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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Chemical in Dehyquart AU 56

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Chemical in Dehyquart AU 56

1. APPLICANTS

Henkel Australia Pty Ltd of 83 Maffra Street BROADMEADOWS VIC 3047 and Ciba Specialty Chemicals Pty Limited of 235 Settlement Road THOMASTOWN VIC 3082 have jointly submitted a standard notification statement in support of their application for an assessment certificate for Chemical in Dehyquart AU 56.

2. IDENTITY OF THE CHEMICAL

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

Marketing Names:	Dehyquart AU 56; Dehyquart AU 46; The Dehyquart formulation constitutes: notified chemical, 90%; and isopropyl alcohol, 10%; Megasoft JET contains 2% of the notified chemical
Molecular Weight:	690 to 800
Spectral Data:	Infrared spectra and a Raman chromatograph were submitted for identification purposes

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 25°C and 101.3 kPa:	White to light yellow waxy paste – notified chemical
Boiling Point:	>150°C (Dehyquart AU 56)
Melting Point:	37 – 42°C (Dehyquart AU 56)
Specific Gravity at 20°C:	0.9902 for notified chemical; 0.62 (Dehyquart AU 56)
Vapour Pressure:	Not determined (see comments below)

Water Solubility:	Not determined (see comments below)
Particle Size:	Paste is not expected to form particles of respirable size
Partition Co-efficient (n-octanol/water):	Not determined (see comments below)
Hydrolysis as a Function of pH:	Not determined (see comments below)
Adsorption/Desorption:	Not determined (see comments below)
Dissociation Constant:	Not determined (see comments below)
Flash Point:	>150°C open cup
Flammability Limits:	Not flammable
Autoignition Temperature:	Not applicable
Explosive Properties:	None
Reactivity/Stability:	Stable and non reactive under normal conditions (see comments below)

Comments on Physico-Chemical Properties

The boiling point of the notified chemical was not determined. However, the formulation containing the notified chemical, Dehyquart AU 56, has a boiling point of greater than 150°C and a melting point of 37-42°C.

The vapour pressure of the notified chemical was not determined. The notifier indicates that the chemical is an organic salt with a relatively high molecular weight. Therefore, it is expected to be relatively non-volatile.

The water solubility of the notified chemical was not determined. The notifier indicates that the chemical has surfactant type properties and that measurement of water solubility would be difficult. It is noted from the ecotoxicity studies of Esterquat C16-C18 (an analogue of the notified chemical) on fish, water flea and algae indicate that the notified chemical would not be readily soluble and solutions of greater than 120 mg/L are cloudy (Section 10). C16-C18 Esterquat is derived from palm oil, which mostly contains saturated fatty acids.

Hydrolysis of the notified chemical was not determined. The notifier indicates that the pH of a 5% solution of the notified chemical is 2 to 3 and that the stability of the notified chemical below pH 5 is practically constant. The notified chemical contains ester linkages that could be expected to undergo hydrolysis under extreme pH. The notifier confirms this by indicating that the main degradation intermediate from the notified chemical does not contain ester groups.

The partition coefficient log P_{OW} of the notified chemical between n-octanol and water was not determined. The notifier indicates that the notified chemical has surfactant type properties and that measurement of partition coefficient would not be meaningful.

The adsorption/desorption coefficient of the notified polymer was not determined. The notifier indicates that the notified chemical is expected to undergo anion-exchange in the environment and adsorb strongly to both silicates and organic matter

The dissociation constant of the notified chemical was not determined. The notifier indicates that the notified chemical is expected to dissociate completely in water. In contrast this assessment finds that the notified chemical is poorly soluble in water, less than 120 mg/L and that above this concentration, it would be expected to aggregate and form a dispersive solution, then precipitate. Furthermore, some of the components of the notified chemical mixture are not quaternized and as free esters would be expected to have lower water solubility. However, any free amine in solution could become protonated. This process may only occur slowly due to steric hinderance.

4. PURITY OF THE CHEMICAL

Degree of Purity: 99.45%

Hazardous Impurities:

Chemical name:	Arsenic
Weight percentage:	below detection limit (< 1 ppm)
Toxic properties:	R23/25 – Toxic by inhalation and if swallowed (NOHSC, 1999b)
Chemical name:	Triethanolamine
CAS No.:	102-71-6
Weight percentage:	below detection limit (0.05%)
Regulatory Control:	Exposure standard: 5 mg/m^3 TWA (NOHSC, 1995)
Toxic properties:	Skin sensitiser; (NOHSC, 1995) Skin and eye irritant. (ACGIH, 1998)

Chemical name:	Heavy metals (as Pb)
Weight percentage:	below detection limit (total as Pb, 10 ppm)
Toxic properties:	R61(1) – May cause harm to the unborn child; R62(3) – Possible risk of impaired fertility; R20/22 – Harmful by inhalation and if swallowed; and R33 – Danger of cumulative effects. (NOHSC, 1999b)

Chemical name:	Dimethyl sulfate
CAS No.:	77-78-1
Weight percentage:	below detection limit (1 ppm)
Toxic properties:	R45(2) – May cause cancer; R26 – Very toxic by inhalation; R25 – Toxic if swallowed; R34 – Causes burns. (NOHSC, 1999b)

Chemical name:	N-nitrosodiethylamine
CAS No.:	-
Weight percentage:	below detection limit (50 ppb)
Toxic properties:	Based on N-nitrosodimethylamine R45(2) – May cause cancer; R26 – Very toxic by inhalation; R25-48/25 – Toxic if swallowed; (NOHSC, 1999b)

Non-hazardous Impurities (> 1% by weight):	none
Additives/Adjuvants:	Isopropanol 10% in Dehyquart AU 56

5. USE, VOLUME AND FORMULATION

The notified chemical is to be used as a textile softener in the industrial processing of cotton and cotton blends.

The notified chemical will not be manufactured in Australia. It will be imported by sea in either 800 kg bulk containers or 200 L drums as Megasoft JET which contains 2% of the notified chemical. No repackaging of Megasoft JET will occur and the original import containers will be transported by road and stored at the notifiers warehouse prior to dispatch to the customer site. Estimated import volumes for Megasoft JET are two tonnes (40 kg of the notified chemical) for the first year increasing to four tonnes (80 kg of the notified chemical) in years two to five.

At the customer site, Megasoft JET is mixed with water in a ratio of 1:4 up to 1:20. The diluted chemical is then applied to cotton and cotton blend textiles by the exhaust method. The extent of exhaustion of notified chemical to textile fibre is 95%.

6. OCCUPATIONAL EXPOSURE

Transport and Storage
Megasoft JET, containing the notified chemical is to be imported in 800 kg bulk containers or 200L drums. Exposure of waterside, transport and storage workers should only occur in the event of accidental spillage.

Dye House
The notifiers estimate eight customer sites where Megasoft JET will be used and the following number and category of workers per site with potential exposure to the notified chemical:

Weighing/Dispersing:	2 operators per shift;
Application:	6 operators per shift;
Drying:	4 operators per shift; and
Laboratory:	2 technicians.

Megasoft JET is dispensed manually from the import containers into a bucket for weighing. The volume weighed depends upon the batch size; at an application rate of 2%, this varies from 0.5kg to 16 kg of Megasoft JET. The weighed Megasoft JET is then diluted with water in an open tank at a ratio of 1:4 to 1:20 (0.4 to 0.1% notified chemical), then pumped into a closed dyeing machine. After completion of the dyeing process, the wet cloth is winched from the machine and spun to remove excess moisture (hydroextraction). It is then dried by passing through a stenter.

The notifiers identified that skin and eye and contact to Megasoft JET can occur at: preparation of the dye stuff (weighing; dilution; addition to the dyeing machine); during dyeing (de-tangling of cloth in the dye machine) and drying (looping wet cloth onto the winch and stenter). The notifier indicated that inhalation exposure to mists or vapours would only exist in the event that aerosol was generated by spraying, or during work in confined spaces or poorly ventilated areas. Engineering controls in use as identified by the notifier, include local exhaust ventilation at the weigh station and dilution vessel. For all operations, existing hygiene practices require the wearing of overalls, protective gloves (PVC, long impervious) and goggles or safety glasses. In the event that inhalation exposure may occur, the notifier recommends the wearing of half face respirators (class A-2 Organic Vapour Cartridge).

Information on the role of the laboratory technicians was not provided in the submission. However, typical duties would involve sampling of the dye for quality control (QC) and potential for skin and eye contact exists. It is expected that technicians would be wearing safety glasses and gloves during these activities.

7. PUBLIC EXPOSURE

It is expected that during transport, storage, processing and disposal, exposure of the general public to the notified chemical will be very low. The public will be exposed to the notified chemical in cotton textile products. However, the majority (95%) of the notified chemical will be firmly fixed to the cotton textile fibres rendering the chemical biologically unavailable.

8. ENVIRONMENTAL EXPOSURE

Release

The notified chemical will be transported by road in the original import containers; potential release would only be through accidental spills. The Material Safety Data Sheet (MSDS) details adequate procedures to protect the environment in these cases.

The notifier indicates that release of the notified chemical during formulation *via* mixing vessels, holding vessels, filling pots, filling lines and empty drums is not expected to be of a significant quantity. The submitted data shows that the notified chemical exhausts onto the fibre of cotton to about 95%. The unfixed 5% pass through the exhausting process as trade waste. The notified chemical constitutes 2% of the 5% quantity released. If a maximum of 100 kg of Megasoft JET were used in a day for 5 tonne of textile, the release of unfixed notified chemical would be 100 g. With a maximum import of 4 tonnes per year then approximately 4 kg of the notified chemical maybe lost per year. The notifier also estimates that the amount lost from washing of equipment and drums will be one kg per 800 kg container. This is equivalent to a loss of 100 g of the notified chemical per year.

The majority of the notified chemical will be fixed to cotton textiles.

Fate

Any small quantities of notified chemical waste at the formulation and processing site that maybe generated from spills and drum washings will be collected together with production effluents through the site waste water treatment plant. The notifier indicates that this will then be released to sewer according to local waste water specifications.

The ready biodegradability of Dehyquart AU 56 was examined by exposure to activated sewage sludge microorganisms in a closed bottle test, OECD TG 301D (Henkel KGaA, 1998). A very brief report was submitted for assessment. Under the conditions of the test 87 to 88% of the test substance was degraded within the 28 day test period. Since the pass level of 60% was reached within the 10 day time window, Dehyquart AU 56 can be regarded as readily biodegradable.

The anaerobic biodegradability of the palm oil derived C16-C18 Esterquat analogue was also examined by exposure to activated sewage sludge microorganisms in an ECETOC screening test (Birch et al, 1989), (Henkel KGaA, 1994d). The notifier indicates that this anaerobic biodegradation test is monitored by means of weekly measurements of biogas formation and, at the conclusion of the test by the carbon dioxide formed and that remaining in solution as dissolved inorganic carbon. In the screening test, 71% of the test substance was degraded

within the 77 day test period. C16-C18 Esterquat can be regarded as readily degradable under the anaerobic test conditions.

The aerobic biodegradability of C16-C18 Esterquat was also examined by exposure to activated sewage sludge microorganisms in a BODIS screening test (a modified OECD TG 301 D closed bottle test for insoluble substances) (Henkel KGaA, 1994e). Under the screening conditions 79% of the test substance was degraded within the 28 day test period. Since the pass level of 60% was reached within the 14 day time window, C16-C18 Esterquat can be regarded as readily biodegradable.

The ultimate fate of the bulk of the notified chemical will be associated with the cotton textiles to which it is applied. The fate will be to landfill, in a very diffuse manner, and in locations country wide where it is expected to readily biodegrade.

The notified chemical shows considerable potential for biotic transformation. It is readily biodegradable as well as slightly unstable in aqueous solution and as such should not bioaccumulate.

9. EVALUATION OF TOXICOLOGICAL DATA

A skin irritation study in rabbits has been conducted on the notified chemical.

In support of a claim for Variation to the Schedule Requirements study reports on analogue substances, Stepantex VS 90, C16-C18 Esterquat, and Dehyquart F75, covering the following toxicological end points have been submitted:

Stepantex VS 90:

Eye Irritation;	
Skin sensitisation:	Buehler Method; Maximisation Method;
Repeat dose toxicity;	90-day, oral; and
Genotoxicity:	mouse micronucleus test; bacterial reverse mutation assay

Stepantex VS 90, a close homologue to Dehyquart AU 56, is a quaternised fatty acid ester and shares the same types of fatty acid, solvent, and solvent-to-chemical ratio as the notified chemical.

C16-C18 Esterquat:

Acute Toxicity - oral;
Skin Irritation – human open epidermal test
Genotoxicity – bacterial reverse mutation assay

C16-C18 Esterquat differs to the notified chemical in that it contains only saturated fatty acid chains.

Dehyquart F75:

Skin sensitisation - human repeated insult patch test.

Dehyquart F75, is a quaternised fatty acid ester but its mix of fatty acid differs to that of the notified chemical.

9.1 Acute Toxicity

Summary of Acute Toxicity

Test	*Species*	*Outcome*	*Reference*
Acute oral toxicity *C16-C18 Esterquat*	Rat	LD_{50}> 2 000 mg/kg	(Henkel KGaA, 1994b)
Skin irritation			
Primary Skin Irritation *Notified Chemical*	Rabbit	Slight to moderate irritant	(Scantox, 1999)
Open Epidermal Test *C16-C18 Esterquat*	Human	Non irritating	(Henkel KGaA, 1994f)
Eye irritation *Stepantex VS 90*	Rabbit	Slight to moderate irritant	(Henkel KGaA, 1993)
Skin sensitisation:			
Buehler Method *Stepantex VS 90*	Guineapig	Non sensitising	(Henkel KGaA, 1991b)
Maximisation Test *Stepantex VS 90*	Guineapig	Inconclusive	(Henkel KGaA, 1991c)
Repeated Insult Patch Test *Dehyquart F75*	Human	Non sensitising	(Pharmaco UK Ltd, 1995)

9.1.1 Oral Toxicity (Henkel KGaA, 1994b)

Test substance:	Esterquat C16-C18
Species/strain:	Rat/Hsd/Win:WU
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	2 000 mg/kg by gavage, dose volume of 20 mL/kg bw
Test method:	OECD TG 401; EC Directive 91/325/EEC
Clinical observations:	No symptoms observed
Mortality:	Nil
Morphological findings:	No treatment related findings. One animal had moderate hydrometra in uterine horns
LD_{50}:	> 2 000 mg/kg
Result:	Esterquat C16-C18 was of low acute oral toxicity in rats

9.1.2 Dermal Toxicity

Variation of Schedule Requirements was claimed by the notifier for this toxicological end point on the basis that a low order of acute toxicity was observed by the oral route with a close analogue.

9.1.3 Inhalation Toxicity

Variation of Schedule Requirements was claimed by the notifier for this toxicological end point on the basis that the notified substance will not be used in a manner which will generate an inhalable mist or vapour.

9.1.4 Skin Irritation

9.1.4.1 Primary Skin Irritation (Scantox, 1999)

Test substance:	Notified chemical (solid opaque paste)
Species/strain:	Rabbit/SPF albino
Number/sex of animals:	3 females
Observation period:	21 days
Method of administration:	0.5 g of test substance (moistened with 3 drops of sterile

distilled water) applied to gauze, then applied to the left and right anterior back of each animal and secured with tape. After 4 hours, the treated skin site was cleaned with soap and lukewarm water.

Test method: OECD TG 404; EC Directive93/21/EEC

Draize scores:

Time after treatment (hours)	***Animal #***					
	1		***2***		***3***	
Erythema/ Eschar	***AL***	***AR***	***AL***	***AR***	***AL***	***AR***
1	1	0	1	1	1	1
24	1	1	1	1	2	2
48	2	2	2	2	3	3
72	2	2	2	2	2	2
Oedema	***AL***	***AR***	***AL***	***AR***	***AL***	***AR***
1	0	0	0	0	0	0
24	1	1	1	1	1	1
48	1	1	1	1	1	1
72	1	1	1	1	1	1

[a] see Attachment 1 for Draize scales.
AL: anterior left field.
AR: anterior right field.

Individual Mean Values (24, 48 & 72 hour observation): Erythema/eschar formation: 1.67, 1.67, 2.33;
Oedema: 1.0, 1.0, 1.0.

Comment: At 72 hours a well defined erythema and a very slight oedema were observed in all animals on both treated sites.
On Days 7 and 14 scale formation was observed in all three animals; it had cleared by Day 21.

Result: The notified chemical was a slight to moderate irritant to rabbit skin

9.1.4.2 Open Epidermal Test (Henkel KGaA, 1994f)

Test substance: Esterquat C16-C18

Study Group: Human volunteers, 7 males, 13 females

Procedure: A 10% dilution of the test substance applied to the volar surface of the forearm, every 30 seconds for a total application period of 30 minutes.

Test method: Burckhardt W (1964) Dermatologica **129**:37

Comment: No dermal irritancy observed throughout the study period

Result: Esterquat C16-C18 was non irritating to human skin following repeat application

9.1.5 Eye Irritation (Henkel KGaA, 1993)

Test substance: Stepantex VS 90

Species/strain: Rabbit/Kleinrussen, Chbb:HM

Number/sex of animals: 3 males

Observation period: 14 days

Method of administration: 0.1 g of neat test substance instilled into the conjunctival sac of the right eye; the left eye served as the control

Test method: OECD TG 405; EC Directive 91/325/EC

Draize scores of nonirrigated eyes:

	Time after instillation																	
Animal	***1 hour***			***24 hours***			***48 hours***			***72 hours***			***7 days***			***14 days***		
Cornea	***All individual scores were zero***																	
Iris	***All individual scores were zero***																	
Conjunctiva	***r***	***c***	***l***	***r***	***c***	***l***	***r***	***c***	***l***	***r***	***c***	***l***	***r***	***c***	***l***	***r***	***c***	***l***
1	1	0	0	2	2	0	2	2	0	1	1	0	0	1	0	0	0	0
2	1	1	0	2	2	1	2	2	1	1	2	1	0	1	0	0	0	0
3	1	0	1	1	1	0	1	1	0	1	1	1	0	0	0	0	0	0

[1] see Attachment 1 for Draize scales
o = opacity a = area r = redness c = chemosis l = lacrimation.

Comment: Mild to moderate erythema and mild chemosis were observed at 72 hours, clearing in all animals by Day 14

Result: Stepantex VS 90 was a slight to moderate irritant to rabbit eyes

9.1.6.1 Skin Sensitisation – Buehler Method (Henkel KGaA, 1991b)

Test substance: Stepantex VS 90

Species/strain: Guineapig/Pirbright white

Number of animals: Female, 10 test animals, 10 control animals

Test method: OECD TG 406 Buehler Method

Induction procedure: Test Animals:
Days 1, 7 and 14: 0.08 mL of 15% w/w test substance in mineral oil applied, via a Square Chamber, to the clipped skin of the anterior left flank for 6 hours;

Control Animals:
same procedure as above, but omitting the test substance and using the vehicle control, physiological saline.

Induction was on the same skin area, 3 times at intervals of one week

Challenge procedure: Test and Control Animals:
Day 28 (2 weeks after final induction): same procedure as induction phase, except 0.08 mL of 5% w/w test substance was applied to the posterior area of both flanks;
grading of dermal responses occurred 24 and 48 hours post exposure;

Challenge Outcome:

Challenge concentration	***Test Animals***				***Control Animals***			
	24 hours*		***48 hours****		***24 hours***		***48 hours***	
	L	***R***	***L***	***R***	***L***	***R***	***L***	***R***
5%	[A]4/10	[A]7/10	[A]6/10	[A]4/10	[A]3/10	[A]2/10	[A]2/10	[A]2/10

* Time after patch removal.
[A] Number of animals exhibiting dermal reactions, Grade 1weak erythema and/or oedema.
L = left. R = right.

Comment:	The degree of dermal reaction observed in test animals was comparable to that observed in the control animals.
Result:	Stepantex VS 90 was non sensitising to guineapig skin

9.1.6 Skin Sensitisation (Henkel KGaA, 1991c)

Test substance:	Stepantex VS 90
Species/strain:	Guineapig/Pirbright white
Number of animals:	20 test females, 10 control females
Test method:	OECD TG 406 Magnusson and Kligman Maximisation Method
Minimal irritating concentration:	A preliminary study showed the minimal irritating concentration (Grade 1 or less) for intradermal induction was 0.5% w/w and for topical induction, 2% w/w.
Induction procedure:	test animals: Day 1: three pairs of intradermal injections (0.1 mL) into the dorsal skin of the scapular region: - Freund's complete adjuvant (FCA) 50% v/v in liquid paraffin; - the test substance, 0.5%; - the test substance 0.5% w/v FCA 50% v/v; Day 7 – 0.5 mL of test substance (5%) placed on a gauze patch, applied to the treated area and held under occlusive dressing for 48 hours; control animals: treated similarly to the test animals omitting the test substance and using the vehicle control, liquid paraffin, for the intradermal injections and topical application
Comment:	Following intradermal and topical induction, no reaction, Grade 1 or Grade 2 dermal reactions were observed in both test and control animals.
Challenge procedure:	test and control animals: Day 21: 0.1 mL of test substance (2%) placed on a gauze patch, applied to the treated area and held under occlusive dressing for 24 hours.
Challenge Outcome:	

	Test Animals	***Naïve Control Animals***

Challenge concentration	*24 hours**	*48 hours**	*24 hours*	*48 hours*
2%	[A]8/20	[A]15/20	[B]8/10	[A]6/10
	[B]11/20	[B]4/20	[C]2/10	[B]4/10

time after patch removal

[A] Number of animals exhibiting dermal reactions, Grade 1 = weak erythema and/or oedema.

[B] Number of animals exhibiting dermal reactions, Grade 2 = moderate and diffuse erythema and/or oedema.

[C] Number of animals exhibiting dermal reactions, Grade 3 = strong erythema and/or oedema.

Comment: Eschar formation was noted in three test and two control animals at 48 hours. The degree of severity of the dermal response was greater in control animals than in test animals. The reactions appear to reflect an irritant response to the chemical or vehicle and any concurrent sensitisation reaction would be masked under these conditions. Therefore, no conclusion can be drawn on the sensitisation potential of the test substance in this study.

Result: Inconclusive

9.1.6.4 Human Repeated Insult Patch Test (Pharmaco UK Ltd, 1995)

Test substance: Dehyquart F75

Study Group: 88 volunteers; comprising males and females

Induction procedure: Induction concentration: 0.5, 1.0, 2.0% active ingredient in distilled water;
Nine repeat applications of the test substance (0.4 mL, 24 hour exposure, applied via an occlusive patch) at 3 applications/week for 3 weeks, to the same skin area of the upper arm, followed by a 2-week rest period;
Negative control was purified water.

Challenge procedure: 1.0% active ingredient in distilled water applied to both arms of each subject

Challenge outcome: No dermal reactions indicative of sensitisation to the test substance or negative control following challenge at 48 and 96 hours post-application.

Test method: (Stotts, 1980)

Result: Dehyquart F75 was not considered sensitising to human skin.

9.2 13 Week Repeated Dose Toxicity (Henkel KGaA, 1991a)

Test substance:	Stepantex VS 90
Species/strain:	Rat/Sprague Dawley CD
Number/sex of animals:	10/sex/group for treatment phase; 5/sex/group for recovery phase (control and high dose animals).
Method of administration:	gavage
Dose/Study duration:	0, 100, 300, 1 000 mg/kg/day for 13 weeks. Recovery animals were maintained for a further 35 days without treatment.
Test method:	OECD TG 407

Mortality:
One male of the 1 000 mg/kg/day group was found dead at Week 12. Two males (1 of the control group, the other of the 300 mg/kg/day group) died under anaesthesia during blood sampling.

Clinical observations:

The male that died suffered weight loss (37g within 3 days) from Week 11.
No other remarkable findings.

Clinical Pathology

Clinical Chemistry:
Week 6 - animals at 1 000 mg/kg/day had significantly increased alanine transferase (ALT) activity and males in addition had increased calcium.
Week 13 - the increased ALT persisted. Significant findings in females were increased alkaline phosphatase (AP) and cholesterol at 1 000 mg/kg/day, and increased creatinine at 100 and 1 000 mg/kg/day. In males, significantly increased potassium at 300 and 1 000 mg/kg/day. Clinical chemistry investigations of recovery animals were not conducted.

Haematology:
Increased platelet counts were observed at Week 6 in males at 300 mg/kg/day. At Week 13 females at 1 000 mg/kg/day had slightly decreased mean cell volume. Haematology investigations of recovery animals were not conducted.

Histopathology:

Treatment phase:
An underlying bacterial infection was present in all animals, manifested by the presence of non dose related histological changes in the liver and salivary gland lymph nodes;
At 1 000 mg/kg/day, the bladder showed increased desquamation, localised regressive changes in the epithelium to focal epithelium denudation without inflammatory reaction in

the submucous area. These findings predominated in males and were suggested as been due to local irritation as no corresponding changes were observed in the kidney, renal pelvis, or urethra;
The omasum at 1 000 mg/kg/day showed thickening of the mucous membrane, inflammatory infiltration in the sub mucosa and isolated ulceration, these changes were considered a local irritation response.

Recovery phase:
Changes to the bladder and omasum were not observed in recovery animals.

Comment:
At 1 000 mg/kg/day, effects related to treatment were observed in the liver (elevated ALT) and effects secondary to treatment (local irritation) were observed in the bladder and omasum. No systemic effects were observed at 300 mg/kg/day.

Result:
The No Observed Adverse Effect Level (NOAEL) determined for Stepantex VS 90 in this study is 300 mg/kg/day.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (Henkel KGaA, 1989a)

Test substance:	Esterquat C16-C18
Strains:	TA 98, TA 100, TA 1535, TA 1537, TA 1538
Metabolic activation system:	liver fraction (S9 mix) from rats pretreated with Aroclor 1254
Concentration range:	The test substance was tested in triplicate in tester strains at the following concentrations: Experiment 1 0, 8, 40, 200, 1 000, 5 000 µg/plate; Experiment 2 0, 25, 50, 100, 200, 400 µg/plate, -S9 0, 22.2, 66.6, 200, 600, 1 800 µg/plate, +S9; Appropriate strain specific positive controls were used. Vehicle control: bi-distilled water. The enzyme activity of the metabolic activation system was checked by testing with 2-aminoanthracene and benzo[a]pyrene on TA98.
Test method:	OECD TG 471 – plate incorporation method
Comment:	Toxicity was noted at 200 µg/plate or above.

Precipitation was noted at 600 μg/plate and above.

There were no marked increases in revertant colony numbers at any concentration, in the presence or absence of metabolic activation.

Concurrent positive controls used in the test induced marked increases in the frequency of revertant colonies and the activity of the S9 fraction was found to be satisfactory.

Result: Esterquat C16-C18 was not considered mutagenic under the conditions of the test.

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (Henkel KGaA, 1989b)

Test substance: Stepantex VS 90

Strains: TA 98, TA 100, TA 1535, TA 1537, TA 1538

Metabolic activation system: liver fraction (S9 mix) from rats pretreated with Aroclor 1254

Concentration range: The test substance was tested in triplicate in tester strains, in the presence and absence of metabolic activation, at the following concentrations:

Experiment 1
0, 8, 40, 200, 1 000, 5 000 μg/plate;

Experiment 2 (plus repeat of strain TA 1538)
0, 6.25, 25, 100, 400, 1 600 μg/plate;

Appropriate strain specific positive controls were used. Vehicle control: Tween 80 in distilled water.

The enzyme activity of the metabolic activation system was checked by testing with 2-aminoanthracene in all strains.

Test method: OECD TG 471 – plate incorporation method

Comment: Toxicity was noted at 200 μg/plate or above.
In the second experiment, small colonies were observed in control plates and treated plates with strain TA 1538 and metabolic activation, independently of tested concentrations (data not provided). Therefore, a repeat experiment of TA 1538 was conducted.

There were no marked increases in revertant colony numbers at any concentration, in the presence or absence of metabolic activation.

	Concurrent positive controls used in the test induced marked increases in the frequency of revertant colonies and the activity of the S9 fraction was found to be satisfactory.
Result:	Stepantex VS 90 was not considered mutagenic under the conditions of the test.

9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse (Henkel KGaA, 1990)

Test substance:	Stepantex VS 90
Species/strain:	Mouse/CFW 1
Number and sex of animals:	6/sex/group
Doses/Method of administration:	Test substance: 5 000 mg/kg by gavage; Positive control: cyclophosphamide, 10 mg/kg by intra-peritoneal injection; Negative Control: distilled water by gavage.
Sampling time:	Test animals were sacrificed 24, 48 or 72 hours after treatment. Animals of the positive and negative control group were sacrificed 24 hours after treatment.
Test method:	OECD TG 474
Comment:	No mortality. Signs at clinical examination were slight pilo-erection. A weak toxic effect (slight reduction in the ratio of polychromatic to normochromatic erythrocytes) was observed in females of the 24 and 48 hour sacrifice groups. No significant increase in micronucleated polychromatic erythrocytes (PCEs) due to treatment with test the substance. The positive control caused a significant increase in micronucleated PCEs.
Result:	Stepantex VS 90 did not induce a significant increase in micronucleated PCEs in bone marrow cells of the mouse *in vivo*

9.4 Overall Assessment of Toxicological Data

Variations to the Schedule Requirement were claimed by the notifier, with submission of data on analogue substances, Stepantex VS 90, Esterquat C16-C18 and Dehyquart F75.

The notified chemical is not expected to cause acute systemic toxicity based on the results of an oral toxicity test with the analogue Esterquat C16-C18. In addition, quaternized fatty acid esters, such as the notified chemical, are generally considered to be of low dermal toxicity.

The notified chemical was a slight to moderate skin irritant in rabbits and is expected to have similar slight to moderate eye irritant properties as observed with Stepantex VS 90 when tested in rabbits. Esterquat C16-C18 was non irritating to human skin following repeat application.

Stepantex VS 90 is considered non sensitising to guinea pig skin in a non-adjuvant study. The results of an adjuvant study using Stepantex VS 90 are confounded by the presence of moderate or strong erythema and/or oedema observed in the majority of control animals at challenge. Therefore, no conclusion can be reached on the skin sensitisation potential of the analogue under the conditions of the test. Signs of skin sensitisation were not observed in a human repeat insult patch test with Dehyquart F75. Based on these findings with analogue substances, the notified chemical is not expected to display skin sensitisation potential.

In a 90 day repeat oral dose study in rats administered Stepantex VS 90, a NOAEL of 300 mg/kg/day was established. At 1 000 mg/kg/day, effects related to treatment were observed in the liver (elevated ALT) and effects secondary to treatment (local irritation) were observed in the bladder and omasum.

In a bacterial reverse mutation test, with and without metabolic activation, Esterquat C16-C18 and Stepantex VS 90 were both considered non mutagenic. Stepantex VS 90 was non genotoxic *in vivo*, in a micronucleus assay. Based on the results of the analogue substances, the notified chemical and its metabolites are also expected to be non genotoxic.

The notified chemical would likely display the same toxicity profile to the analogue substances of similar chemical composition and would be considered non hazardous under the NOHSC Approved Criteria for *Classifying Hazardous Substances Classifying Hazardous Substances* (NOHSC, 1999a).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The notifier has supplied ecotoxicity studies of the notified chemical analogues, C16-C18 Esterquart and Stepantex VS 90, which are summarised in the following tables. Stepantex VS 90 is derived from tallow and like C16-C18 Esterquart is a very similar analogue to the notified chemical. Only concise one-page ecotoxicity reports for Stepantex VS 90 were submitted.

The tests were performed in compliance with OECD/EEC Test Methods and according to OECD Principles of Good Laboratory Practices.

10.1.1 C16-C18 Esterquat

Summary of C16-C18 Esterquat Ecotoxicity Test Results

Test	*Species*	*Results (nominal) mg/L*
Acute Toxicity (Semi-static Test) (EEC Guideline 92/69/EWG)	Zebra Barbels (*Brachydanio rerio*)	96 h LC_{50} = 30-60 96 h NOEC = 30
Acute Toxicity - Immobilisation (Static Test) (EEC Guideline 92/69/EWG)	Water Flea (*Daphnia magna Straus*)	48 h EC_0 = 32 48 h EC_{50} = 32-64 48 h EC_{100} = 64
Growth Inhibition Growth (μ) & Biomass (b) (Static Test) (DIN 38412)	Green Alga (*Scenedesmus subspicatus*)	96 h $E\mu C_{50}$ = 44 96 h E_bC_{50} = 11 96 h NOEC = 4.8

10.1.2 Fish Acute Toxicity (Henkel KGaA, 1994a)

Zebra Barbels were exposed to C16-C18 Esterquat in a range finding test at nominal loading rates of 30, 60, 120 and 240 mg/L for a period of 96 hours under semi-static test conditions. Zebra Barbels were then exposed to C16-C18 Esterquat at nominal loading rates of 1.0, 2.2, 4.8, 11, 23 and 52 mg/L for a period of 96 hours under semi-static test conditions. Based on the findings from both studies the 96 hour LC_{50} was calculated by the notifier to be 42 mg/L. However, the calculation used by the notifier appears to not follow the Stephan method as claimed. Furthermore, the Probit method of calculation cannot be used in this case since there is only one concentration level used between the zero and 100% mortality levels. Therefore, the 96 hour LC_{50} can only be stated as being between 30 mg/L and 60 mg/L. The no observed effect concentration (NOEC) was the 30 mg/L nominal rate. Sub-

lethal effects of exposure were not observed. Chemical analyses were also carried out on test samples with the Total Organic Carbon (TOC) measured at greater than 80% of nominal concentrations. Test fish were also transferred into fresh test media every 24 hours.

10.1.3 Aquatic Invertebrate Acute Toxicity (Henkel KGaA, 1995)

Daphnia magna were exposed to C16-C18 Esterquat at nominal loading rates of 1, 2, 4, 8, 16, 32, 64, 128 and 256 mg/L for a period of 48 hours under static test conditions. Based on these nominal loading rates the 48 hour LC_{50} was calculated by the notifier to be 45 mg/L. As indicated above the 96 hour LC_{50} can only be stated as being between 32 mg/L and 64 mg/L. The NOEC was the 32 mg/L nominal rate. Chemical analyses were also carried out on test samples with similar results to those above. The test media was not changed during the period of the study.

10.1.4 Alga Growth Inhibition Test (Henkel KGaA, 1994c)

After 96 hours exposure of C16-C18 Esterquat to green alga *Scenedesmus subspicatus* at nominal loading rates of 1, 2.2, 4.8, 11 and 23 mg/L, the $E\mu C_{50}$ was 44 mg/L and the E_bC_{50} was 11 mg/L. The NOEC at 96 hours was determined to be 4.8 mg/L. Chemical analysis was not carried out to determine measured concentrations.

10.1.5 Conclusion

The ecotoxicity data for the C16-C18 Esterquat analogue of the notified substance suggests that it is slightly toxic to fish, aquatic invertebrates and slightly to moderately toxic to alga.

10.2 Stepantex VS 90

Summary of Stepantex VS 90 Ecotoxicity Test Results

Test	*Species*	*Results (nominal) mg/L*
Acute Toxicity	Fish	96 h LC_{50} = 3.0
(Semi-static Test)		96 h NOEC = 2.5
(EEC Directive 84/449)		
Chronic Toxicity	*Brachydanio rerio*	14 d LC_{50} = 4.9
(Semi-static Test)		14 d NOEC = 4.0
(OECD TG 204)		
Acute Toxicity -Immobilisation	Water Flea	48 h EC_0 = 28.8
(Static Test)	(*Daphnia magna*)	48 h EC_{50} = 78.3
(DIN 38412 part 11)		
Chronic Toxicity -Immobilisation	Water Flea	21 d NOEC = 2.7
(Static Test)	(*Daphnia magna*)	21 d LOEC = 9.0
(OECD TG 202 B)		
Growth Inhibition	Green Algae	96 h EμC_{50} = 2.0
Growth (μ) (Static Test)	(*Scenedesmus subspicatus*)	96 h NOEC = 0.27
(DIN 38412 part 9)		

The results above indicate that Stepantex VS 90 appears more toxic to fish and algae and less toxic to daphnia than is C16-C18 Esterquart. The notifier also supplied concise one-page ecotoxicity reports on bacteria, plants and earthworms as well as those derived in more complex systems, that are not listed here.

10.2.1 Microorganisms

The notifier did not study the effect of the notified chemical on the respiration of activated sewage sludge microorganisms. However, from ready biodegradation data the notified chemical appears to have no effect on activated sewage sludge microorganisms. Furthermore, a respiration inhibition study was carried out on Stepantex VS 90 under standard method DIN 38412/27 1990 which the notifier indicates corresponds to OECD TG 209. Stepantex VS 90 is a close analog to the notified chemical. The study indicated a first observed effect concentration of 90 mg/L of active substance.

10.6 Conclusion

The ecotoxicity data for the analogue suggests that it is unlikely to affect sewage microorganisms.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The intended use pattern of the notified chemical is not expected to result in a significant release to the environment. During a typical formulation and processing application to 5 tonne of cotton, approximately 110 g of notified chemical may be released to the sewer. If the assessment assumes that the dilution at Metropolitan and Regional waste water treatment plants is 100 and 1 ML per day, respectively, then the predicted effluent environmental concentrations will be 1.1 and 110 µg/L, respectively. In relation to the most sensitive aquatic organism, algae with an estimated E_bC_{50} of 2.0 mg/L for the analogue Stepantex VS 90, environmental safety factors will be 2 000 and 20, respectively. While narrow, the safety factors are likely to be much greater, if dilution into receiving waters, biodegradation and potential adsorption in the sewer are taken into consideration.

In the event of spills and minor releases during transfer operations, satisfactory information on procedures to reduce release to the environment can be found in the MSDS for the chemical.

Given the above, environmental exposure and the overall environmental hazard is expected to be low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Toxicological data on the analogue substances, Stepantex VS 90, Esterquat C16-C18 and Dehyquart F75 indicate the acute oral and dermal toxicity of the notified chemical is expected to be low. The notified chemical was a slight to moderate skin irritant in rabbits, and is expected to be a slight to moderate eye irritant. Based on the results of a non-adjuvant study in guineapigs, and a human repeat patch insult test with analogue substances, the notified chemical is not expected to display skin sensitisation potential. In a 90-day using Stepantex VS 90 in rats, a NOAEL of 300 mg/kg/day was established, based on increased serum alanine transferase activity and microscopic changes suggestive of stomach and bladder irritation at the next (highest) dose. The notified chemical is not expected to be genotoxic.

Based on the data provided the notified chemical would not be determined to be a hazardous according to NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999a).

The notifier has classified Dehyquart AU 56, containing the notified chemical as a hazardous substance, Irritant (Xi) R36/38 – Irritating to Eyes and Skin, based on its isopropanol content (10%).

Occupational Health and Safety

Transport and Storage

The notified chemical in Dehyquart AU 56 will be imported at 2% in a formulated product known as Megasoft JET. Waterside, transport and storage workers should only be exposed to Megasoft JET in the event of accidental spillage. Exposure after a spill would be controlled by use of the recommended practices for spillage clean up given in the MSDS supplied by the notifier.

Dye House

The chemical is used as a textile softener in the cloth dyeing process. The main groups of workers likely to be exposed to Megasoft JET on a regular basis are those involved in chemical weighing and those handling the treated fabric after the exhaust process is completed when the cloth is lead to wash off baths. The chemical is weighed out manually and weighers are stated to wear long PVC gloves, safety glasses, and overalls. Workers handling the wet cloth will also need to use personal protective equipment although at this time 5% of the added chemical remains unfixed and the concentration of notified chemical in the treatment solution is 0.1 to 0.4%. After washing the fabric, the risk of adverse health effects to dyehouse workers handling the fabric should be negligible.

Public Health

Megasoft JET will not be sold directly to the public, but will be formulated and applied to cotton at factories. Once applied to cotton textile, the notified chemical is strongly fixed to the fibre. Given the low toxicity of the notified chemical and the low concentration in the treatment mixture (<0.4%), the potential for public exposure to the notified chemical during all phases of its life cycle, is considered to be low. Based on the above, it is considered that Dehyquart AU 56 will not pose a significant hazard to public health when used in the proposed manner.

13. RECOMMENDATIONS

To minimise occupational exposure to Megasoft JET containing the notified chemical the following guidelines and precautions should be observed:

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (Standards Australia, 1994) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand, 1992);
- Industrial clothing should conform to the specifications detailed in AS 2919 (Standards Australia, 1987) and AS 3765.1 (Standards Australia, 1990);
- Impermeable gloves should conform to AS/NZS 2161.2 (Standards Australia, 1998);
- All occupational footwear should conform to AS/NZS 2210 (Standards Australia/Standards New Zealand, 1994);
- Spillage of the notified chemical should be avoided. Spillages should be cleaned up promptly with absorbents which should be put into containers for disposal;

- Good personal hygiene should be practised to minimise the potential for ingestion;
- A copy of the MSDS should be easily accessible to employees.

If the conditions of use are varied from its use as a softener in the industrial processing of cotton and cotton blends, then greater exposure of the public may occur.

14. MATERIAL SAFETY DATA SHEET

The MSDS for Dehyquart AU 56 was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994).

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

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

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

16. REFERENCES

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Attachment 1

The Draize Scale 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 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