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August 2001

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

BA-20

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Director
Chemicals Notification and Assessment

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1. APPLICANT

Kao (Australia) Marketing Pty Ltd (ABN 59 054 708 299) of 1A The Crescent KINGSGROVE NSW 2208 has submitted a standard notification statement in support of their application for an assessment certificate for BA-20.

2. IDENTITY OF THE CHEMICAL

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

Marketing Name:	BA-20; GA-4 (granules containing BA-20).
Method of Detection and Determination:	Infrared (IR) spectroscopy.
Spectral Data:	An IR spectrum was provided.

3. PHYSICAL AND CHEMICAL PROPERTIES

The physico-chemical data are for the notified chemical.

Appearance at 20°C & 101.3 kPa:	White powder.
Melting Point:	> 250°C
Density:	400 kg/m^3
Vapour Pressure:	Not determined but expected to be low.
Water Solubility:	0.014% at 25°C; 5.7% at 40°C; 32.9% at 60°C.
Partition Co-efficient (n-octanol/water):	log P_{ow} = 1.56 (see comments below).
Hydrolysis as a Function of pH:	Not determined (see comments below).
Adsorption/Desorption:	log Koc = 3.39 (see comments below).

Dissociation Constant:	Not determined (see comments below).
Particle Size:	Particle size distribution of the GA-4 granules used to formulate the imported laundry detergent is that a maximum of 5% of the particles have a diameter less than 350 micrometers.
Flash Point:	Not determined.
Flammability Limits:	Not determined.
Autoignition Temperature:	> 100°C
Explosive Properties:	Not expected to be explosive.
Reactivity/Stability:	Ready hydrolysis in water.

3.1 Comments on Physico-Chemical Properties

The water solubility of the notified chemical was determined by a bench study as follows:
Excess chemical was added to 100 mL of water to obtain a dispersion. This was stirred at the specified temperature for 1 hour. The mixture was filtered at the same temperature and the concentration of the chemical in the resulting filtrate was determined by HPLC. The solubility of the notified chemical in water was 1.4 g/L at 25°C, 57 g/L at 40°C, and 329 g/L at 60°C and the chemical can be regarded as readily soluble in water (Mensink, 1995).

The hydrolysis potential of the notified chemical at pH 7 was determined as part of the test for ready biodegradability. It was found that the chemical abiotically degraded in water by 11% over 28 days, indicating the ester moiety is relatively labile. The notifier has stated that hydrolysis will be accelerated under acidic or basic conditions and significant hydrolysis is expected during normal use of the chemical in washing machines, where the pH of the wash solution is typically around 10.5. In addition, a Quantitative Structure Activity Relationship (QSAR) calculation using "EPIWIN" software estimated t½ for the chemical to be 2 days at pH 8, and 20 days at pH 7. These values are consistent with biodegradability test results and the notifier's predictions.

The partition coefficient of the notified chemical was calculated as a QSAR estimate, using the "EPIWIN" program. The partition coefficient (log Pow) was calculated to be 1.56 and the chemical may be regarded as moderately hydrophilic, with some affinity for the aqueous phase (Mensink, 1995). However, this behaviour is likely to be complicated by the expected surface-active properties of the chemical, due to the close structural resemblance to linear alkylbenzenesulphonates.

The adsorption/desorption behaviour of the notified chemical was calculated with a QSAR estimate, using the "EPIWIN" program. The log Koc was calculated to be 3.39 and the chemical may be regarded as slightly mobile in soils (Mensink, 1995). This result is surprisingly high, and similar to the value expected for the free acid. However, again, this behaviour is likely to be complicated by the expected surface-active properties of the

chemical.

The notified chemical is the sodium salt of a very strong (sulphonic) acid and would remain completely dissociated under environmental conditions (pH 4 - 9).

4. PURITY OF THE CHEMICAL

Degree of Purity: Minimum of 97%

Hazardous Impurities: None known.

Non-hazardous Impurities (> 1% by weight): None known.

Additives/Adjuvants: None.

5. USE, VOLUME AND FORMULATION

The notified chemical will be used as a bleach activator in laundry detergent powder at less than 10%. Ten to fifteen tonnes of the notified chemical will be imported each year for the first five years as the final retail product in 1.5 kg cardboard retail containers and 1.2 kg plastic refill packs. The laundry detergent powder is in granular (reportedly non-dusting) form.

6. OCCUPATIONAL EXPOSURE

Transport and Storage

The notified chemical is imported in shipping containers on pallets wrapped in plastic and strapped securely. The containers are transported by road to the warehouses of a distribution company where unloading and further distribution by road to retail stores occurs. Ten to 20 waterside workers (2 – 3 hours per day, 1 day per month) and 50 – 100 transport drivers (interstate transport: 12 hours per day, 40 –50 days per year; transport to retail outlets, 3 – 4 hours per day, 200 days per year) would only be exposed in the event of accidental spillage. Warehouse workers (1 hour per day, 200 days per year) may potentially be exposed to spilled product from damaged containers. The product is formulated to be non dusting to minimise inhalation exposure. Clean up of small spills is accomplished with an industrial vacuum cleaner fitted with filters. Dermal exposure is prevented by the used of protective clothing. In the event of a large spill, clean up would be accomplished by shovelling the spilled product into suitable containers, which would be sealed and disposed of to landfill as industrial waste.

Retail

More than 5000 retail workers could be involved in removing product cases from pallets, removing individual retail containers from the cases and stacking them on supermarket shelves. Product containers would also be handled at checkouts. Workers would only be expected to be exposed to the product if the packing was damaged. Any spilled material

would be swept or vacuumed and disposed of. Residues would be removed with a mop. These events should be infrequent.

7. PUBLIC EXPOSURE

Public exposure to the notified chemical may occur in the event of a major transport accident involving breakage of containers. However, the potential for public exposure during unloading and distribution is expected to be low. The potential for any contact with the skin or eyes of people using the detergent for the machine washing of clothes, either directly to the skin or indirectly via residue material in laundered clothes, is also low. Exposure of the skin to the powder (either in dry form or as soapy water) will occur among those who wash clothes by hand without gloves. Hand washing also makes an eye splash possible. Some residual chemicals may remain in the fabric, which could result in a persistent low level skin contact when the clothes are worn.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

Release to the environment may occur due to accidental spills during transport and storage of the notified chemical. Minor spills are likely to be released into the sewerage system. In the case of major spills, the formulated chemical will be collected with shovels, by sweeping, or vacuuming. The notifier has indicated that this spilt material will be collected for disposal to landfill as industrial waste. In addition, the spill area may be mopped or hosed down and wash water containing the notified chemical will go to sewer. The notifier has estimated that spillage during transport and storage could result in up to 0.1% (15 kg) of the notified chemical going to landfill.

The notifier has estimated that up to an additional 1% (150 kg) of the notified chemical could be lost as a result of spills in retail stores. This material is likely to ultimately reside in the sewerage system.

It is likely that almost all of the notified chemical, as a component of a retail detergent, will go to domestic sewerage system as a result of end use in washing machines and tubs, with minor residual amounts in ‘empty’ packages which would go to landfill. Therefore, the entire inventory (15 tonnes) could enter the sewerage system.

8.2 Fate

Almost all the notified chemical is likely to be released to the water compartment through the sewerage system.

The notified chemical contains a large hydrocarbon moiety which could be expected to have an affinity for the organic component of sewer sludges and sediments, and a very polar sulphonate moiety, which would be expected to associate with the aqueous phase. The structure of the chemical is very similar to the well known linear alkylbenzenesulphonate (LAS) detergents, with the exception of the carboxylate functionality which is present in the

alkyl chain of the notified chemical. The relatively high calculated value for log Koc (ca 3.39) indicates that the chemical will predominantly associate with sediments and sludges. However, this conflicts with the high water solubility of the chemical (1.4 g/L), and may represent log Koc for the free acid. LAS analogues of the notified chemical are known to adsorb onto surfaces and suspended solids. However, only a relatively small proportion (1.5-3%) is removed in the sewage treatment process (Painter, 1992). Consequently, while a proportion of the notified chemical used may loosely associate with sewage sediments and sludge, it is likely to be mobile in these media and to re-enter the aqueous compartment. In any case, whether the compounds are in either an aqueous or soil environment, they are likely to be effectively degraded through biodegradation or hydrolysis (see below), and are unlikely to persist in either compartment.

The notifier has stated the notified chemical will be subject to significant hydrolytic degradation during the wash cycle, as hydrolysis of the ester moiety will be accelerated under acidic or basic conditions (the pH of the wash solution is expected to be around 10.5). Thus, the chemical is expected significantly degrade before release into the sewerage system. The major routes for degradation and elimination of the compound in the environment are expected to be primarily biological (bacteriological) processes. The initial breakdown products of the chemical are l will be subject to further biodegradation by microorganisms.

The ready biodegradability of the notified chemical powder was determined in accordance with OECD Test Guideline 301C, using the Modified MITI Test (I) (Kurume Research Laboratories, 1994). The notified chemical was exposed to activated sewage sludge microorganisms at a nominal concentration of 0.1% at 25 ± 2°C for 28 days. The activity of the sludge was monitored by using a reference material (aniline), and the relation between old and new sludge was taken into account. Degradation of the notified chemical was determined by comparing Biochemical Oxygen Demand (BOD) and Total Organic Carbon (TOC) values at 7 day intervals, up to 28 days. These results were corrected for recovery rates (101% for water + notified chemical, and 94.0% for sludge + test chemical). After 28 days during which aniline was degraded by 73%, the notified chemical was degraded by 64% (BOD) and 61% (TOC) and the chemical may thus be regarded as inherently biodegradable, but not necessarily readily biodegradable, as it is unclear whether the 60% degradability was achieved within 10 days after 10% biodegradation. A concurrent HPLC analysis of the chemical after 28 days showed 100% biodegradation to one component (hydrolysis product), but BOD measurements indicated that the other hydrolysis product had further degraded.

The relatively low molecular weight and high calculated log Koc (likely to be for the parent acid) of the notified chemical indicates some potential for bioaccumulation (Connell, 1990). However, its biodegradability and high water solubility will greatly limit any bioaccumulation.

9. EVALUATION OF TOXICOLOGICAL DATA

As the notified chemical readily hydrolyses to two components, it was accepted that repeated dose studies for each component could substitute for data on the notified chemical. Component 1 is one hydrolysis product, anticipated to be of higher toxicity. Component 2 is

an analogue of the second hydrolysis product. Summaries of skin and eye irritation studies on a close analogue also were available.

9.1 Acute Toxicity

Summary of the acute toxicity of BA-20

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD50 > 2000 mg/kg	Safepharm Laboratories (1998)
skin irritation	guinea pig	slight irritant	Kao Corporation (1997)
eye irritation	rabbit	slight irritant	Kao Corporation (2001a)
skin sensitisation	guinea pig	non-sensitising	Saitama Institute (2000)

9.1.1 Oral Toxicity (Safepharm Laboratories, 1998)

Species/strain: rat/Sprague-Dawley.

Number/sex of animals: 5/sex.

Observation period: 14 days.

Method of administration: Gavage (oral); dosage: 2000 mg/kg; vehicle: arachis oil.

Test method: OECD TG 401

Mortality: None.

Clinical observations: None.

Morphological findings: None.

LD_{50}: > 2000 mg/kg.

Result: The notified chemical was of very low acute oral toxicity in rats.

9.1.2 Dermal Toxicity

Data not provided.

9.1.3 Inhalation Toxicity

Data not provided.

9.1.4 Skin Irritation

9.1.4.1 BA-20 (Kao Corporation, 1997)

Species/strain: guinea pig/Dunkin-Hartley.

Number/sex of animals: 5 females.

Observation period: 5 days.

Method of administration: Either a 5% or 10% aqueous solution was applied to the flank under semi-occlusive dressing once per day for 4 days. Evaluations were conducted before each application and 24 hours after the last application.

Test method: Not specified.

Draize scores:

Time of observation (days)	***Animal number***									
	1		***2***		***3***		***4***		***5***	
Erythema	***10%*** [a]	***5%*** [b]	***10%***	***5%***	***10%***	***5%***	***10%***	***5%***	***10%***	***5%***
1	0[c]	0	0	0	0	0	0	0	0	0
2	0	0	1	0	1	0	1	1	0	0
3	1	0	0	0	1	0	1	1	0	0
4	1	0	1	0	1	0	1	1	0	1

[a,b] concentrations of test substance [c] see Attachment 1 for Draize scales

Result: The notified chemical at 5% or 10% was slightly irritating to the skin of guinea pigs.

9.1.4.2 Notified Chemical Analogue (testing facility unknown)

Humans (6/sex) were given 3 x 24 hour occluded patches of 0.4 mL of 0.1%, 0.5% and 1.0% (w/v) aqueous solutions with 0.2% w/v sodium lauryl sulphate as a reference irritant. Observations were made before the 2nd and 3rd applications and 24 hours after the 3rd application. The test substance produced moderate dermal irritation but was less irritating at the highest level tested than the irritant control.

9.1.5 Eye Irritation

9.1.5.1 BA-20 (Kao Corporation, 2001a)

Species/strain: rabbit/Japanese White.

Number/sex of animals: 1 female for each concentration of the notified chemical.

Observation period: 2 days.

Method of administration: 0.1 mL of the test substance instilled into the conjunctival sac of one eye; the left eye remained untreated and was the control.

Test method: Similar to OECD TG 405

Draize scores of unirrigated eyes:

	Time after instillation									
Animal	***1 hour***		***3 hours***		***6 hours***		***1 day***		***2 days***	
Cornea	***o***	***a***	***o***	***a***	***o***	***a***	***o***	***a***	***o***	***a***
1 (0.5% BA-20)	0[1]	0	0	0	0	0	0	0	0	0
2 (1% BA-20)	0	0	0	0	0	0	0	0	0	0
Iris										
1	0		0		0		0		0	
2	0		0		0		0		0	

Conjunctiva	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***
1	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0
2	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0

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

Result: The notified chemical at 1% was slightly irritating to the eyes of rabbits.

9.1.5.2 Notified Chemical Analogue (International Research and Development Corporation, 2000a, 2000b)

Two studies were conducted using New Zealand White rabbits, one where the test substance was placed directly on the cornea and one where it was placed in the conjunctival sac.

In study 1, 0.01 cc of the powder was placed directly on the cornea and either rinsed with 20 mL of water 4 seconds post-instillation or not. For the unrinsed group 6 of 6 animals (3/sex) exhibited corneal involvement. The calculated maximum average score was 33.7 and eyes returned to normal in 1 animal in 3, 4 or 14 days and in 3 animals in 7 days. For the rinsed eyes the calculated maximum average score was 20.0, the cornea was involved in 1 of 3 animals and eyes returned to normal in 2 animals in 3 days and in one animal in 7 days. It was concluded that the test substance was a slight to moderate eye irritant.

In the second study either 3 mg of test substance or 0.1 mL of a 10% (w/v) solution of the test substance was placed into the conjunctival sac of one eye. For the neat substance, the eyes of one group were rinsed with 20 mL of water for 4 seconds. Results were as follows:

Treatment	*Maximum average score*	*Number of animals with cornea involvement*	*Days to normal*
3 mg test substance, unrinsed eyes	16.7	2 of 3	2 in 3 days, 1 in 4 days
3 mg test substance, rinsed eyes	5.3	0 of 3	3 in 2 days
0.1 mL 10% test substance	28.0	3 of 3	2 in 4 days, 1 in 21 days

The test substance was judged to be a slight to moderate eye irritant in rabbits.

9.1.6 Skin Sensitisation (Saitama Institute, 2000)

Species/strain: guinea pig/Dunkin-Hartley.

Number of animals: 10 test; 5 controls.

Induction procedure:

days 1 -14

test group: Twice weekly occluded applications of 10% BA-20 were applied for 24 hours twice per week for 2 weeks. An intradermal injection of 0.1 mL of Freund's Complete Adjuvant was administered separately at 2 sites in the patched area of skin once before the 3rd treatment.

control group: The control group received 50% ethanol in water under the same conditions as the test group.

Challenge procedure:

day 21 The flank was shaved and solutions (1, 5 and 10%) of the test substance applied. Sites were scored at 24, 48 and 72 hours.

Test method: Cumulative enhancement protocol (Tsuchiya *et. al*, 1985)

Challenge outcome:

Challenge concentration	*Test animals*			*Control animals*		
	*24 hours**	*48 hours**	*72 hours**	*24 hours*	*48 hours*	*72 hours*

1%, 5% or 10%	0/10**	0/10	0/10	0/5	0/5	0/5

* time after patch removal
** number of animals exhibiting positive response

Result: The notified chemical was not sensitising to the skin of guinea pigs.

9.2 Repeated Dose Toxicity

9.2.1 Component 1 – Notified Chemical Analogue (Safepharm Laboratories, 1991)

Species/strain: rat/Sprague-Dawley.

Number/sex of animals: 5/sex.

Method of administration: Gavage (oral); vehicle: arachis oil.

Dose/Study duration: 0, 150, 400 and 1000 mg/kg/day for 28 days.

Test method: OECD TG 407

Clinical observations

None.

Bodyweight/Food Consumption

No apparent adverse effects.

Clinical chemistry: All treated males exhibited reduced bilirubin which were not dose-related and were within the historical control range; high dose males exhibited elevated calcium levels which were within the historical control range.

Haematology: Sporadic changes in some parameters in the low and mid dose groups.

Macroscopic findings: Incidental findings unrelated to treatment.

Organ weights: Increased relative ovary weights in high dose females with one value outside the historical control range. Other sporadic changes were limited to the intermediate dose animals.

Histopathology

Slight centrilobular hepatocyte enlargement was observed for high dose male rats.

Comment

The liver effects in high dose males were suggestive of an adaptive response. Clinical chemistry changes and elevated ovary weights in high dose females did not have

histopathological correlates.

Result

The No Effect Level (NOEL) was 400 mg/kg/day for 28 days on the basis of liver effects in males.

9.2.2 Component 2 –Hydrolysis Component Analogue (TNO BIBRA International Ltd, 1996; summary only provided)

Ten rats were fed 10% component 2 (about 5 g/kg/day) for 150 days did not develop gross changes in the forestomach or glandular stomach.

Groups of 15 rats were fed component 2 at approximately 2.5 g/kg/day for 47 weeks exhibited normal mortality, growth, organ weights and cellular structure of the liver and intestine.

Twelve male rats given component 2 for 6 weeks at dietary levels approximating 4 g/kg/day exhibited reduced body weight gain, increased plasma triglyceride and cholesterol levels and some indication (not statistically significant) of thrombogenic activity.

An unstated number of dogs fed up to approximately 4.4 g/kg/day of component 2 for 102 days showed no changes in organ weights, structure or function of the liver or kidney, or electrical activity of the heart.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (JBS Inc, 2001)

Strains: *S. typhimurium* TA 100, TA 1535, TA 98, TA 1537; *Escherichia coli* WP2*uvr*A.

Metabolic activation: S9 fraction from the livers of rats treated with Phenobarbital and 5,6-benzoflavone.

Concentration range: 0, 10, 50, 100, 500, 1000 or 5000 microgram/plate initially. Toxicity in preliminary studies required modification of dose levels as follows:

	TA 100 & TA 1535	**WP2*uvr*A**	**TA 98**	**TA 1537**
-S9	0, 2, 5, 10, 20, 39, 78	0, 156, 313 625, 1250 2500, 5000	0, 39, 78 156, 313 625, 1250	0, 5, 10, 20, 39, 78, 156

+S9	0, 20, 39, 78, 156, 313, 625	0, 313, 625, 1250, 2500 5000	0, 20, 39, 78, 156, 313, 625

Test method: OECD TG 471

Comment: Solvent control: dimethylsulfoxide; Postive controls: (a) -S9: 2-(2-furyl)-3-(5-nitro-2-furyl)acrylamide (AF-2): TA 98, TA 100 and WP2*uvr*A; sodium azide, TA 1535; 9-aminoacridine, TA 1537; (b) + S9: benzo(a)pyrene, TA 100, TA 98 and TA 1537; 2-aminoanthracene, TA 1535, WP2*uvr*A.

Similar numbers of back mutant colonies were observed regardless of the addition of the notified chemical to bacterial suspensions prior to plating with or without rat liver S9 fraction was included. Negative controls were within historical limits and positive controls demonstrated the sensitivity of the test system.

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

9.3.2 Chromosomal Aberration Assay in Chinese Hamster Lung (CHL) Cells (Shin Nippon Biomedical Laboratories Ltd, 2001)

Cells: CHL

Metabolic activation system: S9 fraction from the livers of male Sprague-Dawley rats treated with phenobarbital/ 5,6-benzoflavone.

Dosing schedule:

Metabolic Activation	*Experiment Number*	*Test concentration (microgram/mL)*	*Controls*
-S9	1	treatment time = 6 hours, harvest time = 24 hours 0, 262.1, 327.7, 409.6, 512, 640*, 800*, 1000* microgram/mL	Positive: mitomycin C 0.15 microgram/mL

	2	treatment time = 24 hours = harvest time 0, 104.9, 131.1, 163.8, 204.8, 256*, 320*, 400*	Positive: mitomycin C, 0.05 microgram/mL
		treatment time = 48 hours = harvest time 0, 83.9, 104.9, 131.1, 163.8*, 204.8*, 256*, 320*	Positive: mitomycin C, 0.05 microgram/mL Negative for all cultures: 0.5% carboxy methylcellulose sodium aqueous solution
+S9	2	treatment time = 6 hours, harvest time = 24 hours 0, 262.1, 327.7, 409.6, 512, 640#, 800#, 1000# microgram/mL	Positive: benzo(a)pyrene, 20 microgram/mL Negative: 0.5% carboxy methylcellulose sodium aqueous solution

* cultures in which toxicity precluded metaphase analysis, other cultures were selected for metaphase analysis;
# frequency of cells with structural aberrations judged as positive.

Test method: OECD TG 473

Comment: The positive and negative controls were within the historical control ranges.

The frequency of cells with structural chromosomal aberrations was elevated in the presence of metabolic activation at dose levels of 640 – 1000 microgram/mL. It is possible that toxicity of the notified chemical in the cultures without S9 fraction precluded the detection of induction of chromosomal aberrations. The positive experiment was not repeated.

Result: The notified chemical was clastogenic under the conditions of the test when tested in the presence of metabolic activation.

9.3.3 Micronucleus Assay in the Bone Marrow Cells of the Mouse (Mitsubishi Chemical Safety Institute, 2001)

Species/strain: mouse/CD-1.

Number and sex of animals: 6 males/ dose group.

Doses:	0, 500, 1000 and 2000 mg/kg.
Method of administration:	Gavage (oral), twice at a 24-hour interval. Bone marrow harvest 24 hours after the last treatment.
Test method:	OECD TG 474
Comment:	The percentage of polychromatic erythrocytes appeared to be unaffected by treatment.
Result:	The notified chemical was non clastogenic under the conditions of the test.

9.4 Overall Assessment of Toxicological Data

The notified chemical was of very low acute oral toxicity (LD50 > 2000 mg/kg). A 10% solution was slightly irritating to guinea pig skin. A 1% solution was a moderate dermal irritant in humans when applied 3 times for 24 hours per application. A 1% solution was slightly irritating to rabbit eyes. In a second study either 0.01 cc of an analogue was applied directly to the cornea or 3 mg or 0.1 mL of a 10% solution instilled into the conjunctival sac. The analogue was a slight to moderate eye irritant in rabbits. The notified chemical was not a skin sensitiser in guinea pigs.

Repeated dose toxicity studies were conducted on one of the hydrolysis products of the notified chemical and on an analogue of a second hydrolysis product. The NOEL for the hydrolysis product was 400 mg/kg/day for 28 days. Studies on the analogue of the second product were reported as summaries. Weight of evidence suggests this component exhibits little systemic toxicity.

The notified chemical was not mutagenic in bacteria nor clastogenic in bone marrow cells of mice as measured by induction of micronuclei. However, it was clastogenic as measured by induction of chromosomal aberrations in CHL cells in the presence of metabolic activation.
The notified chemical is not determined to be a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999). However, as the notified chemical was tested at less than 100% for skin and eye irritation, it is possible the neat substance could be classified as a skin and eye irritant.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following ecotoxicity test data were provided by the notifier:

Test	***Species***	***Results***
Acute Fish Toxicity	Japanese killifish (*Himedaka*)	LC50(96 h) = 29.3 mg/L NOEC (72 h) > 22.2 mg/L
Acute Immobilisation of Freshwater Invertebrates	Daphnid (*Ceriodaphnia dubia*)	EC50(48 h) = 28 mg/L NOEC(48 h) = 12.5 mg/L

Algal Inhibition	*Selenastrum capricornutum*	EC50(72 h) = 12 mg/L NOEC (72 h) = 6 mg/L

* NOEC - no observable effect concentration

Acute Toxicity to Fish (Kao Corporation, 2001b)

This test was performed in accordance with OECD Test Guideline 203. An abbreviated test report was provided. The test organism was the Japanese Killifish (*Himedaka*). 8 fish were exposed to the notified chemical for a period of 96 hours. The test medium was exchanged every 24 hours after the initiation of the experiment. Mortalities were recorded at 3, 6, 24, 48, 72 and 96 hours from the time of exposure. Fish were exposed to nominal concentrations of 22.2, 33.3, 50.0, 75.0, and 112.5 mg/L. Ecotoxicity values were calculated by the Probit method, based on nominal test concentrations.

The 96 hour LC_{50} for the notified chemical was 29.3 mg/L, the 96 hour NOEC was >22.2 mg/L and the chemical is thus considered to be slightly toxic to fish.

Acute Toxicity to Aquatic Invertebrates (CSIRO, 2001a)

This test was performed in accordance with USEPA test protocols. The test organism was the freshwater crustacean, *Ceriodaphnia dubia*. Nominal test solution concentrations of 100, 50, 25, 12.5, 6.25 and 1.25 mg/L were employed. A distinct precipitate was visible at notified chemical concentrations of 10 and 100 mg/L (the stock solutions). Stirring, shaking and gentle heating did not aid dissolution. This observation seems to be at odds with the results of the water solubility bench study (see comments on physico-chemical properties), where a solubility of 1.4 g/L was determined. This may the due to the presence of salt constituents in the synthetic softwater used for daphnid cultures, which include calcium and magnesium salts that will precipitate certain detergents. The numbers of immobile *C. dubia* were recorded at 24 and 48 hours. The reference toxicant and one set of controls were tested in quadruplicate (20 organisms per concentration) for quality control purposes. Statistical analysis of the test data was carried out using ToxCalc Version 5.0.23 (Tidepool Software). After testing the data for normality and homogeneity of variance, data were transformed using ArcSine square. The EC_{50} was calculated using Trimmed Spearman-Karber analysis. Bonferroni's t-Test or Dunnetts Multiple Comparison Test was used to determine which treatment concentrations were significantly different to controls, in order to estimate LOEC and NOEC values.

The 48 hour EC_{50} was 28 mg/L, and the 48 hour NOEC was 12.5 mg/L, suggesting that the notified chemical is slightly toxic to daphnids. Physical effects seen at concentrations >12.5 mg/L confounded the interpretation of toxicity effects. All reported values are nominal concentrations.

Algal Inhibition Test (CSIRO, 2001b)

This test was performed in accordance with OECD test guideline 201. The test organism was the unicellular green alga *Selenastrum capricornutum* obtained from laboratory cultures maintained under axenic conditions at 24 ± 2°C. Cells of the alga in the exponential growth phase, after washing to remove culture medium, were used in the algal bioassays for the test.

The bioassay was carried out in EPA medium with EDTA. Each vial was inoculated with 1.4-2.0 x 10^4 cells/mL of a *S. capricornutum* suspension. Vials were incubated at 24 ± 2°C under

continuous light at 4000 ± 10% lux on an orbital shaker (100 rpm). Cell density in each treatment was determined after 72 hours by counting cells using a Coulter Multisizer IIE particle analyser with 70 μm aperture. The pH at each test concentration was determined at the beginning and end of the tests.

Three replicate cultures of the control and each concentration of the test substance were employed. Nominal test solution concentrations of 1, 6, 12, 25, 50, 75 and 100 mg/L were employed. As for the daphnid acute immobilisation test, test concentrations of the notified chemical above 12 mg/L exceeded the solubility limit of the chemical, with visible signs of precipitation. However, light intensity controls showed that there was no significant inhibition of algal cell yield (4% inhibition) caused by light attenuation by the notified chemical precipitate. This indicated that any algal growth inhibition observed was due to chemical toxicity, rather than light suppression.

The 72-hour EC_{50} was 12 mg/L, and the 72 hour NOEC was 6 mg/L. The notified chemical may be regarded as slightly toxic to algae. All reported values pertain to nominal concentrations.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The majority of the notified chemical will be discharged to the sewerage system as a result of household use in washing machines. The Predicted Environmental Concentration (PEC), based on the entire inventory of the chemical discharged to sewer, and an Australia-wide use pattern with no dilution in receiving waters and no adsorption to sludges is calculated below:

Maximum Amount of Notified Chemical Discharged to Sewer:	15 tonnes
National Population:	19,000,000
Daily Water Use/Person:	150 L
PEC:	14.4 microgram/L

Taking into account dilution in receiving waters, the PEC is more than 3 orders of magnitude less than the lethality index of the most sensitive aquatic organism tested, namely the 12 mg/L EC50 for algae. Therefore, the notified chemical is not expected to pose a significant environmental risk to aquatic organisms. In addition, the chemical is likely to be significantly degraded during the wash cycle before it enters the sewer, with further abiotic and biotic degradation occurring in the aquatic compartment.

The high water solubility and biodegradability of the notified chemical should preclude bioaccumulation.

Overall, the environmental risk presented by the introduction of the notified chemical is predicted to be low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Hazard Assessment

The notified chemical was of very low acute oral toxicity in rats (LD50 > 2000 mg/kg). A 10% solution was slightly irritating to guinea pig skin and a 1% solution was a moderate dermal irritant in humans on repeated application. A 1% solution was a slight eye irritant in rabbits. An analogue of the notified chemical was a slight to moderate eye irritant in rabbits at a concentration of 10%. The notified chemical was not a skin sensitiser in guinea pigs. No target organ toxicity was identified in repeated dose studies of one of the hydrolysis products and an analogue of the other hydrolysis product. The notified chemical was not mutagenic in bacteria nor clastogenic in bone marrow cells of mice as measured by induction of micronuclei. However, it was clastogenic as measured by induction of chromosomal aberrations in CHL cells in the presence of metabolic activation.

Although it is likely that the notified chemical would be a skin irritant and an eye irritant, the tests were only performed with dilute solutions of either the notified chemical or analogues and no classification can be made according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

The notified chemical is to be imported at a low concentration in laundry detergent. The MSDS for the laundry detergent lists potential health effects as eye, skin and respiratory irritation but states that the detergent is not classified as hazardous according to NOHSC criteria. It may be expected that repeated or prolonged contact would lead to irritant effects.

Occupational Health and Safety

The notified chemical will be imported in standard laundry detergent retail packs up to 1.5 kg capacity. Exposure of workers involved in transport or storage of detergent containers should only occur in the event of accidental spillage.

Retail workers involved in unpacking palettes containing detergent packs, in stacking shelves and at the checkouts should only be exposed in the unlikely event of damage to packaging. In this case inhalation exposure is limited by the use of a non-dusting formulation. Spillage is expected to be cleaned up with a vacuum cleaner or dust-pan and brush and put into a container for disposal. Dermal exposure in these circumstances should be minimal and is further controlled by wearing protective clothing. As the notified chemical is present in detergent at a low concentration and there is limited opportunity for exposure, the risk of irritant effects in workers should be low.

Public Health

Public exposure to the notified chemical during transport and distribution and at retail outlets is predicted to be minimal. The potential for contact with the skin or eyes of people using the detergent for the machine washing of clothes, either directly to the skin or indirectly via residue material in laundered clothes, is also low. Exposure to the skin or eyes may occur if the detergent is used for hand-washing but the risk of irritant effects is expected to be low given the concentration of the notified chemical in the detergent.

13. RECOMMENDATIONS

Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical in laundry detergent:
  - spillage should be cleaned up with an industrial vacuum cleaner and placed into appropriate containers for disposal.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical in laundry detergent:
  - gloves and protective clothing should be worn when cleaning up spills; for major spills a dust mask should be employed.

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

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

- If products and mixtures containing the notified 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(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 and detergent product containing 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).

These MSDS were provided by the applicant as part of the notification statement. They are reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

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