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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Chemical 2 in Petro Products

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Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Akzo Nobel Chemicals Pty Ltd
Suite 10, 89 High St
Kew Victoria 3101

NOTIFICATION CATEGORY
Standard: Chemical other than polymer (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: Chemical identity, Impurities and additives and adjuvants, Spectral data, Import volumes, concentration of the notified chemical in products.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: melting point, density, vapour pressure, water solubility, dissociation constant, particle size, flash point, flammability, auto ignition temperature, explosive properties, reactivity.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None.

NOTIFICATION IN OTHER COUNTRIES
None.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Petro 22 liquid (30-50% notified chemical)
Petro 22 powder (>60% notified chemical)
Petro BAF liquid (30-50% notified chemical)
Petro BAF powder (>60% notified chemical)
Petro 11 liquid (30-50% notified chemical)
Petro 11 solid (>60% notified chemical)
Petro BA liquid (30-50% notified chemical)
Petro BA powder (>60% notified chemical
Morwet 3008 liquid (30-50% notified chemical)
Morwet 3008 powder (>60% notified chemical)
Petro ULF liquid (30-50% notified chemical)
Petro LBA
Morwet EFW

OTHER NAME(S)
Sodium alkylnaphthalenesulfonate

METHODS OF DETECTION AND DETERMINATION

METHOD Infrared spectra of products were provided.

3. COMPOSITION

DEGREE OF PURITY
Not applicable. The notified chemical is a complex mixture.

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
No hazardous impurities are expected to be present above the levels that would result in classification of the notified chemical as a hazardous substance.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
Imported by sea, as a component of liquid or powdered products, in 200 kg drums or bulk bags (500 kg).

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	30-100	30-100	30-100	30-100	30-100

USE
Surface-active hydrotropes used at <10% in a number of applications. Main applications are: hard surface cleaning (e.g. floors); metal cleaning (high alkaline and acid cleaners); rinse aid (e.g. dishwashing machines); and carpet cleaning.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Sydney or Melbourne ports.

TRANSPORTATION AND PACKAGING
Imported 205 L drums or 500 kg bags are transported from the wharf by road to sites of reformulation or to warehouses for later distribution. Reformulated products containing <10% notified chemical are transported by road in <1 L – 205 L containers.

5.2. Operation description

At the formulation sites, products containing the notified chemical (liquids are 30-50% notified chemical, solids are >60% notified chemical) are added to 150-200,000 L stainless steel mixing vessels, either directly from a 205 L drum, via a manifold and metering system from a drum or storage vessel, or from smaller drums or buckets that have been pre weighed. Other ingredients are added and the formulation is stirred for 1-4 hours.

The product containing <10% notified chemical is packed off by gravity feed, or by pneumatic filling, into containers ranging in size from <1 L (generally plastic containers) to 205 L (drums). Product sampling occurs via pipette. The products may be sold to retail outlets or to cleaning corporations, or distributed to repackagers. Vessels and filling lines are cleaned between batches by flushing the system with water.

The cleaning products as supplied are usually diluted at least 1:10 prior to application, to give concentrations in the final cleaning products of <1% notified chemical. These products are generally applied by one of the following methods:

- Application to a cloth or sponge, and wiping surfaces
- Spraying surfaces, followed by wiping
- Applying product with a mop or brush
- Applying product as a liquid stream, for example using a squeeze bottle or high pressure

- Soaking objects in product, followed by rinsing or wiping.
- Application by machine, for example in hot and cold water pressure cleaners, including steam or foam cleaning.

The notified chemical may also be used as a component of brewery cleaner, used to wash stainless steel vats or tanks. Formulation will be similar to that described above except that the resultant solution contains 25 – 48% caustic soda and filled to 1000 L isotainers or road tankers. After arrival at the brewery, conductivity controlled dosing to vats or tanks occurs, the vats or tanks are washed, and the waste water is disposed of to trade waste sewer after pH adjustment. Isotainers or tankers are rinsed at the formulator's site.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Transport and storage	50	4 hours/day	52 days/year
Warehouse	10	2 hours/day	100 days/year
Formulation process operator	100	2.5 hours/day	52 days/year
Quality control	5	1 hour/day	52 days/year
Packaging	20	3 hours/day	52 days/year
End use	5000	0.5 hours/day	365 days/year

Exposure Details

Transport, storage and warehouse workers are unlikely to come into contact with the notified chemical except in the case of a spill or container leak.

Formulation process operators may be exposed to liquids containing 30-50% notified chemical or solids containing >60% notified chemical. Exposure (dermal, inhalation or ocular) is most likely to occur when adding the product containing the notified chemical to mixing vessels. Exposure is limited by exhaust ventilation and PPE, including overalls, gloves, safety goggles and boots. Exposure during quality control is possible, but will be limited by PPE and the relatively small volume of samples taken. For formulation of the brewery cleaner, controls required to control exposure to the solution containing a high level of caustic soda will ensure low exposure to the notified chemical.

Packaging workers may be exposed to products containing <10% notified chemical. Containers are filled either by gravity feed or by pneumatic filling. Exposure will be limited by exhaust ventilation and PPE, including overalls, gloves, safety goggles and boots.

End users may be exposed to products containing up to 10% notified chemical, although in general the final concentration used for cleaning is <1%. Incidental dermal exposure to <10% notified chemical may occur through splashes or contamination of the outside of the packaging. There is the potential for low level albeit regular dermal and accidental ocular contact by the public with the notified chemical during use of cleaning products. Where products are applied using spray bottles or as a liquid stream, there is the potential for aerosol formation and inhalation exposure. Oral exposure could occur from residues of the cleaning products if used to wash food containers and utensils and if these articles are not rinsed after washing. It is expected that residues would be low, and transfer to ingested food would be even lower. Gloves or eye protection may be worn during some cleaning tasks.

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5.4. Release

RELEASE OF CHEMICAL AT SITE

Once imported, the notified chemical is transported to reformulation sites, where the notified chemical is blended with other ingredients and repackaged. From here, the formulated products containing the notified chemical will either be sold to end-users, or transported to other sites for repackaging into end-use containers. Environmental release may arise from accidental spills, during handling and transport, from equipment cleaning and maintenance, and from residues in import and intermediary

containers. It is expected that residual notified chemical in import containers will account for <1% of the total imported volume, and will either be incinerated or disposed of to landfill. It is expected that spills and washings will be disposed as trade-waste to sewer.

RELEASE OF CHEMICAL FROM USE
Given the nature of the products in which the notified chemical is used, it is expected that effectively the entire total imported volume will eventually be released to sewer after use. Residual notified chemical within end-use containers may account for 1% of the total imported volume, and this is expected to be disposed of to landfill.

5.5. Disposal

Apart from approximately 2% of the total imported volume which is expected to be disposed of to landfill, the remainder is expected to be disposed of to sewer after use, though the rate that this occurs will vary between uses.

5.6. Public exposure

Consumers may be exposed to products containing up to 10% notified chemical, although in general the final concentration used for cleaning is <1%. Incidental dermal exposure to <10% notified chemical may occur through splashes or contamination of the outside of the packaging. There is the potential for low level albeit regular dermal and accidental ocular contact by the public with the notified chemical during use of cleaning products. Where products are applied using spray bottles or as a liquid stream, there is the potential for aerosol formation and inhalation exposure. Oral exposure could occur from residues of the cleaning products if used to wash food containers and utensils and if these articles are not rinsed after washing. It is expected that residues would be low, and transfer to ingested food would be even lower. Accidental oral exposure of young children to cleaning products is also possible. Gloves or eye protection may be worn during some cleaning tasks.

6. PHYSICAL AND CHEMICAL PROPERTIES

Physical and chemical properties are not available for the notified chemical as it is not isolated. Values given here are for Petro 11 powder.

Appearance at 20ºC and 101.3 kPa	Tan powder (amber liquid when in aqueous solution)
Melting Point/Freezing Point	>124ºC
Remarks	The melting point of analogous chemicals of lower MW is >124°C.
Density	1200 kg/m^3
Remarks	No test report provided.
Vapour Pressure	Not determined.
Remarks	Expected to be low based on structure. Calculated by EPIWIN 3.12 from representative structure to be less than 10^{-9} kPa.
Water Solubility	Soluble in water.
Remarks	>100 g/L. No test report provided. Ecotoxicity tests report that the notified chemical was readily soluble at 1 g/L.
Hydrolysis as a Function of pH	Not determined
Remarks	There are no hydrolysable functionalities in the notified chemical.
Partition Coefficient (n-octanol/water)	Not determined
Remarks	This cannot be readily tested given the surfactant nature of the notified chemical.

Adsorption/Desorption Not Determined

Remarks While soluble, it is expected that the notified chemical may potentialy adsorb to soil, based upon its surfactant nature.

Dissociation Constant Not determined.

Remarks The pKa for benzene sulfonic acid is calculated to be –2.8.

Particle Size Not determined. Expected to be in the inspirable range (10 – 100 μm).

Flash Point >94ºC

Remarks From MSDS.

Flammability Limits Not expected to be flammable.

Remarks Based on flashpoint.

Autoignition Temperature Not determined.

Explosive Properties Not determined.

Reactivity Not determined.

7. TOXICOLOGICAL INVESTIGATIONS

Toxicology data were obtained on products containing the notified chemical and on analogue chemicals.

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50 1646 mg/kg bw[a]; 5620 mg/kg bw[b]	harmful
Rat, acute dermal LD50 > 2000 mg/kg bw[c]	low toxicity
Rabbit, skin irritation[a]	moderately irritating
Rabbit, eye irritation[a]	severely irritating
Guinea pig, skin sensitisation – non-adjuvant test[a]	evidence
Dog, repeat dose oral (gavage) toxicity – 90 days[d].	NOAEL = 104.1 mg/kg bw/day
Genotoxicity – bacterial reverse mutation[e]	non mutagenic

[a] Morwet 3008 (>60% notified chemical); [b] Petro 11 (>60% notified chemical); [c]Petro BAF (>60% notified chemical); [d]Petro AG (96 – 98% notified chemical); Petro ULF liquid (30 – 50% notified chemical).

Robust summaries were provided for certain analogues of the notified chemical:

Endpoint and Result	*Test Substance*	*Assessment Conclusion*
Rat, acute oral LD50 1100 mg/kg bw	Analogue #1	low toxicity
Rat, acute oral LD50 1410 mg/kg bw	Analogue #2	low toxicity
Genotoxicity – in vitro Ames test	Analogue #1	negative
Genotoxicity – in vitro Ames test	Analogue #2	negative
Genotoxicity – in vitro chromosomal aberration	Analogue #2	negative
Genotoxicity – in vitro chromosomal aberration	Analogue #3	negative
Genotoxicity – in vitro chromosomal aberration	Analogue #4	weak positive
Genotoxicity – in vivo micronucleus test	Analogue #3	negative

7.1. Acute toxicity – oral

TEST SUBSTANCE — Morwet 3008 (>60% notified chemical)

METHOD
- Species/Strain: Rat/HSD:SD
- Vehicle: Water
- Remarks - Method: No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	750	m:0/5 f:0/5
2	5/sex	1500	m:2/5 f:3/5
3	5/sex	2500	m:5/5 f:3/5
4	5/sex	5050	m:5/5 f:5/5

LD50: 1646 mg/kg bw (95% confidence level: 1100-2732 mg/kg bw)

Signs of Toxicity: Clinical signs of toxicity included piloerection, nasal discharge, salivation, diarrhoea, activity decrease, respiratory chirp and gurgle, and ataxia. Other signs included crust around the nose and eyes, and staining of the muzzles. Ptosis, polyuria and gasping were also exhibited in animals that died. Surviving animals were asymptomatic by day 8.

	Animals that died had slightly decreased body weights. Body weight gain in surviving animals was unaffected by the test substance.
Effects in Organs	Animals that died on test revealed discolouration of the contents of the gastrointestinal tract and gas in the gastrointestinal tract, and matting and staining of the muzzle and genital hair. Animals surviving to termination of the study revealed no observable abnormalities.
Remarks - Results	None.
CONCLUSION	The notified chemical is harmful via the oral route.
TEST FACILITY	Stillmeadow Incorporated (1995a).

7.2. Acute toxicity – oral

TEST SUBSTANCE	Petro 11 (>60% notified chemical)
METHOD	The notified chemical in water was administered to male rats by oral gavage. Food was withheld for 3-4 hours prior to dosage, and was available freely at other times. During the seven-day study period, the animals were closely observed at 0, 1, 4, and 24 hours on the day of administration, and daily thereafter, until day 7, when surviving animals were sacrificed. Autopsies were performed on all animals.
Species/Strain	Rat/Sprague-Dawley
Vehicle	Water.
Remarks - Method	None.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	31.6	m:0/5 f:0/5
2	5/sex	100	m:0/5 f:0/5
3	5/sex	316	m:0/5 f:0/5
4	5/sex	1000	m:0/5 f:0/5
3	5/sex	3160	m:0/5 f:0/5
4	5/sex	10000	m:5/5 f:5/5

LD50	5620 mg/kg bw
Signs of Toxicity	Clinical signs of toxicity included depression characterised by inactivity, laboured respiration, ataxia, sprawling of the limbs, ptosis, and depressed righting and placement reflexes. Body weight gain in surviving animals was unaffected by the test substance.
Effects in Organs	Necrosis of animals that died on test revealed congestion of the lungs, kidneys, and adrenals, and irritation of the gastrointestinal tract. Animals surviving to termination of the study revealed no observable abnormalities.
Remarks - Results	None.

CONCLUSION	The test substance is of low toxicity via the oral route.
TEST FACILITY	Petrochemicals Company Inc (1959).

7.2. Acute toxicity – dermal

TEST SUBSTANCE	Petro BAF (>60% notified chemical)
METHOD	Skin on the back (~30% of the total body surface) of rabbits was clipped 24 hours prior to application, and in one male and two females, abraded by making four shallow epidermal incisions immediately prior to application of the test article moistened with 3 mL of water. The exposure period was 24 hours, and the skin was then washed with warm tap water. Animals were observed directly after removal of the test substance, and daily for 14 days after exposure.
Species/Strain	Rabbit/New Zealand albino rabbits
Vehicle	None.
Type of dressing	Occlusive
Remarks - Method	None.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	1m/2f	2000 mg/kg bw	0

LD50	>2000 mg/kg bw
Signs of Toxicity - Local	Slight to moderate erythema, oedema and atonia was observed on days 1-9, subsiding on day 10 in most animals. Slight desquamation, increasing to marked desquamation was noted beginning day 4-5 and continuing through the study. On days 4 to 7 slight fissuring was observed. On day 4 of the study the test areas were leathery to touch and eschar formation was then noted on day 5, continuing throughout the study. Exfoliation began on day 6 to 13 and continued through the study.
Signs of Toxicity - Systemic	One rabbit was observed to have difficulty breathing, nasal discharge, nictating membranes reddened and swollen with marked lacrimation on days 1 through 14.
Effects in Organs	None reported.
Remarks - Results	Application of the notified chemical resulted in marked irritation and some signs of systemic toxicity.
CONCLUSION	The test substance is of low toxicity via the dermal route.
TEST FACILITY	WIL Research Laboratories, Inc (1980).

7.3. Acute toxicity – inhalation

No test reports provided. Exposure to powders is unlikely to be high and continuous during reformulation and the notified chemical is at least a moderate skin irritant. Therefore, an acute inhalation toxicity study cannot be justified.

7.4. Irritation – skin

TEST SUBSTANCE	Morwet 3008 (>60% notified chemical)
METHOD	EPA 540/9-84-014 Pesticide Assessment Guidelines, Subdivision F, Hazard Evaluation: Human and Domestic Animals.
Species/Strain	Rabbit/New Zealand White

Number of Animals	6 (1m/5f)
Vehicle	Test material was moistened with water.
Observation Period	14 days
Type of Dressing	Semi-occlusive.
Remarks - Method	None.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Erythema/Eschar	1.78	3	14 days	1
Oedema	1.56	3	14 days	1

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

Remarks - Results	Skin irritation worsened after the initial 72-hour observation period. At 7 days, the average erythema score was 2.67, reducing to 1.67 on day 10. At 7 days, the average oedema score was 1.83, reducing to 1 on day 10. Atonia was observed in one animal at 24 hours, and in all animals at 24 and 72 hours. Eschar and/or desquamation were observed in 5/6 animals on days 7 and 10, and desquamation was observed in two animals at day 14.
CONCLUSION	The test substance is moderately irritating to the skin.
TEST FACILITY	Stillmeadow Incorporated (1995b).

7.4. Irritation – skin

TEST SUBSTANCE	Petro 22 liquid (30-50% notified chemical)
METHOD	Primary Irritation Study – FHSLA
Species/Strain	Rabbit/New Zealand White
Number of Animals	6
Vehicle	None.
Observation Period	72 hours.
Type of Dressing	Occlusive/Semi-occlusive.
Remarks - Method	Two areas on the back of 6 rabbits was clipped and one was abraded by making four shallow epidermal incisions immediately prior to application of 0.5 mL test article to both shaved areas. The exposure period was 24 hours. It is not clear if the skin was washed after 24 hours. Observations were only conducted at 24 and 72 hours.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Intact skin				
Erythema/Eschar	1	2	24 hours	0
Oedema	0	0	-	-
Abraded skin				
Erythema/Eschar	1.2	2	72 hours	1
Oedema	0.3	1	24 hours	0

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

Remarks - Results	On abraded skin, very slight oedema was observed in 3/6 animals at 24 hours; and very slight erythema persisted until 72 hours.
CONCLUSION	The test substance is slightly irritating to the skin.

TEST FACILITY BTL (1975).

7.5. Irritation – eye

TEST SUBSTANCE Petro 22 liquid (30-50% notified chemical)

METHOD Draize Eye irritation Study – Wolcott Modification.
Species/Strain Rabbit/New Zealand White
Number of Animals 6
Observation Period 7 days.
Remarks - Method 0.1 mL of undiluted test substance was instilled into the conjunctival sac. In 6 animals, the eyes were unwashed. In 3 animals the eyes were washed 2 seconds after exposure. In 3 animals the eyes were washed 4 secs of exposure.

The OECD guideline does not recommend washing of the eye in this test. Thus, only the unwashed results are reported here.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	2.0	2	7 days	1
Conjunctiva: chemosis	0.7	2	3 days	-
Conjunctiva: discharge	1.4	3	5 days	-
Corneal opacity	1.1	2	4 days	-
Iridial inflammation	0	-	-	-

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

Remarks - Results Hyperemia (redness) of the conjunctivae was noted in one animal at the end of the test period (7 days). Hyperemia cleared on day 5 or 6 in the other 5 animals.

CONCLUSION The test substance is moderately irritating to the eye.

TEST FACILITY BTL (1975).

7.5. Irritation – eye

TEST SUBSTANCE Morwet 3008 (>60% notified chemical)

METHOD EPA 540/9-84-014 Pesticide Assessment Guidelines, Subdivision F, Hazard Evaluation: Human and Domestic Animals.
Species/Strain Rabbit/New Zealand White
Number of Animals 6 (1m/5f)
Observation Period 21 days
Remarks - Method 0.1 mL by volume (3.64 mg) of test material was placed into the conjunctival sac of each animal. In some animals, the eyes were washed with water for one minute beginning 30 seconds after treatment. The OECD guideline does not recommend washing of the eye in this test. Thus, only the unwashed results are reported here.

Eye observations were conducted at 1, 24, 48 and 72 hours, and at 4, 7, 10, 14, 17 and 21 days. Following the 24-hour observation, sodium fluorescein was used to examine the corneas.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	2.6	3	21 days	1
Conjunctiva: chemosis	1.3	3	14 days	0
Conjunctiva: discharge	1.8	3	10 days	0
Corneal opacity	1.3	2	21 days	1
Iridial inflammation	0	0	None.	0

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

Remarks - Results

All animals had positive fluorescein staining at the 24-hour observation. In one animal, this persisted for 21 days, in the other animals, the positive staining resolved by 7 days.

Stippling was apparent in all animals, resolving within 72 hours.

Conjunctival redness persisted in two animals for 21 days. This resolved at days 4-14 in the other animals.

Corneal opacity persisted in two animals for 21 days. Apparent invasion of the cornea by blood vessels was observed in these animals at days 17 and 21.

CONCLUSION The test substance is severely irritating to the eye.

TEST FACILITY Stillmeadow Incorporated (1995).

7.6. Skin sensitisation

TEST SUBSTANCE Morwet 3008 (>60% notified chemical)

METHOD EPA 540/9-84-014 Pesticide Assessment Guidelines, Subdivision F, Hazard Evaluation: Human and Domestic Animals.

Species/Strain Guinea pig/Hartley Albino

PRELIMINARY STUDY Maximum Non-irritating Concentration:
topical: 75%

MAIN STUDY

Number of Animals Test Group: 5m/5f Control Group: 5m/5f

INDUCTION PHASE Induction Concentration:
topical: 400 mg moistened with 0.01 mL water

Signs of Irritation Very faint to faint erythema was observed at 24 and 48 hours following the first induction. 24 hours after the second and third inductions strong erythema was observed, with or without oedema.

CHALLENGE PHASE

1st challenge topical: 75%

Remarks - Method The test guideline closely follows the OECD guidelines for a Buehler test.

RESULTS

Animal	*Challenge Concentration*	*Average Skin Reactions after challenge*	
		24 h	*48 h*
Test Group	75%	2.25	3
Control Group	75%	0.29	0.79

Remarks - Results The test material elicited moderate to strong erythema in all induced test-group animals, while the naïve animals exhibited very faint to moderate

erythema. At 24 hours 1 control animal had a Draize score of 1 and 5 animals had a score of 0.5 which would rated as negative. By contrast 3 test animals had scores of 2 and the remaining 7 animals had scores of 3.

1-chloro-2,4-dinitrobenzene was used as a positive control and gave the appropriate response.

CONCLUSION There was evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.

TEST FACILITY Stillmeadow Incorporated (1995d).

7.7. Repeat dose toxicity

TEST SUBSTANCE Petro AG Special (96 – 98% notified chemical)

METHOD A 90-day feeding study was conducted in Beagle Dogs in 1966 in line with recommendations by the US FDA in 1965.

Species/Strain	Dog/Beagle
Route of Administration	Oral – diet
Exposure Information	Total exposure days: 90 days Dose regimen: 6 days per week
Vehicle	None.
Remarks - Method	Dogs were allowed access to food for 1 hour per day on the 6 days per week feeding times.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*		*Mortality*
		M	F	
I (control)	3\sex	0	0	None
II (low dose)	"	8.7	9.2	"
III (mid dose)	"	29.0	35.8	"
IV (high dose)	"	90.8	104.1	"

Mortality and Time to Death
None.

Clinical Observations
Normal behaviour with no signs of excitation or depression in all dogs. Body weight gain was as expected, ie lower in all animals initially due to handling. One high dose male showed a net weight loss during the study. Food consumption was approximately equivalent in all groups.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
Sporadic non-dose related findings in some parameters were not considered to be due to treatment. Generally, no haematological, renal, hepatic or metabolic effects were found.

Effects in Organs
No effects on organ weights were observed. A range of histopathological findings were noted. However, these were not more prevalent in the treated animals and no specific dose-related effects were identified.

Remarks – Results
None.

CONCLUSION
The No Observed Effect Level (NOEL) was established as the highest dose tested: 104.1 mg/kg bw/day in this study, based on the lack of any treatment related effects at any dose level.

TEST FACILITY Petrochemicals Company (1966).

7.8. Genotoxicity – bacteria

TEST SUBSTANCE Petro ULF (liquid, 30 – 50% notified chemical)

METHOD Modification of method of Ames B N *et al.* (1975).
Plate incorporation procedure

Species/Strain	*S. typhimurium*: TA1538, TA1535, TA1537, TA98, TA100
Metabolic Activation System	Aroclor 1254 induced rat liver microsomal enzymes.
Concentration Range in Main Test	a) With metabolic activation: 0 - 5 µL/plate b) Without metabolic activation: 0 - 5 µL/plate
Vehicle	None.
Remarks - Method	None.

RESULTS

Metabolic Activation	*Test Substance Concentration (µL/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	0.31		Not stated	Negative
Present				
Test 1			"	Negative

Remarks - Results The highest concentration of test compound used in the main test was said to result in approximately 35% survival and a detectable reduction in numbers of spontaneous revertants. Negative controls were within historical limits and positive controls demonstrated the sensitivity of the test.

CONCLUSION The test substance was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY EG & G Mason Research Inst (1979).

7.9. Genotoxicity – in vitro – chromosomal aberrations

Two analogues of the notified chemical have been tested for induction of chromosomal aberrations.

TEST SUBSTANCE Analogue #3

METHOD OECD TG 473 In vitro Mammalian Chromosome Aberration Test.

Cell Type/Cell Line	Chinese Hamster Ovary (CHO) Cells
Metabolic Activation System	Aroclor 1254 induced rat liver microsomal enzyme fraction.
Vehicle	tetrahydrofuran
Remarks - Method	None.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	20, 40, 80	16 hours	16 hours
Test 2	20, 40, 80	16 hours	16 hours
Test 3	80, 120, 160	40 hours	40 hours
Present			

Test 1	20, 40, 80	16 hours	16 hours
Test 2	20, 40, 80	16 hours	16 hours
Test 3	80, 120, 160	40 hours	40 hours

All cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 160		80	Negative
Test 2			"	"
Test 3		160	"	"
Present				
Test 1	> 160		"	"
Test 2			"	"
Test 3			"	"

Remarks - Results

In the initial experiment without activation and 16-hour harvest there was a statistically significant increase in chromosomal aberrations at one dose level but this was the sole observation and was assumed to have arisen by chance.

The positive and negative controls gave the expected responses.

CONCLUSION

The test substance was not clastogenic to CHO cells treated in vitro under the conditions of the test.

TEST SUBSTANCE

Analogue #4

METHOD

OECD TG 473 In vitro Mammalian Chromosome Aberration Test.

Cell Type/Cell Line	Chinese Hamster Ovary (CHO) Cells
Metabolic Activation System	Aroclor 1254 induced rat liver microsomal enzyme fraction.
Vehicle	tetrahydrofuran
Remarks - Method	None.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	10, 20, 40	16 hours	16 hours
Test 2	10, 20, 40	16 hours	16 hours
Test 3	10, 20, 40	40 hours	40 hours
Present			
Test 1	10, 20, 40	16 hours	16 hours
Test 2	10, 20, 40	16 hours	16 hours
Test 3	10, 20, 40	40 hours	40 hours

All cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	160		40	Negative
Test 2			"	"
Test 3			"	"

Present		
Test 1	“	“
Test 2	“	“
Test 3	“	“

Remarks - Results: In the initial experiment without and with activation at the 16-hour harvest there was a dose-related statistically significant increase in chromosomal aberration. This was not observed in the other assays.

The positive and negative controls gave the expected responses.

CONCLUSION: The test substance was clastogenic to CHO cells treated in vitro under the conditions of the test but not reproducibly.

7.10. Genotoxicity – in vivo

Analogue #1 tested for induction of chromosomal aberrations in vitro was also tested in vivo in the Mammalian Erythrocyte Micronucleus Test.

TEST SUBSTANCE: Analogue #3

METHOD: OECD TG 474 Mammalian Erythrocyte Micronucleus Test.
Species/Strain: Mouse/CD-1
Route of Administration: Oral – gavage
Vehicle: Peanut oil.
Remarks - Method: None.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
I (vehicle control)	5/sex	0	24 hours
II (low dose)	“	500	“
III (mid dose)	“	1000	“
IV (high dose)	“	2000	“
V (positive control, CP)		20	“

CP=cyclophosphamide.

RESULTS
Doses Producing Toxicity: None.
Genotoxic Effects: None.
Remarks - Results: Positive and negative controls gave the expected responses. There was no bone marrow toxicity.

CONCLUSION: The notified chemical was not clastogenic under the conditions of this in vivo mammalian erythrocyte micronucleus test.

8. ENVIRONMENT

8.1. Environmental fate

8.1.1.a Ready biodegradability

TEST SUBSTANCE: Petro 22

METHOD
- Inoculum: Primary clarifier supernatant from a primarily domestic STP.
- Exposure Period: 28 d
- Auxiliary Solvent: Nil
- Analytical Monitoring:
- Remarks - Method: The test contained one control, one reference, and one treatment group, with two replicates per group. The reference group was dosed with sodium benzoate at a concentration of 20 mg C/L. The treatment group was dosed with test substance at a concentration of 20 mg C/L.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
2	5.0	2	56.0
5	22.1	5	75.3
9	31.3	9	97.2
13	41.0	13	96.8
16	43.1	16	96.4
20	44.4	20	97.3
23	47.2	23	98.9
26	48.4	26	101.1
29	49.1	29	101.3

Remarks - Results: The test substance evolved an average of approximately 49% of the maximum theoretical CO_2 production. Although significant degradation of the test substance was observed, the test substance may not be considered readily biodegradable since 60% of theoretical CO_2 production was not achieved within 28 days.

The viability of the inoculum and validity of the test was supported by the reference substance, sodium benzoate, degrading an average of approximately 101%. The reference substance yielded approximately 75% of the theoretical maximum CO_2 by day 5 of the test, thereby fulfilling the criteria for a valid test.

CONCLUSION: While significant biodegradation of the test substance occurred, the criterion for ready biodegradable was not achieved. Therefore, the test substance is inherently biodegradable.

TEST FACILITY: Wildlife International (1995a)

8.1.1.b Ready biodegradability

TEST SUBSTANCE: Petro BA Liquid

METHOD
- Inoculum: Primary clarifier supernatant from a primarily domestic STP.
- Exposure Period: 28 d
- Auxiliary Solvent: Nil
- Analytical Monitoring:

Remarks - Method The test contained one control, one reference, and one treatment group, with two replicates per group. The reference group was dosed with sodium benzoate at a concentration of 20 mg C/L. The treatment group was dosed with test substance at a concentration of 20 mg C/L.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
2	2.2	2	59.45
6	30.45	6	77.85
9	41.05	9	83.7
12	46.65	12	92.8
15	46.1	15	95.25
20	50.2	20	97.2
23	51.55	23	98.35
26	52.95	26	98.85
29	53.75	29	99.75

Remarks - Results The test substance evolved an average of approximately 54% of the maximum theoretical CO_2 production. Although significant degradation of the test substance was observed, the test substance may not be considered readily biodegradable since 60% of theoretical CO_2 production was not achieved within 28 days.

The viability of the inoculum and validity of the test was supported by the reference substance, sodium benzoate, degrading an average of approximately 100%. The reference substance yielded approximately 78% of the theoretical maximum CO_2 by day 6 of the test, thereby fulfilling the criteria for a valid test.

CONCLUSION While significant biodegradation of the test substance occurred, the criterion for ready biodegradable was not achieved. Therefore, the test substance is inherently biodegradable.

TEST FACILITY Wildlife International (1995b)

8.1.1.c Primary biodegradability

TEST SUBSTANCE Petro BAF

METHOD Presumptive Shake-Flask Bacterial Culture Method of the Soap and Detergent Association (SDA).

Inoculum Laboratory shake-flask activated sludge culture
Exposure Period 8 d
Auxiliary Solvent Nil
Analytical Monitoring

Remarks - Method The bacterial culture was first adapted to the specific alkyl aryl sodium sulfonate detergent present in the Petro BAF sample, for which it was to be used later for evaluation of surfactant biodegradability during the 8-day shake-flask test. Test substance detergent was adapted to the activated sludge bacterial culture by subjecting it to a minimum of two 72-hour bacterial transfers in a shake-flask medium containing 30 mg/L (on a 100%-active basis) of the detergent in the sample under test. A sterilised microbial growth-promoting basal medium containing 30 mg/L of the test substance was then aseptically inoculated with 10 mL/L of the microorganisms which had already been preadapted. The mixture in the flask was then loosely capped and incubated at 25-30°C and aerated by continuous agitation of the flask for 8 days.

Biodegradation was determined by measuring the reduction in methylene blue anionic-active substance (MBAS) from the shake-flask culture media, immediately after inoculation and again on the 7th and 8th days of the test period. Percent removal was calculated from the reduction in surfactant content. The result of the test was the average of the 7th and 8th day percent removals.

A blank flask control unit (containing all materials except the test substance was also run concurrently by the Shake-Flask procedure. Also, with each run, there was included one unit fed Dodecene-1 derived Linear Alkyl Sulfonate (LAS) as a control on sludge suitability and operating conditions.

RESULTS

Test substance	
Day	*% Degradation*
7	91.3
8	92.6

Remarks - Results

The test substance had an average percent MBAS removal of 91.9%. As the test substance was found to have a biodegradability value that exceeded 90% removal of MBAS, the test substance was considered to be adequately biodegradable and require no further testing according to SDA standards.

The result for dodecene-1 derived LAS was 98.8% removal thereby indicating the suitability of the activated sludge for use in this SDA procedure.

CONCLUSION

According to the SDA standards, the test substance is described as adequately biodegradable.

TEST FACILITY

United States Testing Company (1970)

8.1.2. Bioaccumulation

REMARKS

Test not performed. The notified chemical is unlikely to bioaccumulate as it is biodegradable and is unlikely to partition to fat, based upon the high water solubility.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE

Petro 11

METHOD

Species	Murray River Rainbow Fish (*Melanotaenia fluviatilis*).
Exposure Period	96 h
Auxiliary Solvent	Nil
Water Hardness	Not Provided
Analytical Monitoring	Temperature, pH, conductivity and dissolved oxygen.
Remarks – Method	Treated Sydney tap water was used as the diluent water for the test. Treatment involved passing the water through sand and carbon filters before storage in epoxy lined concrete tanks. Prior to use in the bioassay, the stored waster was filtered through 5 µm carbon filter cartridges and finally UV sterilised. A stock solution of the chemical was prepared by dissolving the chemical in the treated water to give a concentration of 1

g/L. This solution was then appropriately diluted to produce concentrations of 10, 50, 100, 200, 400 and 800 mg/L for the conduct of the test. A diluent water control was also prepared. 4 replicates for each test concentration and control were prepared, containing 5 randomly selected fish each.

This is an Imbalance Test (not defined) only and the NOEC and LOEC values were calculated, after appropriate transformation of data, using the ANOVA and Dunnetts test. The EC50 value was determined using the trimmed Spearmen-Karber Method.

RESULTS

Concentration mg/L		*Number of Fish*	*Percent Imbalanced*		
Nominal	*Actual*		*0 h*	*48 h*	*96 h*
0		20	0	5%	5%
10		20	0	5%	5%
50		20	0	5%	5%
100		20	0	15%	15%
200		20	0	35%	35%
400		20	0	100%	100%
800		20	0	100%	100%

EC50	211.3 mg/L at 96 hours.
LOEC	200.0 mg/L at 96 hours.
NOEC	100.0 mg/L at 96 hours.
Remarks – Results	Temperature of the solutions ranged between 22.4 and 26.6°C. Conductivity of the sample solutions ranged between 191.2 and 450.5 µS/cm. Overall, the pH values for the sample solutions ranged between 7.40 and 8.08. The percentage saturation of dissolved oxygen was maintained well above 60% in all sample solutions, which meets the requirements of OECD TG 203 for fish toxicity tests.

CONCLUSION The test substance, Petro 11, is very slightly toxic (Mensink *et al*, 1995) to fish and is not classified according to GHS (United Nations, 2003).

TEST FACILITY University of Technology, Sydney (2004)

8.2.2. Acute/chronic toxicity to aquatic invertebrates

TEST SUBSTANCE Petro 11

METHOD ESA SOP 101, based on USEPA (1993) – Static, non-renewal.

Species	*Ceriodaphnia cf dubia*
Exposure Period	48 hours
Auxiliary Solvent	Nil
Water Hardness	Not provided
Analytical Monitoring	Temperature, pH, conductivity and dissolved oxygen.
Remarks - Method	Dilute Mineral Water (DMW) was used as the diluent for the toxicity tests and as the culture medium for the culturing of the test organisms. DMW was prepared 24-48 h prior to use by diluting Perrier mineral water to a concentration of 20% (vol/vol) with deionised water. A vitamin B12 and selenium supplement was added to the DMW to give final concentrations of 10 and 2 µg/L respectively. Six concentrations of Petro 11 powder were prepared in 250 mL beakers by diluting a 100 g/L working stock with DMW and subsequently homogenising the test solutions. A positive control, using was conducted in parallel, using potassium chloride as the toxicant.

The EC50 estimates (with 95% confidence limits) were determined using the trimmed Spearman-Karber method. The NOEC and LOEC were determined by performing a Steels Many-one Rank Test for non-parametric data.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0		20	0	0
6.25		20	0	0
12.5		20	0	2
25		20	0	6
50		20	7	11
75		20	6	13
100		20	10	15

EC50	95.2 mg/L at 24 hours (95% CI: 74.3-158.1 mg/L) 45.2 mg/L at 48 hours (95% CI: 31.7-64.5 mg/L)
LOEC	25.0 mg/L at 48 hours
NOEC	12.5 mg/L at 48 hours
Remarks - Results	The test substances was described as being readily soluble in DMW dilution water at 100 mg/L. Temperature of the solutions were held at 25±1°C. There were no reported deviations from the test protocol.

CONCLUSION The test substance, Petro 11, was found to be harmful to *Ceriodaphnia cf dubia* (United Nations, 2003).

TEST FACILITY Ecotox (2004)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE Petro 11

METHOD OECD TG 201 Alga, Growth Inhibition Test.
USEAP Protocol, 1994.

Species	*Selenastrum capricornutum*.
Exposure Period	72 hours
Concentration Range	Nominal: 0, 0.4, 1.1, 3.3, 10, 30, 100 mg/L
Auxiliary Solvent	EDTA
Analytical Monitoring	
Remarks - Method	A primary stock solution of 10 g/L (w/v) Petro 11 was prepared in USEPA medium (+EDTA). This was diluted further to form a secondary stock of 1 g/L (w/v) Petro 11. The six test concentrations were subsequently prepared. After mixing well, 6 mL of each test solution was dispensed into 20 mL silanised glass scintillation vials (each in triplicate). Each vial was inoculated with $1.3X10^4$ cells/mL of a *Selanastrum* suspension. Five concentrations of the reference toxicant copper (14.3 – 114.3 µg Cu/L) and a control were prepared in 50 mL USEPA (+EDTA) medium. The bioassay was acceptable if copper toxicity (IC50) was within the cusum chart limits and if growth rate in the controls was within the normal range for *Selenastrum* (2.0 ± 0.5 doublings/day). The 72 h IC50, LOEC and NOEC values were calculated using ToxCalc Ver. 5.0.23 (Tidepool Software).

RESULTS

IC50 *mg/L at 72 h*	*Growth LOEC* *mg/L at 72 h*	*NOEC* *mg/L at 72 h*
>100	>100	100

Remarks - Results The control growth rate criteria were satisfied, validating the test.

CONCLUSION The test substance, Petro 11, was not toxic to the alga with no significant inhibition of algal growth at any concentration tested.

TEST FACILITY CSIRO (2004)

8.2.4. Inhibition of microbial activity

REMARKS This test was not performed. For naphthalene sulfonic acids the literature presents a 17 h EC50=133 mg/L (Greim, 1994).

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified chemical will be imported into Australia, where it will be reformulated with other ingredients to form household and industrial cleaners. Nearly all of the notified chemical may potentially be disposed of to sewer after use, with only small quantities, including that proportion remaining as residual in containers and from major spills, being disposed of to landfill.

In sewer, the notified chemical may associate with suspended particles and sediment. In landfill, the notified chemical is not expected to be highly mobile and may adsorb to soil, where over time it should slowly degrade through biotic and abiotic processes to simple carbon and nitrogen based compounds.

Based on the worst-case scenario of 100% notified chemical being released to the aquatic environment via the sewer, with nil removal, a predicted environmental concentrations (PECs) of the notified chemical have been calculated:

Amount entering sewer per year	100,000 kg
Number of days per year	365
National population	20.4 million
Litres per person	200 L
PEC_{River}	67.027 µg/L.
PEC_{Ocean}	6.703 µg/L.

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m^2/year (10 ML/ha/yr). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 0.1 m of soil (density 1000 kg/m^3). Using these assumptions, irrigation with a concentration of 67.027 µg/L may potentially result in a soil concentration of approximately 670.27 µg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 3.35 and 6.7 mg/kg respectively.

The potential for the notified chemical to bioaccumulate is low due to its high level of water solubility.

9.1.2. Environment – effects assessment

The results of the ecotoxicological studies indicate that the notified chemical is harmful to invertebrates (96 h LC50 = 45.2 mg/L). A PNEC has therefore, been calculated using a safety factor of 100, resulting in PNEC = 452 µg/L.

9.1.3. Environment – risk characterisation

The Risk quotient (RQ) values, where RQ = PEC/PNEC, for freshwater and marine receiving environments have been calculated for the "worst case" scenario, as shown in the table below.

Worst Case	PEC µg/L	PNEC µg/L	RQ
River	67.027	452	0.15
Ocean	6.703	452	0.01

As the RQ for both river and marine receiving waters are below 1.0, the proposed diffuse use of the notified chemical, at current expected import volumes, is unlikely to pose an unacceptable risk to the aquatic environment. When only 25% release to freshwater is taken into account, the RQ reduces to 0.04.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Exposure of workers involved in transport and storage of powders containing more than 60% or liquids containing 30 – 50% notified chemical is only likely to occur in the event of accidental breach of containers.

Exposure of workers involved in reformulation activities will primarily occur during transfer of liquids or powders from the import containers to the mixing vessels. Local exhaust ventilation is used to control inhalation exposure to powders or aerosols and appropriate PPE is used to control inhalation, dermal and ocular exposure. Cleaning and maintenance of equipment can potentially result in exposure and is expected to be controlled by the use of appropriate PPE.

Packing of cleaning products would typically be automated and should result in limited worker exposure. QC testing should also result in limited exposure due to the low volumes of product tested.

Workers involved in use of the cleaning products can potentially be exposed. Exposure could be mainly dermal and could involve concentrations up to 10% for the undiluted form. After dilution to <1%, exposure can be dermal but, if sprayed, may also be via inhalation and may be ocular.

9.2.2. Public health – exposure assessment

The public may be exposed to <10% notified chemical in the undiluted form and <1% following dilution. Exposure will be mainly dermal but ocular and inhalation exposure may occur, particularly if the diluted product is sprayed.

9.2.3. Human health – effects assessment

The notified chemical was harmful via the oral route in rats (LD50 = 1646 mg/kg) but was of low acute toxicity via the dermal route. It was a moderate skin irritant but a severe eye irritant in rabbits and was a skin sensitiser in guinea pigs. A 90-day repeat dose oral toxicity study in dogs did not reveal any specific organ toxicity (NOAEL = 104.1 mg/kg bw/day). The notified chemical was not mutagenic in bacteria and close analogues were not convincingly genotoxic in in vitro chromosomal aberration studies in CHO cells and also one of these analogues was not genotoxic in an in vivo mouse micronucleus assay.

Based on the available data, the notified chemical is classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) and is assigned the risk phrases R22: harmful if swallowed; R41: risk of serious damage to eyes; R43: may cause sensitisation by skin contact. R41 is assigned on the basis that effects were still seen at the end of the observation period.

9.2.4. Occupational health and safety – risk characterisation

There is a low risk of adverse health effects to transport and storage workers except in the event of accidental breach of the containers. In this case serious eye damage from dispersion of powder formulations containing the notified chemical is possible.

There is a risk of serious eye damage and skin and respiratory sensitisation to workers weighing out and transferring powders containing the notified chemical to mixing vessels. However, this should be adequately controlled by the use of local exhaust ventilation provided it is used for all weighing operations, correctly adjusted and properly maintained. In addition, PPE is commonly used by workers involved in cleaning product formulation and this should further reduce the risk of adverse health effects. The risk of respiratory sensitisation should be minimised when liquids are transferred to mixing vessels and once the powders are dissolved. The applicant has suggested that the powders are not of respirable size but this has not been measured. Therefore, routine atmospheric monitoring will be necessary to keep atmospheric levels as low as possible and workers should undergo regular health checks to monitor potential health problems involving the respiratory tract.

Cleaning and maintenance operations and QC testing could potentially lead to serious eye damage and/or skin sensitisation and the risk should normally be minimised by the use of adequate PPE. Packing lines are typically automated and the risk of adverse health effects to

workers should be low during these operations.

Workers diluting concentrated cleaning products for use in various applications are at risk of serious eye damage if the products are transferred from gloves to eyes. Workers spraying products on to surfaces are at risk of skin and respiratory sensitisation but the risk of eye irritation should be minimised by the fact that the concentration of notified chemical in the diluted product is less than 1%.

9.2.5. Public health – risk characterisation

The public health risk will be similar to workers diluting concentrated cleaning products for use in various applications, namely, risk of serious eye damage if the products are transferred from gloves to eyes. Members of the public spraying products on to surfaces are at risk of skin and respiratory sensitisation but the risk of eye irritation should be minimised by the fact that the concentration of notified chemical in the diluted product is less than 1%.

10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

10.1. Hazard classification

Based on the available data the notified chemical is classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*. The classification and labelling details are:

R22: Harmful if swallowed
R41: Risk of serious eye damage
R43: May cause sensitisation by skin contact

and

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

Acute toxicity	Hazard category: 4	Hazard statement: Harmful if swallowed
Eye irritation	Hazard category: 1	Hazard statement: Irreversible effects on the eye
Skin Sensitisation	Hazard category: 1	Hazard statement: May cause allergic skin reaction

With respect to the environment, the notified chemical is classified as Chronic Category 3.

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio:

The chemical is not considered to pose a risk to the environment based on its reported use pattern.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is Low Concern to occupational health and safety for formulation activities due to the adequate engineering controls but High Concern for use of cleaning products by spraying as use of adequate respiratory protection is unlikely in all cases.

10.3.2. Public health

There is High Concern to public health when products are used in spray applications.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the products containing the notified chemical provided by the notifier were in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 2003). They are published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

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

12. RECOMMENDATIONS

REGULATORY CONTROLS
Hazard Classification and Labelling

- The NOHSC Chemicals Standards Sub-committee should consider the following health hazard classification for the notified chemical:
  - R22: Harmful if swallowed
  - R41: Risk of serious eye damage
  - R43: May cause sensitisation by skin contact
- Use the following risk phrases for products/mixtures containing the notified chemical:
  - ≥ 25%: R22: Harmful if swallowed
  - ≥ 10%: R41: Risk of serious eye damage
  - 5% ≤ conc ≤ 10%: R36: Irritating to eyes
  - ≥ 1%: R43: May cause sensitisation by skin contact
- The National Drugs and Poisons Standing Committee (NDPSC) should consider the notified chemical for listing on the SUSDP.
- Products containing more than the percentage specified of notified chemical and available to the public must carry the following warning statements and safety directions on the label:
  - 5%: Irritant, Avoid contact with eyes
  - 1%: (Repeated) exposure may cause sensitisation, Avoid contact with skin; Wear protective gloves when mixing or using
  - Any percentage: Breathing spray mist is harmful and may cause an asthma-like reaction, Avoid breathing spray mist.

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical as introduced and in formulated products:
  - Local exhaust ventilation should be employed at sites of potential dust cloud or aerosol generation.
- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as diluted for use and in formulated products:

- Cleaning by spray should be conducted in areas of good general ventilation
- Spills should be cleaned up promptly and placed in containers for disposal

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced, as diluted for use, and in formulated products:
  - Respiratory protection against imported powders where dust can be generated or in the absence of local exhaust ventilation;
  - Impervious gloves;
  - Safety goggles or face shields

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

- Atmospheric monitoring should be conducted periodically by formulators of cleaning products to measure workplace concentrations of dust during formulation of the notified chemical.

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

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

Environment

Disposal

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

Emergency procedures

Spills/release of the notified chemical should be physically contained, collected and disposed of in an appropriate manner.

12.1. Secondary notification

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

(1) Under Section 64(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.

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