (μg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main test*	*Precipitation*	*Genotoxic Effect*
Present				
Test 1	100	100	1000	No
Absent				
Test 1	33.3	33.3	1000	No

Remarks - Results: The notified chemcial is considered negative for inducing sister chromatid exchange in CHO cells in the presence or absence of metabolic activation.

CONCLUSION: The notified chemical did not induce sister chromatid exchanges in CHO cells treated in vitro under the conditions of the test.

TEST FACILITY: Hazelton (1988)

9.4.2.2 Chromosomal Aberrations

TEST SUBSTANCE: INTERSEPT

METHOD: Not specified.
Cell Type/Cell Line: Chinese Hamster Ovary (CHO).
Metabolic Activation System: Rat liver S9 fraction.
Vehicle: dimethylsulfoxide
Remarks - Method: Positive controls:
mitomycin C (0.5 μg/mL) without S9, and
cyclophosphamide (50 μg/mL) with S9.

Metabolic Activation	*Test Substance Concentration (μg/mL)*	*Exposure Period*	*Harvest Time*
Present			
Test 1	5.0, 7.5, 10.0, 25.0	2 hours	10 hours
Test 2	5.0, 7.5, 10.0, 25.0	2 hours	10 hours
Absent			
Test 1	2.5, 5.0, 7.5, 10.0	7.3 hours	10 hours
Test 2	2.5, 5.0, 7.5, 10.0	17.3 hours	20 hours

RESULTS

Metabolic Activation	*Test Substance Concentration (μg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main test*	*Precipitation*	*Genotoxic Effect*
Present	100		1000	

Test 1		50		No
Test 2		50		No
Absent	33.3		1000	
Test 1		7.5		No
Test 2		10		No

Remarks - Results: The notified chemical is considered negative for inducing chromosomal abberation in CHO cells in the presence or absence of metabolic activation.

CONCLUSION: The notified chemical was not clastogenic to CHO cells treated in vitro under the conditions of the test.

TEST FACILITY: Hazelton (1987)

9.4.2.3 Mouse Lymphoma Mutagenicity

TEST SUBSTANCE: INTERSEPT

METHOD: Not specified.
- Cell Line: Mouse lymphoma L5178Y
- Metabolic Activation System: Rat liver S9.
- Vehicle: dimethylsulfoxide
- Remarks - Method: Positive controls: methyl methanesulfonate (without S9), and methylcholanthrene (with S9).

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Expression Time*	*Selection Time*
Present				
Test 1	5.0, 10.0, 12.5, 15.0, 17.5, 20.0	4 hours	2 days	10 – 14 days
Test 2	7.5, 10.0, 12.5, 15.0, 17.5, 20.0	4 hours	2 days	"
Absent				
Test 1	1.25, 2.50, 5.00, 10.0, 12.5	4 hours	2 days	"
Test 2	1.25, 2.50, 5.00, 7.50, 10.0, 12.5	4 hours	2 days	"

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main test*	*Precipitation*	*Genotoxic Effect*
Present	> 31.3			
Test 1		> 5.0	No	No

Test 2		> 7.5	No	No
Absent	> 15.6			
Test 1		> 1.25	No	No
Test 2		> 2.5	No	No

Remarks - Results: The notified chemical is considered negative for inducing mutation in mouse lymphoma cells in the presence or absence of metabolic activation.

CONCLUSION: The notified chemical was not mutagenic to mouse lymphoma cells treated in vitro under the conditions of the test.

TEST FACILITY: Corning Hazelton (1996).

9.5 Reproductive and Developmental Toxicity

TEST SUBSTANCE: INTERSEPT

METHOD: Not specified.
- Species/Strain: Rat/Crl:CD BR
- Route of Administration: Oral – gavage.
- Exposure Information: Dose regimen: Gestation days 6 - 15
- Vehicle: Corn oil.
- Remarks - Method

RESULTS

Group	*Number & Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
Control	25 females	0	
Low	"	125	
Mid	"	250	1
High	"	500	4

Mortality & Time to Death

One mid dose female died on gestation day 8 as a result of a gavage error.

Four high dose females were found dead during the experiment. One high dose female died following dosing on gestation day 12. Other three animals died on gestation day 10, 14 and 14, respectively.

Clinical Observations

Urine stains in all treated groups during the treatment period with the highest incidence in high dose animals. Excess salivation and hypoactivity occurred in all treated groups in a dose-related pattern.

When compared to the corresponding control data, significantly lower mean body weights were observed in mid and high dose animals in a dose related pattern. Significantly lower mean body weight change was observed in these groups on gestation days 6–8 and 0–20. During gestation days 6–8, all treated groups showed a weight loss. In addition, the high dose group exhibited significantly lower weight gain on days 12–16.

Necropsy

Necropsy observations for the animals that died during gestation consisted of discoloured lungs and stomach containing compound-like substance in one mid dose female.

Dilated renal pelvis(es) occurred in both test and control animals. Four females at high dose had reddened stomach, and two of them had filmy material in their stomach. One high dose female had enlarged adrenals.

Reproductive parameters

Gravid uterine weights, pregnancy rates, mean number of corpora lutea, mean number of implantation sites and mean implantation efficiency were unaffected by treatment.

	Control	Low-dose	Mid-dose	High-dose
Gravid uterus weight change	56.4 g	51.9 g	46.7 g	44.5 g
Pregnancy rate	100%	96%	96%	96%
Number of corpora lutea	15.1	15.2	15.0	15.5
Implantation site	13.9	13.5	13.3	14.0
Implantation efficiency	92%	87%	88%	90%

Foetal Observations

When compared to the controls, the high dose females had significantly higher mean percent early and total resorptions, higher mean percent postimplantation loss, lower mean percent live foetuses, lower live female foetal bodyweight, and combined male and female live foetal bodyweight.

There was a significant positive trend in the incidence of foetal litter external malformations in the test animals and the incidence in the high dose group was significantly higher than control. No external malformations were noted in the control group. In the low dose group one foetus had a filamentous tail. In the mid dose group one foetus exhibited gnathocephaly (headless monster with jaws), another exhibited microphthalmia and umbilical hernia and a third, umbilical hernia. In the high dose group external malformations were cleft palate and anophthalmia (one foetus), umbilical hernia (one foetus), umbilical hernia, microphthalmia and spina bifida (one foetus), extra hind limb (one foetus), malformed head (one foetus), anophthalmia (two foetuses) and hump back (one foetus).

Soft tissue variations were related to treatment and were mainly localised in the kidneys and brain. There were no malformations noted in controls and low dose animals. However, there was a significant positive trend in the incidence of soft tissue malformations and the increase in the high dose group was significantly higher than control. The only malformation for the mid dose was umbilical hernia in one foetus. For the high dose group the following malformations were observed: malformed head (one foetus), hydrocephaly (one foetus), additional cartilage dorsal to spinal cord in mid dorsal thoracic region (one foetus), anophthalmia (3 foetuses) and cleft palate (6 foetuses).

Skeletal variations including delayed ossification of the hyoid, skull, pelvic girdle, vertebrae and sternebrae were observed in all groups with the highest incidence in the high dose group. For skeletal malformations, there was a significant positive trend in the incidence of foetal litter malformations and the increase in the high dose group was significantly higher than control. There were no skeletal malformations in the control group, one foetus with filamentous tail in the low dose group and one foetus with gnathocephaly in the mid dose group. The high dose group malformations consisted of vertebral anomaly with or without associated rib anomaly in two foetuses, the same anomaly with exencephaly in one foetus, fused cervical vertebrae with forked/fused rib(s) in one foetus, fused cervical vertebrae in one foetus and supernumery limb in one foetus.

	Foetal incidence (%)				Litter incidence (%)			
	control	low	mid	high	control	low	mid	high
External variation	0.3	0	0.3	1.3	4.0	0	4.2	15
External malformation	0	0.3	1.3	3.5	0	4.2	8.3	30
Soft tissue variation	0.6	3.8	4.0	19	4.0	21	25	50
Soft tissue malformation	0	0	0.7	9.8	0	0	4.2	35
Skeletal variation	64	72	68	82	96	100	88	100
Skeletal malformation	0	0.6	0.7	5.3	0	4.2	4.2	20

The combined number of foetuses (litters) with malformations were 0(0), 1(1), 4(2) and 17(9) for the control, low, mid and high dose groups, respectively. The percentage of malformations in control, low, mid and high-dose groups were 0, 4, 8 and 45%, respectively.

Remarks – Results

Adverse effects which were determined to be treatment related in this study were:

- Four deaths in the high dose group.
- Clinical signs including hypoactivity, salivation and stained fur.
- Reduced mean bodyweight gain.
- Foetal viability was 73% with evidence of in utero growth retardation, delayed ossification of the bones and delayed soft tissue development.
- The 17 foetuses with malformations amongst 9 litters of the high dose group were statistically significant.

CONCLUSION	The no adverse effect level (NOAEL) was considered to be 125 mg/kg/day based on the clinical signs, reduced bodyweight gain, and embryo and foetal toxicity.
.	
TEST FACILITY	Hazelton (1989b).

9.6 Other Toxicological Data

The notifier also provided three toxicity studies using carpet extract. A piece of carpet of 10 square inches was extracted with 1 L of sterile water for 1 hour at 49°C. The concentration of the notified chemical in the extract was below limit of quantification and could not be calculated.

9.6.1 ACUTE ORAL

TEST SUBSTANCE Carpet extract

METHOD FHSA 38:187
Species/Strain Rat/Sprague Dawley.
Vehicle Not specified
Remarks - Method Appears similar to OECD TG 401.

RESULTS

Group	*Number & Sex of Animals*	*Dose mL extract/kg*	*Mortality*
1	10 males	0.00	0/10
2	"	0.46	0/10
3	"	1.00	0/10
4	"	2.15	0/10
5	"	4.64	1/10
6	"	10.00	0/10

LD50 > 10 mL extract/kg bw.
Signs of Toxicity None.
Effects in Organs None.
Remarks - Results The death of a rat in group 5 was due to dosing error

CONCLUSION Inconclusive.

TEST FACILITY Raltech Scientific Services Inc (1978).

9.6.2 Skin Irritation

TEST SUBSTANCE Carpet extract

METHOD FHSA CFK 38:187.
Species/Strain Rabbit/New Zealand White
Number of Animals 6
Observation Period 72 hours
Vehicle Not specified.
Type of Dressing Taped gauze patch.
Remarks - Method 24 hour exposure

RESULTS

Lesion	*Mean Score**		*Maximum Value*		*Maximum Duration of Any Effect*		*Maximum Value at End of Observation Period*	
	abraded	intact	abraded	intact	abraded	intact	abraded	intact
Erythema/Eschar	0.5	0.1	1	1	72 h	72 h	1	1
Oedema	0	0	0	0			0	0

*Calculated on the basis of the scores at 24 & 72 hours for ALL animals.

Remarks - Results No readings at 48 hours.

CONCLUSION The carpet extract is slightly irritating to the skin.

TEST FACILITY Raltech Scientific Services Inc (1978).

9.6.3 Eye Irritation

TEST SUBSTANCE Carpet extract

METHOD CFR Vol 43
Species/Strain Rabbit
Number of Animals 9: eyes were unwashed in 6 rabbits and washed in 3 rabbits.
Observation Period 7 days
Remarks - Method No details of method were provided.

RESULTS

Unwashed eyes

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	0.06	1	24 h	0
Conjunctiva: chemosis	0	0		0
Conjunctiva: discharge				
Corneal opacity	0	0		0
Iridial inflammation	0	0		0

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

Washed eyes all zero

Remarks - Results Data of discharge (conjunctiva) were not provided.

CONCLUSION	The carpet extract is not irritating to the eye.
TEST FACILITY	Raltech Scientific Services Inc (1978).

9.7 Overall Assessment of Toxicological Data

The notified chemical was of low acute oral toxicity in rats (LD50 = 2300 mg/kg) and low acute dermal toxicity in rabbits (LD50 > 2000 mg/kg). Nevertheless, the LD50 of 1900 mg/kg in females suggests that the notified chemical is harmful via the oral route. The notified chemical was harmful via the inhalation route in rats, was corrosive to the skin and caused severe eye irritation in rabbits. In addition, it was a skin sensitiser in guinea pigs in a Magnusson and Kligman test.

The notified chemical was not genotoxic in a bacterial reverse mutation test, sister chromatid exchange test, in vitro chromosomal aberration test or mouse lymphoma mutation test.

From a 90-day dietary study in rats, the NOEL was determined to be 62.5 mg/kg/day for males based on forestomach lesions and lenticular degeneration, and 37.5 mg/kg/day for females based on lenticular degeneration. A report of reproductive and development study was provided. The no adverse effect level (NOAEL) was considered to be 125 mg/kg/day in female rats based on the clinical signs, reduced bodyweight gain, and embryo and foetal toxicity.

According to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999), the notified chemical was classified as a hazardous substance with risk phrases of R20 (Harmful by inhalation), R34 (Causes burns), R43 (May cause sensitisation by skin contact), and R63 (Possible risk of harm to the unborn child).

The notifier also provided toxicity studies on carpet extract. Concentration of the notified chemical in the carpet extract was below the analytical limit. The carpet extract seems to be of low acute oral toxicity in rats, is non-irritating to eyes but slightly irritating to the skin in rabbits.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following ecotoxicity data and associated reports were provided in the notification.

10.1. Acute toxicity to fish

TEST SUBSTANCE	INTERSEPT
METHOD	US EPA Test Guideline (OPP) 72-1
Species	Rainbow trout (*Salmo gairdneri*)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	40-48 mg $CaCO_3$/L
Temperature	12 °C
Dissolved oxygen	5.4-9.3 mg/L

pH	7.1-7.6
Analytical Monitoring	None
Remarks – Method	Static methodology without renewal of test media (Analytical Biochemistry Laboratories, 1988a).

RESULTS

Concentration mg/L		Number of Fish	Mortality			
Nominal	Actual		24h	48h	72h	96h
0	Not measured	10	0	0	0	0
0.1	Not measured	10	0	0	0	0
0.18	Not measured	10	0	0	0	0
0.32	Not measured	10	0	0	0	0
0.56	Not measured	10	0	0	0	0
1.0	Not measured	10	0	0	0	0
1.8	Not measured	10	0	4	10	10

LC50	1.3 mg/L at 72 hours, 95% confidence interval 1.0-1.8 mg/L. Raw survival data analysed using standard statistical techniques (binomial and moving average).
NOEC (OR LOEC)	1.0 mg/L at 96 hours.
Remarks	The solutions were all prepared by appropriate dilutions of a stock solution which was assayed at 294 mg/L of INTERSEPT test material using a method based on the solution phosphorus concentration.. Although no sub lethal effects were observed at nominal concentration of 1.0 mg/L and less after 96 hours exposure, the fish exposed at (nominally) 1.8 mg/L showed loss of equilibrium, and quiescence prior to dying throughout the 96 hour exposure period.
CONCLUSION	According to the US EPA toxicity scale, the notified substance is classified as being moderately toxic to this species of fish, although the LC50 of 1.3 mg/L indicates that it is close to being ranked as highly toxic.
TEST FACILITY	Analytical Biochemistry Laboratories (1988a).

10.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	INTERSEPT
METHOD	US EPA Test Guideline (OPP) 72-2
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	162-180 mg $CaCO_3$/L

Temperature	19-22°C
Dissolved oxygen	7.6-9.1 mg/L
pH	7.3-8.1
Analytical Monitoring	Occasional assay of solution phosphorus content.
Remarks - Method	Static methodology without renewal of test media (Analytical Biochemistry Laboratories, 1988b.)

Results

Concentration mg/L		Number of D. magna	Percent Immobilised	
Nominal	Actual		24 h	48 h
0	Not measured	20	0	0
.056	Not measured	20	0	0
0.10	Not measured	20	35	45
0.18	Not measured	20	15	30
0.32	Not measured	20	10	20
0.56	Not measured	20	40	60
1.0	Not measured	20	55	80
1.8	Not measured	20	15	100
3.2	Measured at 92% of nominal – ie. 3.0 mg/L.	20	100	100

LC50	0.34 mg/L at 48 hours (95% confidence interval 0.26-0.43 mg/L). Raw immobilisation data analysed using standard statistical techniques (binomial and moving average).
NOEC (or LOEC)	0.056 mg/L at 48 hours
Remarks	The tests were actually performed in duplicate using 10 *daphnia* instars in each test vessel. There appeared to be an uneven trend in the number of immobilised daphnia at all nominal exposure concentrations, and this may be associated with unequal exposure due to the surfactant nature of the material.
CONCLUSION	According to the US EPA scale, the notified substance is classified as being highly toxic to this species of aquatic invertebrate.
TEST FACILITY	Analytical Biochemistry Laboratories (1988b).

10.3 Chronic toxicity to aquatic invertebrates

TEST SUBSTANCE	INTERSEPT
METHOD	OECD TG 202
Species	*Daphnia magna*
Exposure period	21 days
Auxiliary solvent	Acetone

Analytical Monitoring	None
Remarks - Method	A summary report only of this work was submitted, and many details of the experimental conditions are not available for this assessment. However, the test was conducted using flow through conditions and was apparently conducted according to the protocols of OECD TG 202. The test solutions were prepared using acetone as an auxiliary solvent, and the measured concentrations of test material in the solutions were always within 88% of the nominal concentrations. No further details of the analytical methods or results were provided. The test was conducted with a control and measured test substance concentrations of 0 (control), 0.055, 0.11, 0.22, 0.44 and 0.88 mg/L.
Results	The number of daphnia used at each test concentration was not specified, but it was noted that none of the animals survived the 21 day exposure to the two most concentrated solutions while at least 80% survived at the lower exposure levels. There was no significant differences in the number of progeny produced by females exposed to the 0.055 and 0.11 mg/L solutions and the controls (ie. around 110 offspring/female), but there was significant decrease in reproduction for those populations exposed to the 0.22 mg/L solution (and higher concentrations). The data was analysed by non linear interpolation to give the 21 day EC50 of 0.3 mg/L. The Maximum Acceptable Toxicant Concentration (MATC) was determined as 0.16 mg/L.
21 day EC50	0.30 mg/L (95% confidence 0.22-0.44 mg/L)
21 day NOEC	0.11 mg/L
21 day LOEC	0.22 mg/L
21 day MATC	0.16 mg/L
Remarks - Results	
CONCLUSION	According to the toxicity scale of Mensink et al (1995) these results indicate that the new compound is slightly toxic to this species under conditions of chronic exposure.
TEST FACILITY	Springborn Laboratories Inc.

10.4 Algal growth inhibition test

TEST SUBSTANCE	INTERSEPT

METHOD	OECD TG 201 (Springborn Laboratories Inc.)
Species	*Selenastrum capricornutum*
Exposure Period	72 hours
Concentration Range Nominal	0 (control), 0.64, 1.3, 2.5, 5.0, 10 and 20 µg/L. Both biomass (cell numbers) and the rate of biomass increase were monitored over the 72 hour period, and both indicators were significantly lower than those of the controls at all treatment levels..
Concentration Range Actual	On average the measured concentrations were 84% of the nominal ones.
Remarks - Method	A summary report only of this work was submitted, and many details of the experimental conditions are not available for this assessment. However, the test was conducted using static conditions and was apparently conducted according to the protocols of OECD TG 201. Although no details were provided the measured concentrations of test material in the solutions were always within 84% of the nominal concentrations. The test was conducted with a control and measured test substance concentrations between 0 (control) and 20 µg/L, with biomass and rate of biomass increase monitored daily. The data was analysed using linear regression techniques.

Results

Biomass		Growth	
72 h E_bC50	72 h NOEC	72 h E_bC50	72 h NOEC
µg/L	µg/L	µg/L	µg/L
3.3	< 0.64	21	0.64

Remarks - Results	Both biomass (cell numbers) and the rate of biomass increase were monitored over the 72 hour period, and both indicators were significantly lower than those of the controls at all treatment levels.
CONCLUSION	Based on the toxicity scale of the US EPA the new compound is classified as being very highly toxic to this species.
TEST FACILITY	Springborn Laboratories Inc.

10.5 Inhibition of microbial activity

TEST SUBSTANCE	INTERSEPT
METHOD	Aerobic respirometry – similar to OECD TG 301 F.
Inoculum	
Exposure Period	310 hours (13 days)
Concentration Range Nominal	0 (control), 10, 30 and 50 mg/L
Remarks – Method	The object of this test was to measure the rate of bacterial respiration in a medium containing a readily utilised carbon source (benzoic acid at a concentration of 300 mg/L), and to compare this rate with that obtained when the system also contained the test material at concentrations of 10, 30 and 50 mg/L (National Sanitation, 1988).

Results

IC50	> 50 mg/L
NOEC	30 mg/L
Remarks	Approximately 50% inhibition of respiration compared with the controls was observed, but there was no significant difference in the 10 and 30 mg/L systems.

CONCLUSION	The notified chemical is not inhibitory to bacterial respiration at exposure compounds of 30 mg/L, although some inhibitory effect may be encountered at higher exposure concentrations.
TEST FACILITY	National Sanitation (1988).

10.6 Earthworms

TEST SUBSTANCE	INTERSEPT
METHOD	OECD TG 207 (Analytical Biochemistry Laboratories, 1995).
Species	Earthworm (*Eisenia foetida*)
Exposure Period	14 days
Analytical Monitoring	None
Remarks – Method	Four replicates at each exposure, using 10 worms in each test vessel.

Results

Concentration mg/kg		Number of Worms	Mortality	
Nominal	Actual		7 day	14 day
0	Not measured	40	0	0
500	Not measured	40	0	0
1000	Not measured	40	3	3

Results		
	Remarks	Burrowing times were not affected by the presence of INTERSEPT in the soil. It was also noted that all worms including those in the controls had lost body weight after the 14 day exposure. The control worms had lost 18% body weight, those in the 500 mg/kg treatment 12% and those in the 1000 mg/kg treatment 14%, and these results contain no toxicity implications and probably reflect nutrient deficiencies in the soil or other unrecorded effects.
CONCLUSION		The new chemical appears to exhibit some toxicity to this worm species at exposure levels of 1000 mg/kg and above.
TEST FACILITY		Analytical Biochemistry Laboratories (1995).

11. ENVIRONMENTAL RISK ASSESSMENT

11.1 Exposure assessment

The new chemical is intended as a biocide for use in synthetic carpet manufacture, and assuming import quantities of 9 tonnes per annum, as a worst case it is estimated that up to 8% (540 kg) of the new chemical may be lost each year as a result of spills and waste during various manufacturing and application activities. The majority of this is expected to be placed into landfill although some may be incinerated.

The fate of most of the imported chemical will be closely associated with that of old carpet, and most of this is expected to be placed into landfill. The new chemical is a component of a cured polymer adhesive layer between the carpet proper and its flexible backing, and as the carpet backing and adhesive matrix are slowly broken down by the bacterial and abiotic processes operative in the landfills the compound will be released, primarily to soil. Here it is expected to be relatively immobile due to its expected high affinity for the organic component of soils and sediments, and would then be mineralised through bacterial action to water and oxides of carbon and nitrogen, while the phosphorus content would be converted to phosphate and would become associated with soil minerals.

Since most of the waste chemical associated with manufacture of the precoat and from unused precoat itself is also expected to be placed into landfill, this would also be degraded as described.

If any old carpet were to be incinerated this would also completely destroyed, and the phosphate would become associated with ash and ultimately the soil.

11.2 Effects assessment

The new chemical has been demonstrated to be acutely toxic to fish and highly toxic to daphnia under acute exposure conditions and in a 21 day survival and reproduction test. Moreover, it is very highly toxic to green algae with an E_bC50 of only 3.3 µg/L.

However, the use pattern of the chemical suggests that very little would reach the water compartment from its use in carpet manufacture or through its function in the carpet, and any incidental releases would be diffuse and at low levels. Also if released to water it is expected that potential for toxicity to aquatic species would be mitigated through the chemical becoming associated with sediments and its susceptibility to biodegradation.

The chemical is not expected to bioaccumulate in aquatic species.

Although a test on the chemical demonstrated some toxicity to earth worms at soil concentrations of 1000 mg/kg, it is unlikely that the compound would enter the wider soil compartment in concentrations likely to be of concern.

11.3 Risk characterisation

The use pattern of the new chemical as described in the notification dossier, together with the expectation that it will not be environmentally persistent indicates that when used as indicated it presents a low risk to the environment.

Nevertheless, the compound is highly toxic to aquatic species and every effort should be made to prevent releases to the water compartment.

11.4 Conclusion

The chemical is not considered to pose a risk to the environment based on its reported use pattern. However, due to its high toxicity to aquatic species any large release to water courses (eg. resulting from transport accidents) are expected to cause significant environmental damage.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Hazard Assessment

The notified chemical was of low acute oral toxicity in rats and low acute dermal toxicity in rabbits. However, it was harmful via the inhalation route in rats. The notified chemical was corrosive to the skin and caused severe eye irritation in rabbits. In addition, it was a skin sensitiser in guinea pigs in a Magnusson and Kligman test.

The notified chemical was not genotoxic in a bacterial reverse mutation test, sister chromatid exchange test, in vitro chromosomal aberration test or mouse lymphoma mutation test.

From a 90-day dietary study in rats, the NOEL was determined to be 62.5 mg/kg/day for males based on forestomach lesions and lenticular degeneration, and 37.5 mg/kg/day for females based on lenticular degeneration. A report of a reproductive and development study was provided. The no observed adverse effect level (NOAEL) was considered to be 125 mg/kg/day in female rats based on the clinical signs, reduced bodyweight gain, and embryo and foetal toxicity.

According to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999), the notified chemical was classified as a hazardous substance with risk phrases of R20 (Harmful by inhalation), R22 (Harmful if swallowed), R34 (Causes burns), R43 (May cause sensitisation by skin contact), and R63 (Possible risk of harm to the unborn child).

The notifier also provided toxicity studies on carpet extract. The concentration of the notified chemical in the carpet extract was below the analytical limit. The carpet extract seems to be of low acute oral toxicity in rats, is non-irritating to eyes but slightly irritating to the skin in rabbits.

According to the MSDS, INTERSEPT is a combustible liquid.

Occupational Health and Safety

Exposure of workers during transportation or warehousing of the notified chemical in 205 L steel drums should only occur in the event container rupture. Should rupture occur, spread of the notified chemical will be limited by its viscosity.

The chemical is first neutralised with ammonium hydroxide prior to manufacture of the carpet precoat. The 205 L drums are lifted mechanically and tilted to release the contents into an open mixing vat. The viscosity of notified chemical should limit the potential for dermal or ocular exposure and workers are required to wear PPE because the notified chemical is corrosive. Under these conditions worker exposure is unlikely. The drums contain a removable plastic liner which the notifier estimates will contain a residual amount of 100 – 150 mL of the notified chemical. Worker exposure during removal of these plastic liners, initially to landfill but, at a later date, as feedstock for the manufacture of the carpet backing should be low given the viscosity of the notified chemical and the use of PPE. Worker exposure during QA sampling and testing should also be low for the same reasons. In addition, neutralisation should reduce the potential for skin and eye irritancy so that risk of these effects to workers should be lower. Although the mixing vat is open and no exhaust ventilation is used, inhalation exposure to the notified chemical is likely to be low given its low vapour pressure and the fact the aerosols are not generated during mixing (according to the notifier). On balance, although worker exposure on average is likely to be low, even occasional contact with the notified chemical is undesirable given it is corrosive, skin sensitising and teratogenic. Therefore, adequate PPE must be worn by all workers likely to come in contact with the notified chemical.

Following neutralisation of the notified chemical, it is pumped via an enclosed line to a 1000 L storage tank, to the carpet precoat mixing vat where the concentration of the notified chemical is reduced to 1.5% and then to bulk tankers. At this concentration there should be little risk to workers of skin or eye irritancy or reproductive effects. Although skin irritation was observed in the skin sensitisation study in control animals at rechallenge with 2.5% notified chemical, the neutralised chemical may be less likely to exhibit this effect. According to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999), the concentration cut-off for classifying a mixture as R63 is 5%. Therefore the precoat would not be classified as R63. However, according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999), the precoat would be classified as a skin sensitiser as it is above the concentration cut-off of 1%. Taken together, the reduced hazard of the precoat coupled with the use of an automated system and the use of

PPE suggests that the risk of adverse health effects to workers should be low, although adequate PPE should still be required to protect against skin sensitisation.

The carpet precoat is transported to the carpet manufacturing plant, added to an application tank via enclosed transfer and applied to the carpet via a roller. Exposure to workers at this stage should be minimal and the risk of adverse health effects should be low. However, again, adequate PPE is required to minimise the risk of skin sensitisation from intermittent exposure due to spillage. Once the precoat is dried on the finished carpet, the notified chemical is encapsulated and would not be bioavailable.

Public Health

Exposure of the general public as a result of transport and disposal of products containing the notified chemical is assessed as being negligible. Direct public exposure to the notified chemical will be widespread and will occur primarily as a result of dermal contact with treated carpet products. As carpets wear small particles may become a part of dust and could be inhaled. Ingestion exposure is also possible, especially in young children, as a consequence of dermal contact with treated carpet and transfer of material from the hands to the mouth.

The tables below give an overview of the estimated doses and margins of safety for several toxicological effects for each exposure scenario. For skin irritation the NOEL was assumed to be at the limit of detection (1ppm) or 1μg/cm^2 for wipe samples. For eye irritation it was assumed that an eye has a volume of 4 cm^3 and the carpet extract tested contained 12 mg/cm^3. In the skin sensitisation test a concentration of 1.25% INTERSEPT gave a similar response to the control group and therefore a dose of 1250 mg/cm^2 was considered to be the NOEL.

Irritation and sensitisation effects

Effect	Total dose	NOEL	Margin of safety
Skin irritation	0.05 μg/cm^2	1 μg/cm^2	20
Eye irritation	0.005 μg/eye	48 μg/eye	9600
Skin sensitisation	0.05 μg/cm^2	1250 μg/cm^2	25 000
Pulmonary sensitisation	2 x 10^{-8} μg/cm^2	1250 μg/cm^2	6 x 10^{10}

Acute systemic effects

Scenario	Total dose (μg/kg)	NOEL (μg/kg)*	Approx. margin of safety
Adult worker	3.1-55.8	230 000	4000
Adult nursing home	4.5-82	230 000	3000
Pregnant	2.3-48	230 000	5000
Child	17-300	230 000	800

*NOEL derived from acute oral LD_{50}

Chronic systemic effects

Scenario	Total dose (μg/kg)	NOEL (μg/kg)	Approx. margin of safety
Adult worker	3.1-55.8	37 500	700

Adult nursing home	4.5-82	37 500	460
Pregnant	2.3-48	37 500	800
Child	17-300	37 500	130

Developmental effects

Scenario	Total dose (µg/kg)	NOEL (µg/kg)	Approx. margin of safety
Adult worker	3.1-55.8	125 000	2000
Adult nursing home	4.5-82	125 000	N/A
Pregnant	2.3-48	125 000	450
Child	17-300	125 000	N/A

The smallest margin of safety was for skin irritation. Although the estimated dose was only 20 times higher than the estimated NOEL, the assumptions used in this calculation were relatively conservative and therefore the margin of safety may be even greater. In general the estimated margins of safety are relatively high, suggesting that significant risk to public health is unlikely after exposure to carpets treated with INTERSEPT.

13. RECOMMENDATIONS

Regulatory controls

- The NOHSC Chemicals Standards Sub-committee should consider the following health hazard classification for the notified chemical:
  - R20 (Harmful by inhalation), R34 (Causes burns), R43 (May cause sensitisation by skin contact), and R63 (Possible risk of harm to the unborn child).

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - ≥ 25%: R20, R34, R43, R63; ≥ 10%: R34, R43, R63; ≥ 5%: R36, R38, R43, R63; ≥ 1%: R43.

Control Measures

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical as introduced, during neutralisation and precoat manufacture:
  - Manufacturing processes should be enclosed where possible.

- Employers should implement the following safe work practices to minimise occupational exposure to the notified chemical as introduced, during neutralisation and precoat manufacture:
  - Avoid spillage and generation of aerosols.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced, during neutralisation and during precoat manufacture:

– Impervious clothing and footwear
– Impervious gloves
– Chemical goggles or faceshield

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.

- Workers should be informed of the reproductive hazards of the notified chemical prior to entering the area in which it is to be used.

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

13.1 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
– The use pattern of the new chemical changes such that increased exposure to the aquatic environment is anticipated. In this case full test reports for the *Daphnia* chronic study and the algal toxicity study should be provided.
– If the conditions of use are varied from use in carpet pre-coat materials at concentrations up to a maximum of 1.5%, greater exposure of the public may occur. In such circumstances, further information may be required to assess the hazards to public health.

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.

No additional secondary notification conditions are stipulated.

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.

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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.
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

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