File No: NA/966

October 2001

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Sensiva SC 50

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Director
Chemicals Notification and Assessment

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1. APPLICANT

Schwarzkopf Pty Ltd of 20 Rodborough Road, Frenchs Forest, NSW 2068 (ABN 21 000 076 782) and Chemiplas Australia Pty Ltd of Lot 1, Canley Vale Road, Wetherill Park, NSW 2164 (ABN 29 003 056 808) submitted a standard notification statement in support of their application for an assessment certificate for **Sensiva SC 50.** No application has been made for information relating to **Sensiva SC 50** to be exempt from publication in the Full Public or Summary Reports.

2. IDENTITY OF THE CHEMICAL

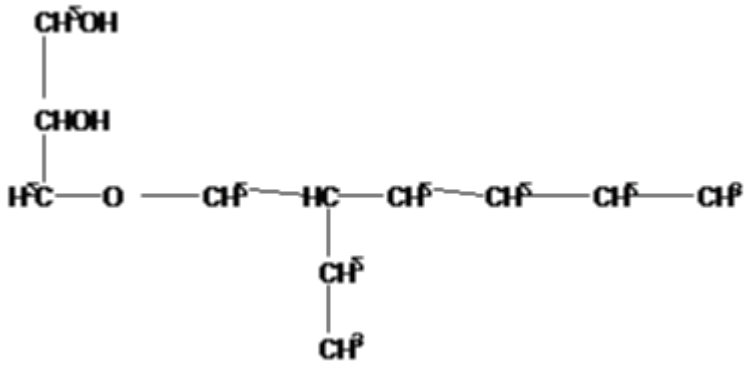
Chemical Name: 3-[(2-Ethylhexyl)oxy]-1,2-propanediol

Chemical Abstracts Service (CAS) Registry No.: 70445-33-9

Marketing Name: Sensiva SC 50
Fa Men Deodorant (0.3% notified chemical)

Molecular Formula: $C_{11}H_{24}O_3$

Structural Formula:



Molecular Weight:	204.3
Method of Detection and Determination:	The notified chemical was detected and characterised using ultraviolet (UV), infrared (IR) and nuclear magnetic resonance (NMR) spectroscopy.
Spectral Data:	UV, IR and NMR spectra were provided.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C & 101.3 kPa:	Colourless to pale yellow viscous liquid
Boiling Point:	> 285°C
Relative Density:	0.9503 ± 0.5% at 20°C
Vapour Pressure:	Interpolated = 0.30 ± 0.03 Pa at 25°C Upper limit = 25 Pa at 25°C
Henry's Law Constant:	Using Interpolated VP = 3.41 x 10^{-2} Pa.m^3/mol Using Upper limit VP = 2.84 Pa.m^3/mol
Water Solubility:	1.8 g/L at 22.5°C
Partition Co-efficient (n-octanol/water):	log P_{ow} = 2.53
Hydrolysis as a Function of pH:	$T_{1/2}$ at pH 4.0, 7.0, 9.0 > 1 year
Adsorption/Desorption:	Not determined
Dissociation Constant:	Not determined
Flash Point:	152°C (closed cup)
Flammability Limits:	Not determined. The notified chemical is combustible.
Autoignition Temperature:	250°C
Explosive Properties:	Not explosive
Reactivity/Stability:	Stable

3.1 Comments on Physico-Chemical Properties

The vapour pressure (VP) of the notified chemical was determined using the Static Method according to the protocols and guidelines of OECD TG 104: Vapour Pressure Curve. Two

series of measurements were performed. The first series of 80 measurements was determined at temperatures of 21.85 and 28.26ºC. During these measurements a continuous decrease in vapour pressure was observed. As a consequence, the sample vessel containing the test substance was evacuated for approximately 2 hours to remove volatile impurities. The second series of 115 measurements was determined at 3 different temperatures (23.74, 30.24 and 36.74ºC). A relatively small drop in vapour pressure was observed during the first 70 measurements taken at 23.74ºC. After the first 70 measurements, measurements were conducted at the 2 higher temperatures and the vapour pressure stabilised, indicating the vapour pressure shows ideal behaviour (RCC NOTOX, 1992).

A vapour pressure curve was constructed using vapour pressure determinations from the second series of measurements. To determine a value for vapour pressure for each temperature, the vapour pressure readings in each series of measurements were averaged. The vapour pressure at 25ºC was interpolated from the vapour pressure curve to be 0.30 Pa ± 0.03 Pa. To estimate an upper limit of vapour pressure as taken directly from the container, measurements made at 21.85ºC were back extrapolated to 25ºC, using the slope of the vapour pressure curve. The upper limit vapour pressure was estimated to be 25 Pa (RCC, NOTOX, 1992).

Henry's Law Constant (H) was calculated from the vapour pressure (VP), the water solubility (S), and the molecular weight (MW) of the notified chemical through the following relationship: H = VP x MW/S. The value of H derived from the upper limit VP indicates the notified chemical will be moderately volatile from water or moist soil. The value of H derived from the interpolated VP indicates the chemical will be slightly volatile from water or moist soil (Mensinck *et al*. 1995).

The substance is soluble in water. The water solubility test was carried out in accordance with the protocols of OECD TG 105, using average solubility determined from 10 samples, with the lower limit of saturation concentrations being 1.76 g/L and the upper limit of saturation concentration being 2.07 g/L (International Bio Research, 1992a).

The test substance was found to be more soluble in n-octanol than in water. The partition coefficient was determined using the protocols and methods of OECD TG 107 (shake flask method). The partition coefficient averaged for 10 samples was Pow = 342 (International Bio Research, 1992b).

A preliminary hydrolysis as a function of pH test (OECD TG 111) was carried out at pH 4, 7, and 9, and 50ºC over a period of 120 hours. The substance did not undergo significant degradation over the test period as determined by gas chromatography (International Bio Research, 1992c).

The adsorption coefficient was not provided. The notification dossier states that the adsorption to organic matter is not expected to be extensive given the partition coefficient.

The dissociation constant was not determined because the notified chemical does not contain any dissociable groups.

Duplicate tests for flash point were conducted. Flashes were observed at 152°C in the first test and 154°C in the second test.

4. PURITY OF THE CHEMICAL

Degree of Purity: > 99%

Hazardous Impurities: None

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

Additives/Adjuvants: None

5. USE, VOLUME AND FORMULATION

The notified chemical will be used as a bacteriocidal agent in the manufacture of aerosol deodorants. Thirty kilograms of notified chemical will be imported initially in ready-to-use aerosol products in pressurised aluminium cans. For subsequent local production, the notified chemical will be imported neat in 10kg polyethylene flasks. Three hundred kilograms will be imported in the first year increasing to 1500 kg by the fifth year.

6. OCCUPATIONAL EXPOSURE

Import and Transport

Notified chemical in imported polyethylene flasks and ready-to-use aerosol cans will not be accessed prior to manufacture and end-use respectively. Therefore, exposure of 6-8 transport personnel working approximately 2-3 hours/day, 5-10 days/year is not expected and will only occur as a result of accidental breach of containers.

Deodorant Manufacture

Approximately 50 personnel working 8 hours/day for 100 days/year will be involved in the formulation of deodorant products containing the notified chemical. The notified chemical will be poured from import containers into a closed 1000 L stainless steel mixing vessel where the chemical will be mixed with other ingredients. The mix will then be pumped via an enclosed filling line to a multi-head filling machine where the final product will be transferred automatically to 100 g aluminium aerosol cans. At this point the notified chemical will be present at 0.3%. The aerosol containers will then be packed automatically into cardboard cartons and stored until distribution.

Dermal and/or ocular exposure to the notified chemical may occur from the manual decanting from import containers. In addition, similar exposure may occur from spillage during filling of aerosol containers. Exposure, mostly dermal, may occur also during cleaning and routine maintenance of the mixing vessels and filling machinery.

Because of the low vapour pressure of the notified chemical, inhalation exposure during decanting from the import containers is unlikely. Despite the possibility of aerosol formation during filling operations, inhalation exposure at this point is also unlikely due to the low concentration of notified chemical present (0.3%) and exhaust ventilation fitted to the filling machinery.

To control exposure, reformulation staff will wear personal protective equipment consisting of overalls, safety shoes, disposable latex gloves and safety glasses.

Quality control will be conducted by 2-4 research and development staff working approximately 1 hour/day for 150 days/year. Workers will manually sample from the 1000L mixer and test the mix in a quality control laboratory. Exposure will be controlled by personal protective equipment consisting of long-sleeved laboratory coats, impervious gloves, face mask and safety glasses. Inhalation exposure will be controlled by the low vapour pressure of the notified chemical, natural ventilation at the point of sampling and the use of fume cupboards during laboratory analysis.

Distribution and Retail Operations

Ready-to-use deodorant containing the notified chemical will be transported by road to retail outlets where approximately 5000 or more retail staff working on average 1 hour/day for 50 days/year will unload the deodorant product from cartons and stack them onto shelves. Although the use of personal protective clothing in addition to normal everyday apparel is uncertain during these operations, transport and retail workers will only be exposed to the notified chemical as a result of accidental breach of the pressurised aluminium containers. If this occurs, exposure is likely to be only slight due to the low concentration of notified chemical (0.3%) in the deodorant.

7. PUBLIC EXPOSURE

Contact with the notified chemical through transport accidents or through other means of environmental contact is not likely and the potential for public exposure in these circumstances is minimal. Contact with the notified chemical may be dermal or by inhalation. The degree of exposure to the notified chemical among consumers who use the aerosol product may range from low to high depending on the frequency of application, the care taken with applications, the amount of aerosol product applied on any occasion and the frequency of body washing. Contact will be dermal as intended but eye contact and inhalation are also possible.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

No release of the notified chemical is anticipated during transport, storage and handling of the product, Fa Men Deodorant, unless an accidental spill occurs and the containers are ruptured. Release of the notified chemical is expected to occur via three main routes: during end use (>98%), product manufacturing (<1%), and disposal of the product containers (<1%).

Manufacturing

Some release of the notified chemical will occur at the manufacturing site during the formulation processes mainly through small operational spills, in aerosols, and during equipment cleaning. However, release during manufacturing is expected to be small because all procedures are conducted using enclosed automated systems designed to reduce spills and

prevent aerosol creation. During equipment cleaning, the mixing tanks and filling lines are rinsed out and the waste water sent to an on-site waste water treatment facility.

It is anticipated that 50 batches of final product, containing 1000 kg a batch, will be produced each year. Out of each 1000 kg batch of final product, about 10 kg (containing 30 g notified chemical) will be sent to the on-site treatment plant. The waste water treatment systems at the formulator consists of a 30,000 L tank, a solids operator, a grease remover, automatic pH adjustment, and a dissolved air flotation (DAF) tank. Treatment capacity is 10,000 to 20,000 L/hour.

Assuming the entire 1000 kg batch is released to the treatment facility in a day, then 30 g of notified chemical will be released to the sewer from the manufacturing site. At a treatment capacity of 10,000 L per hour, approximately 0.375 mg/L of notified chemical will be released to the sewer each hour. This amount would be further diluted when it enters the metropolitan treatment plant.

End Use

The majority of the notified chemical (1500 kg/year by year 5) will be released during use of the deodorant product. End users will apply the deodorant by spraying it to their under-arms. About 5 g of the aerosol (0.015 g of notified chemical) will be used per application. It is expected that most of the deodorant will be deposited under the arms, and will eventually be washed off in the shower. A small amount may adhere to clothing or be released into the air in aerosol droplets.

Container Disposal

The notifier estimates that 1% of the chemical will remain in the import containers after emptying or about 15 kg notified chemical annually. It is expected that the empty containers will be disposed of in landfill sites.

About 2% (30 kg/year) of the notified chemical is expected to remain in the container after the deodorant is used up. It is anticipated that the used containers will be disposed of to landfill via domestic garbage collection.

8.2 Fate

Usage patterns indicate that over 99% of the notified chemical in the deodorant will ultimately be released into the domestic sewage treatment system predominantly when it is washed off the skin and to a much lesser extent during manufacturing. A small amount of the chemical remaining in used containers will be disposed of in landfill.

In the sewage treatment facilities, most of the chemical is expected to become associated with the water compartment due to its high water solubility. No adsorption data were provided in the notification dossier, but the notified chemical is not expected to exhibit significant adsorption to organic matter or sediments in the water compartment given its ready water solubility and relatively low partition coefficient. Any chemical persisting in the sewage system after treatment is expected to enter the marine and freshwater environments mainly in solution, with a small amount likely to remain in the sewage sludge adsorbed onto organic matter.

The notified chemical is not readily degraded by micro-organisms under aerobic conditions, but is ultimately biodegradable. In a ready biodegradation test (Closed Bottle Test OECD TG 301D), performed using micro-organisms in sewage sludge, only 8.2% of the notified chemical was degraded over 5 days, while 20.6% was degraded at the end of the 28-day test period. This compared to 62.9% of the reference substance, sodium benzoate, degraded after 21 days and 69% degraded after 28 days (IBR, 1991a), which indicates the test was viable.

An Inherent Biodegradability Test (modified Zahn-Wellens OECD TG 302B) was conducted at a constant temperature of 21 ± 2ºC to compare the degradation of the notified chemical (TOC =303.2 mg/L) against a reference substance, sodium benzoate (TOC = 266.7 mg/L), using an inoculum and a mineral nutrient medium. Also included in the test was a blank sample containing the notified chemical in test water without inoculum or a mineral nutrient. The test resulted in 40% degradation of the notified chemical after 12 days, 69% after 26 days, and 70% after 28 days, compared to 97% of the reference substance degraded after 7 days. Losses of 36% of the test substance occurred in the blank test sample within 28 days, hence, more than half of the losses of the notified chemical occurring over the test period were probably due to abiotic degradation processes. The losses were attributed to either adsorption or evaporation (IBR, 1992d). The vapour pressure at 25ºC indicates the substance is moderately volatile. Henry's Law Constants calculated using an average and an upper limit for VP indicate the notified chemical would be slightly to moderately volatile from water or moist soils.

The notified chemical meets several of the criteria describing chemicals with a potential to bioaccumulate (Connell, 1990). For example, much of the ability of a substance to cross biological membrane depends on its chemical structure and molecular weight. Chemicals with a high proportion of aliphatic bonds, and with molecular weights between 100 and 600, have an increased bioaccumulation potential, compared to substances of higher molecular weights. Maximum potential to accumulate occurs at a MW of about 350 (Connell, 1990). The notified chemical has a structure dominated by C-C bonds, and a molecular weight of 204 g/mol.

Another important property giving chemicals the potential to accumulate in organisms is the balance between its hydrophilicity and lipophilicity. Chemicals with log P_{ow} values between 2 and 12 have the capacity to bioaccumulate, and show a maximum accumulation potential at values of about 6. In addition, chemicals with a water solubility less than 18 mole/L, can potentially bioaccumulate. A maximum capacity to bioaccumulate occurs at water solubilities of about 0.002 mole/L (Connell, 1990). The log P_{ow} of the notified chemical is 2.53, and hence bioaccumulation potential is at the lower end of the accumulation potential scale. The water solubility of the chemical is 0.009 mol/L, which is in the same magnitude of water solubilities of substrates with a high accumulation potential.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of Sensiva SC 50.

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 2000mg/kg	Bien (1991a)
acute dermal toxicity	rat	LD_{50} > 2000mg/kg	Bien (1991b)
acute inhalation toxicity	rat	LC_{50} = 2.83 – 3.22 mg/kg	Blagden (1998)
skin irritation	rabbit	mildly irritating	Kaufmann (1997)
eye irritation (neat solution)	rabbit	severely irritating	Kaufmann (1991)
eye irritation (5% solution)	rabbit	mildly irritating	Kaufmann (1992)
skin sensitisation	guinea pig	not sensitising	Buchholz (1991)

9.1.1 Oral Toxicity (Bien, 1991a)

Species/strain:	Rat, Wistar
Number/sex of animals:	5 males, 5 females
Observation period:	14 days
Method of administration:	Oral (gavage)
Test method:	OECD TG 401
Mortality:	None
Clinical observations:	Clinical signs consisting of reduced activity, reduced tone, ventral position, abnormal gait, increased salivation, piloerection, irregular respiration and hemorrhagic nasal discharge were observed up to 24 hours post administration. Weight gains were normal in all animals.
Morphological findings:	No test article-dependent changes were found.
LD_{50}:	> 2000mg/kg
Result:	The notified chemical was of low acute oral toxicity in rats.

9.1.2 Dermal Toxicity (Bien, 1991b)

Species/strain:	Rats, Wistar
Number/sex of animals:	5 males, 5 females
Observation period:	14 days
Method of administration:	2.17 mL of neat test substance applied to shaved, intact skin via a porous gauze fixed with elastic dressing.
Test method:	OECD TG 402
Mortality:	None
Clinical observations:	No abnormal clinical signs were observed. Weight gain was normal in all animals.
Morphological findings:	No signs of erythema or oedema were observed. Draize[i] scores of zero were assigned for all animals at all clinical assessments.

[i] see Attachment 1 for Draize scales

LD_{50}:	> 2000mg/kg
Result:	The notified chemical was of low dermal toxicity in rats.

9.1.3 Inhalation Toxicity (Blagden, 1998)

Species/strain:	Rat, Sprague-Dawley
Number/sex of animals:	5 males and 5 females per group
Observation period:	14 days
Method of administration:	Nose only inhalation exposure (aerosol) for 4 hours – dynamic (continuous flow) system
Doses:	1.89, 2.96, 4.98 mg/L (mean achieved atmospheric concentration)
Test method:	OECD TG 403
Mortality:	In the highest dose group 1 (4.98mg/L), mortality was observed in 4 males and 5 females. In group 3 (2.96 mg/L) mortality was observed in 3 males and 2 females and in group 2 (1.89mg/L) 1 male only.

Clinical observations:	Common abnormalities noted were wet fur, hunched posture, lethargy, piloerection and increased or decreased respiratory rate. Additionally, laboured and noisy respiration, ptosis and red/brown staining around the snout were observed in some animals. Signs of coma, ataxia, gasping respiration, frequent sneezing, pallor of the extremities, exophthalmos and tiptoe gait were also observed occasionally. During week 1, the surviving high-dose male and several mid-and low-dose surviving females showed reduced bodyweight gain. During week 2, one low-dose female showed bodyweight loss.
Morphological findings:	Deceased animals or those euthanased showed lung abnormalities including dark or abnormally reddened appearance, pale patches, enlargement and an isolated incidence of haemorrhage. The deceased male in the low-dose group also showed an abnormally dark liver with an accentuated lobular pattern. At necropsy at the end of the study, lungs of the surviving high-dose male showed several raised areas and the lungs of two low-dose females showed dark foci.
Comment:	Rapid deaths, severe respiratory changes and abnormal colouration and enlargement of lungs indicate the lung as a target organ and that the test material exerted an irritant effect in the respiratory tract.
LC_{50}:	All animals: 3.07mg/L (3070mg/m^3) Males: 2.83mg/L (2830mg/m^3) Females: 3.22mg/L (3220mg/m^3)
Result:	The notified chemical was of low to moderate acute inhalational toxicity in rats.

9.1.4 Skin Irritation (Kaufmann, 1997)

Species/strain:	Rabbit, New Zealand White
Number/sex of animals:	3, sex not specified
Observation period:	4 days
Method of administration:	0.5mL of neat test substance applied to shaved, intact skin and covered with a semi-occlusive dressing fixed with elastic tape.

Test method: OECD TG 404

Draize scores:

	Time after treatment				
Animal #	***30-60 min***	***1 day***	***2 days***	***3 days***	***4 days***
Erythema					
1	0[a]	0	0	0	0
2	0	1	1	0	0
3	0	1	1	1	0
Oedema					
1	0	0	0	0	0
2	0	0	0	0	0
3	0	0	0	0	0

[a] see Attachment 1 for Draize scales

Result: The notified chemical was mildly irritating to the skin of rabbits.

9.1.5 Eye Irritation (100% Solution) (Kaufmann, 1991)

Species/strain: Rabbits, New Zealand White

Number/sex of animals: 3, sex not specified

Observation period: 21 days

Method of administration: 0.1 mL of test article introduced into the conjunctival sac of the left eye; control right eyes remained untreated.

Test method: OECD TG 405

Draize scores of unirrigated eyes:

	Time after instillation						
Animal	***1 hour***	***1 day***	***2 day***	***3 days***	***7 days***	***14 days***	***21 days***
Cornea	***o***	***o***	***o***	***o***	***o***	***o***	***o***
1	0[1]	0	1	1	1	0	0
2	0	1	1	1	1	1	1
3	0	0	0	0	0	0	0
Iris							
1	1	1	1	0	0	0	0

2	0		0		0		0		0		0		0	
3	0		0		0		0		0		0		0	
Conjunctiva	***r***	***c***	***r***	***c***	***r***	***c***	***r***	***c***	***r***	***c***	***r***	***c***	***r***	***c***
1	3	3	2	2	2	2	2	2	1	1	0	0	0	0
2	3	2	3	3	3	3	2	2	1	1	1	0	0	0
3	3	3	3	3	3	3	3	2	1	2	1	0	0	0

[1] see Attachment 1 for Draize scales
o = opacity r = redness c = chemosis

Comment: Ocular secretion occurred in one animal one hour post application. Control eyes showed no abnormal clinical signs.

Conjunctival redness and chemosis was observed in all animals. Conjunctival signs persisted for up to 14 days. Corneal opacity in one animal failed to resolve after 21 days.

Result: The neat notified chemical caused severe damage to the eyes of rabbits.

9.1.6 Eye Irritation (5% Solution) (Kaufmann, 1992)

Species/strain: Rabbits, New Zealand White

Number/sex of animals: 3, sex not specified

Observation period: 21 days

Method of administration: 0.1 mL of a 5% solution of test article in sterile water introduced into the conjunctival sac of the left eye; control right eyes remained untreated.

Test method: OECD TG 405

Comment: Conjunctival redness (score 1[1]) was noted in all three animals one hour after administration. Conjunctival irritation was resolved completely within 24 hours. No other signs of irritation to the cornea, iris or conjunctiva were noted.

Result: The 5% solution of notified chemical was mildly irritating to the eyes of rabbits.

[1] see Attachment 1 for Draize scales

9.1.7 Skin Sensitisation (Buchholz, 1991)

Species/strain: Guinea pig, Pirbright White

Number of animals: Test: 10 males, 10 females
Control: 10 males, 10 females

Induction procedure: Intradermal injections followed by dermal application

test group: day 0 — Three pairs of 0.1mL intradermal injections into the shaved neck region:

- Freunds complete adjuvant (FCA)/water 1:1
- Test substance 0.5% in peanut oil
- Test substance 0.5% in FCA/saline 1:1

day 7 — Neat test substance applied via saturated filterpaper patch to shaved neck region and held under occlusive dressing for 48 hours.

control group: Treated similarly to test animals omitting test substance from intradermal injections and topical applications.

Challenge procedure:

day 21 — 50% test substance in peanut oil applied via saturated filterpaper patch to shaved neck region and held under occlusive dressing for 24 or 48 hours.

Test method: OECD TG 406 (Magnusson and Kligman maximisation test)

Challenge outcome:

Challenge concentration	• *Test animals* • *24 hours**	• *48 hours**	• *Control animals* • *24 hours*	• *48 hours*
50%	0/20**	0/20	0/20	0/20

* 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 13 Week Repeated Dose Toxicity (Longobardi, 1999)

Species/strain: Rats, Sprague Dawley

Number/sex of animals: 10 males and 10 females per group, including additional recovery phase animals (control and high dose)

Method of administration: Oral (gavage), doses of 0, 50, 200 and 800mg/kg/day using polyethylene glycol 400 as vehicle.

Dose/Study duration: 13 weeks

Test method: OECD TG 407

Clinical observations:
Three males, one from the low-dose group and 2 from the high-dose group, 1 female from the mid-dose group and 1 female from the control group died during the study. The deaths could not be attributed to treatment.

Mild but sporadic, statistically significant increases in food consumption were observed in mid-dose females and high-dose animals of both sexes. No differences were observed during the recovery period. No significant changes in body weight gain compared to controls were observed.

Daily post-dose signs included salivation generally in mid- and high-dose groups and matted fur generally observed in the high-dose group. High-dose group animals also exhibited abnormally noisy respiration. Weekly clinical observations revealed a high incidence of skin/fur staining and matted fur in mid- and high-dose groups. Noisy respiration was observed also in some animals from these groups with the incidence increasing with time. An increased incidence of subcutaneous masses was observed also in high-dose animals.

Neurotoxicology tests consisting of a functional observation battery and motor activity assessment at termination revealed no changes related to the test substance. Opthalmoscopic examination during test and recovery periods revealed no toxicologically significant lesions.

Clinical chemistry/Haematology
Statistically significant changes were observed for some clinical parameters compared to controls. However, these changes were slight, sporadic, without dose-related trends, inconsistent between sexes and within ranges of historical control data. Therefore, these were deemed of no toxicological significance.

During week 5, statistically significant reductions in percentages of lymphocytes were observed in high-dose animals of both sexes and low-dose females. In high-dose males, the significant reduction in lymphocytes was still evident at week 13 and during recovery. Monocytes were increased in all animals of both sexes at week 5 but not at week 13. At week 5, neutrophils were increased in low- and high-dose females but not at week 13. At week 13 high-dose males showed increases compared to controls. These variations were considered of doubtful toxicological significance as they appeared sporadic, nor shared between sexes and were within the normal acceptable range of background data for the species.

Pathology:
No treatment-related macroscopic observations were noted in sacrificed animals at the end of treatment or recovery periods or in those that had died during the study.

A statistically significant increase in absolute and relative-to-bodyweight liver weights was observed in males of all treatment groups and females from the high-dose group during the treatment period. At the end of the recovery period, relative liver weights in males were still increased. Absolute and relative kidney weights were increased in low- and high-dose females during the treatment period. However, this increase was not apparent at the end of the recovery period.

In high-dose animals, generalised hepatocytic hypertrophy was observed with the increase in high-dose males reaching statistical significance compared to controls. An increased incidence of renal mineralisation (not statistically significant) was observed in high-dose females. These effects were not present at the end of the recovery period.

Histopathology
In high-dose animals, generalised hepatocytic hypertrophy was observed with the increase in high-dose males reaching statistical significance compared to controls. An increased incidence of renal mineralisation (not statistically significant) was observed in high-dose females. These effects were not present at the end of the recovery period.

Comment:
Increases in liver weights were the only toxicologically significant finding at low-dose levels. This was not accompanied by changes in clinical parameters expected with functional impairment of this organ.

Result:
On the basis of increases in liver weights at all doses, a no observed adverse effect level (NOAEL) could not be established. Therefore, the lowest dose of 50 mg/kg/day was established as the lowest observable adverse effect level (LOAEL) for the test substance.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (Grötsch and Leimbeck, 1991)

Strains:	TA 98, 100, 1535, 1537
Metabolic activation:	Aroclor-induced rat liver microsome S9 fraction
Concentration range:	0, 0.0024, 0.012, 0.06, 0.3, 1.5 µL/plate
Test method:	OECD TG 471
Comment:	The level of dilution of test substance in water vehicle was not stated. In a preliminary toxicity test, a significant toxicity effect was observed in TA 100 at 1.56µL/plate. This was confirmed in the main study, where toxicity was observed at the top concentration, 1.5µg/plate. TA1535 was similarly affected in the main test.

	Control plates without test substance showed normal rates of reverse mutations. Positive controls also behaved accordingly. With the test substance, no mutagenic effect, with or without metabolic activation was observed.
Result:	The notified chemical was non mutagenic under the conditions of the test.

9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse (Lindena, 1992)

Species/strain:	Mouse, BOR:NMRI
Number and sex of animals:	30 males, 30 females
Doses:	1000 and 2000 mg/kg
Method of administration:	Oral (gavage)
Test method:	OECD TG 474
Comment:	Reduced activity, alterations in tone, abnormal gait, squatting position, salivation were observed in individual animals up to one hour post-administration. No mortality was observed. Both positive and negative controls behaved accordingly. Polychromatic erythrocyte numbers were decreased significantly in all female dose groups. No statistically significant increases in micronucleated polychromatic erythrocytes at any timepoint were observed.
Result:	The notified chemical was non clastogenic under the conditions of the test.

9.4 Overall Assessment of Toxicological Data

The notified chemical was shown to be of very low and low acute oral and dermal toxicity respectively with an LD_{50} for both exposure routes of > 2000mg/kg. Acute inhalation toxicity in rats was low to moderate with an LC_{50} for males at 2.83mg/L and for females 3.22mg/L (as aerosol).

In a skin irritation study in rabbits, the notified chemical was shown to be mildly irritating. In two separate eye irritation studies in rabbits, neat notified chemical induced severe eye damage due to persistent corneal effects whilst a 5% solution induced only mild irritation. Conjunctival irritation was moderate to severe in the study with undiluted chemical.

The notified chemical was shown to be non-sensitising in a guinea pig maximisation study.

In a 13 week repeat dose oral toxicity study in rats, a LOAEL of 50mg/kg/day was established on the basis of increased liver weights at all doses. At the top dose (800mg/kg/day), hepatic hypertrophy and an increased incidence of renal mineralisation was observed in male and female animals respectively.

The notified chemical was non-mutagenic and non-clastogenic in an in vivo bacterial reverse mutation assay and in vivo bone marrow micronucleus assay respectively.

According to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1999) the notified chemical should be classified Harmful (Xn) and Irritant (Xi) with the risk phrases R20 – Harmful by Inhalation and R41 – Risk of Serious Damage to Eyes.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The notifier provided ecotoxicity test studies for fish, daphnia and algae. The results of these tests are summarised in the table below. All tests were performed in compliance with OECD/EEC Test Methods and according to OECD Principles of Good Laboratory Practice, unless otherwise stated.

Test	***Species***	***Results***
Acute Toxicity to Fish	Zebra Fish *Brachydanio Rerio*	96 h EC_{50} = 60.2 mg/L NOEC 26 mg/L
Acute Immobilisation/ Reproduction	Water Flea *Daphnia Magna*	48 h EC_{50} = 78.3 mg/L NOEC = 36 mg/L
Algal Growth Inhibition	Green Algae *Scenedesmus subspicatus*	72 h EbC_{50} = 48.3 mg/L 72 h ErC_{50} = 84.3 mg/L NOEC = 22 mg/L

* NOEC - no observable effect concentration

Fish

A preliminary rangefinding test was carried out over 96 hours against 10 Zebra fish per concentration, using nominal test concentrations of 0.1, 1, 10, 100, and 1000 mg/L of the test substance. All fish exposed to 100 and 1000 mg/L test concentration died within 2 to 4 hours of the test. No fish died when exposed to concentrations of 0.1 to 10 mg/L over the 96 hour test period (IBR, 1991b).

Following the rangefinding test, a definitive static test was performed over a period of 96 hours against 10 Zebra fish (per treatment), using 8 nominal concentrations between 10 mg/L and 100 mg/L using a serial dilution factor of 1.4 of the notified chemical. The test was conducted in de-chlorinated tap water, held at a temperature of 25°C, the pH range varying between 7.5 and 8.5. Dissolved oxygen was in excess of 6.0 mg/L and total hardness was 250 mg/L $CaCO_3$.

All of the fish exposed to nominal concentrations of 100 and 71 mg/L died within 2 to 4

hours. There were no fish mortalities in the nominal concentrations of 51, 36, 26, 19, 14, and 10 mg/L during the definitive test. Fish exposed to a concentration of 51 mg/L displayed a tendency to stay at the bottom of the test aquarium, some fish lay on their sides and some showed convulsions. Fish exposed to a concentration of 36 mg/L stayed at the bottom of the aquarium, but showed no other abnormal behaviour. Fish exposed to concentrations of 26 mg/L and below showed no abnormal effects. Therefore, the NOEC was determined to be 26 mg/L of the notified chemical. The 96 hr LC_{50} was determined as the geometric mean from LC_0 to LC_{100}.

Daphnia

A preliminary rangefinding test was performed over 48 hours against 20 daphnia per concentration using nominal concentrations of 0.1, 1.0, 10, 100, and 1000 mg/L of test material. Two reference groups exposed to 0.4 and 1.4 mg/L of a reference substance, potassium dichromate, and one control group were run concurrently with the rangefinding test. All of the *Daphnia* exposed to nominal concentrations of 1000 and 100 mg/L were immobilised during the rangefinding test (IBR, 1991c).

A definitive static test was performed over a 48 hour period against 20 daphnids per concentration (4 groups of 5 daphnids) using 10 nominal test concentrations between 19 and 360 mg/L (using a serial dilution factor of 1.4) of the test substance. The test was conducted in a prepared test medium comprising purified water and required ionic components. The temperature was 20°C, the pH range varied between 8.0 and 8.3, dissolved oxygen was in excess of 7.7 mg/L and total hardness was approximately 259 mg/L $CaCO_3$. Two reference groups exposed to 0.4 and 1.4 mg/L of a reference substance potassium dichromate, and one control group were run concurrently with the definitive test.

After 48 hours, all of the *Daphnia* exposed to concentrations >190 mg/L were immobilised during the definitive test. The percentage of animals immobilised at lower concentrations ranged from 90% at 140 mg/L to 15% immobilised at 51 mg/L. No immobilisations were observed in animals exposed to concentrations below 36 mg/L. The 48 hr EC_{50} value was calculated by means of the Probit analysis (Finney, 1971). The NOEC was determined to be 36 mg/L of the notified chemical.

Algae

An Algal Growth Inhibition test was performed to assess the effects of the notified chemical on the growth of the green alga, *Scenedesmus subspicatus.* A preliminary rangefinding test was performed against the algae over a period of 72 hours, using nominal test concentrations of 0 (control), 0.1, 1.0, 10 and 100 and 1000 mg/L of test material (Dengler, 1995).

Following the rangefinding test, a definitive test was performed over a period of 72 hours against green algae containing nominal cell densities of 10^4 cells/mL and using 5 nominal concentrations (differing by a factor of 1.8) between 9.53 and 100 mg/L, of the notified chemical. Test temperatures were maintained at between 21°C and 23°C. Illumination intensities were maintained at 8000 lux. Increases in pH values over the test period did not exceed 0.5 pH units. The algal growth rate and the algal biomass were inhibited by the presence of the test material as follows: ErC_{10} =50.23 mg/L; ErC_{50} = 84.3 mg/L; EbC_{10} = 25.88 mg/L; and EbC_{50} = 48.28 mg/L.

Bacteria

An EC_{50} value of 560 mg/L is given in the MSDS for the Bacteria Toxicity Test (OECD TG 209). However, no test report is provided in the notification dossier for this test. A Performance Inhibition Test report conducted during the ready biodegradation test (OECD 301 D) is included. This latter test was conducted to determine whether the notified chemical had an inhibitory effect on the biodegradation test system (IBR, 1991a). The notified chemical did not inhibit the test system at the concentrations used in the test (ie. 1 mg/L), indicating no adverse effects on micro-organisms in the inoculum at this test concentration.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Approximately 1,500 kg of the notified chemical will be released to the sewer predominantly as a result of washing the deodorant off the body in the shower. A smaller amount, ~45 kg, of the chemical will be disposed of in landfill in used containers each year.

Release to the sewage system is expected to be continuous and occur in small pulses throughout the year, with most releases likely to occur in metropolitan areas, ie. large cities. As a worst case scenario, based on an import volume of 1500 kg, the Predicted Environmental Concentration (PEC) of the notified chemical is 1.5 µg/L per year. In determining the PEC value, the following assumptions were made:

- All of the 1500 kg of chemical imported in one year is released into the sewer over a 365 day period, with no removal of the chemical by adsorption or degradation, giving a daily release of 4100 g.

- Release occurs throughout the whole country, with a sewer output based on 18 million people using water at an average volume of 150 L per day per person, giving a daily sewer out put of 2700 ML.

The static toxicity tests indicate that the notified chemical is slightly toxic to fish, freshwater invertebrates and algae. However, the final PEC of the notified chemical is several orders of magnitude lower than the concentrations found to be toxic to aquatic organisms. Hence, safety margins towards aquatic organisms are expected to be high.

The biodegradation tests indicate the chemical is not readily degraded, however, it is expected to eventually degrade both biotically and abiotically once it enters the natural environment. The Henry's Law Constant suggests volatilisation from water and soils will be an important abiotic degradation pathway.

The physical and chemical properties of the notified chemical indicate some potential to cross biological membrane and to bioaccumulate. However, the concentrations of the chemical encountered by organisms in the aquatic environment are expected to be very low because of the very high dilution rates in the release processes. Therefore it is unlikely that the chemical would exist at levels which could accumulate and pose a threat to organisms.

Given the above considerations, the notified chemical is not expected to pose any significant hazard to aquatic organisms. The low import volumes and the anticipated nationwide use of the product indicate that the levels of release of the chemical to the aquatic environment will

be low, and significantly lower than the levels of exposure shown to be toxic to aquatic organisms.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Hazard Assessment

The notified chemical was shown to be of very low and low rat acute oral and dermal toxicity respectively. Low to moderate acute inhalation toxicity was noted also in rats.

In a skin irritation study in rabbits, the notified chemical was shown to be mildly irritating. In an eye irritation study in rabbits, neat notified chemical induced severe eye damage due to persistent corneal effects and moderate to severe conjunctival irritation. In a separate rabbit eye irritation study a 5% solution induced only mild irritation.

The notified chemical was shown to be non-sensitising in a guinea pig maximisation study.

In a 13 week repeat dose oral toxicity study in rats, a LOAEL of 50mg/kg/day was established on the basis of increased liver weights at all doses. At the top dose (800mg/kg/day), hepatic hypertrophy and an increased incidence of renal mineralisation was observed in male and female animals respectively.

The notified chemical was non-mutagenic and non-clastogenic in an in vivo bacterial reverse mutation assay and in vivo bone marrow micronucleus assay respectively.

According to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1999) the notified chemical should be classified Harmful (Xn) and Irritant (Xi) with the risk phrases R20 – Harmful by Inhalation and R41 – Risk of Serious Damage to Eyes.

Aerosol products containing the notified chemical are classified Class 2.1 dangerous goods in accordance with the Australian Dangerous Goods Code (Federal Office of Road Safety, 1998).

Occupational Health and Safety

During the manufacture of deodorant aerosol products containing 0.3% notified chemical, exposure to the notified chemical is incidental as the process is largely enclosed and automated. However, reformulation personnel may experience dermal and ocular exposure to the notified chemical following spillage during pouring from import containers. At this stage, inhalation exposure is unlikely due to the low vapour pressure of the notified chemical. However, inhalation exposure, in addition to dermal and ocular exposure, may occur for reformulation workers involved in servicing the multi-head filling machine where fugitive aerosols may be encountered.

Ocular exposure to the notified chemical is likely to be accompanied by irritation, or in the case of neat chemical, possible serious, permanent eye damage. Local irritation is likely if skin exposure occurs. If inhalation exposure to neat notified chemical occurs, respiratory irritation is likely, depending on the dose.

The results of toxicological testing indicate that possible system toxicity may result from repeated exposure to the notified chemical. However, given the enclosed nature of the formulation process and incidental exposure, the risk of such adverse health effects is low.

The health hazards of the notified chemical underlines the importance of exposure controls consisting of a combination of personal protective equipment and engineering controls such as exhaust ventilation at sites of potential aerosol formation. In particular, safety goggles are essential to prevent eye damage.

Because exposure would only occur in the result of an accident, exposure of transport and warehouse workers who will move and store both neat notified chemical and reformulated deodorant is unlikely. Similarly, the risk to retail workers is low.

Public Health

The aerosol product containing the notified chemical is intended to be applied to the underarm area on a daily basis. The notified chemical is at a very low concentration in the aerosol product and provided it is used as intended only a very small amount of the notified chemical will be applied to restricted areas of the skin at any one application.

The notified chemical may accumulate at the site of application if it is not removed by regular washing. However, the notified chemical is not a skin sensitiser and prolonged accumulation to the point where skin irritation can occur is unlikely. On this basis and noting the toxicity profile of the notified chemical, it is considered that the notified chemical will not pose a significant hazard to public health when used as intended.

13. RECOMMENDATIONS

Regulatory controls

- The NOHSC Chemicals Standards Sub-committee should consider the following health hazard classification for the notified chemical:

  - R20 – Harmful by Inhalation
  - R41 – Risk of Serious Damage to Eyes
  - S39 – Wear eye protection

- Use the following risk/safety phrases for products/mixtures containing the notified chemical at the following cutoff concentrations:

  - ≥ 25%: R20 – Harmful by Inhalation, R41 – Risk of Serious Damage to Eyes
  - 10 - < 25%: R41 - Risk of Serious Damage to Eyes
  - 5 - <10%: R36 – Irritating to Eyes
  - ≥ 5%: S39 - Wear eye protection

Control Measures

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical:

  – Avoid generation of aerosols

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced:

  – Safety goggles when handling large quantities; safety glasses when handling small quantities
  – Impermeable clothing and footwear
  – Impermeable gloves

  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 Subsection 64(1) of the Act; if

  – conditions of use are varied from use as a component of aerosol body deodorant or the concentration in products is increased to more than 1%;

or

(2) Under Subsection 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.

14. MATERIAL SAFETY DATA SHEET

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

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

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Attachment 1

The Draize Scale (Draize, 1959) for evaluation of skin reactions is as follows:

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

The Draize scale (Draize *et al*., 1944) for evaluation of eye reactions is as follows:

CORNEA

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

CONJUNCTIVAE

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

IRIS

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

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