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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Stepantex Esterquat

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Director
Chemicals Notification and Assessment

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FULL PUBLIC REPORT

Stepantex Esterquat

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Colgate Palmolive Pty. Limited (ABN 79 002 792 163)
Level 15, 345 George Street
SYDNEY NSW 2000.

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:

- Chemical name
- CAS Number
- Molecular formulae
- Structural formulae
- Molecular weight
- Spectral data

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:

- Acute Dermal Toxicity
- Acute Inhalation Toxicity
- Induction of Germ Cell Damage
- Bioaccumulation

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
CEC 563, CEC 566

2. IDENTITY OF CHEMICAL

OTHER NAME(S)
Stepantex VK 90
Stepantex VS 90
Stepantex VT 90

MARKETING NAME(S)
Stepantex Esterquat

METHODS OF DETECTION AND DETERMINATION

ANALYTICAL METHOD	UV Absorbance IR Spectra GPC
Remarks	
TEST FACILITY	Not determined.

3. COMPOSITION

DEGREE OF PURITY
75.6%

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will not be manufactured in Australia. It will be imported by sea in 200 L drums and isotainers as Stepantex VT 90, which contains 75.6% of the notified chemical.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	> 100	> 100	> 100	> 100	> 100

USE
The notified chemical is used in household and industrial products (softeners, fabric conditioners, anti-statics).

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Not known

IDENTITY OF RECIPIENTS
Colgate Palmolive Company
50 Marple Avenue
Villawood NSW 2163

TRANSPORTATION AND PACKAGING
The product will be imported and transported by road in Dangerous Goods approved 200 L drums or isotainers.

5.2. Operation Description

The notified chemical, Stepantex Esterquat, is imported as the primary component in the product Stepantex VT 90. The concentration of Stepantex Esterquat in Stepantex VT 90 is 75.6%, the remainder being made up predominantly of isopropanol. The product Stepantex VT 90 is received by road in isotainers or in some cases by 200 L drums. The isotainer is then heated by steam within a contained area until the Stepantex VT 90 becomes liquid. Stepantex VT 90 is then discharged by a single unloading pump into a 42 tonne storage tank on site, where it is maintained at a temperature of 60^{o}C under agitation/circulation. Following quality assurance, the product is transferred *via* heated pipeline to the mixer as required; 500 kg to 2000 kg of Stepantex VT 90 is transferred at a time depending on formula type and batch size of the final product. Following the emulsion process, which takes approximately 30-60 minutes, the finished product is transferred to the finished product storage tank, where it is then transferred by stainless steel dedicated pipeline directly to the filling machine for packaging in either HDPE bottles or EVA sachets, which are packed into cardboard boxes and palletised for transport. The entire process is highly automated.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Research and development	3	6 hours/day	15 days/year
Quality control	5	4 hours/day	30 days/year
Dispensing and compounding	8	8 hours/day	30 days/year
Production	25	8 hours/day	30 days/year

Exposure Details

Stepantex Esterquat will be imported as a component of the product Stepantex VT 90 in either 200 L dangerous goods approved steel drums or 20 000 L isotainer. Exposure to workers involved in the importation, transport and storage is not expected to occur except in the unlikely event of accidental spillage.

On arrival at Colgate-Palmolive's Villawood site the Stepantex VT 90 is transferred to a storage tank and workers directly involved in the connection and disconnection of hoses used in the transfer may be exposed to the notified chemical by unexpected drips and splashes of residual product from hoses and cam-lock fittings or similar.

Workers involved in the research and development and the quality control analysis of incoming Stepantex VT 90 may also be exposed to the notified chemical in an undiluted state. Laboratory workers wear laboratory coats, gloves and safety glasses.

Transfer of Stepantex VT 90 to the mixer, where the final consumer products are formulated, occurs within an enclosed series of pipes and tanks. Addition and mixing of material to the batch is controlled via computer by an operator in a nearby enclosed room, and as a result exposure to either the Stepantex VT 90 or the formulation containing the notified chemical is unlikely during this stage of manufacture.

The final consumer formulation is transferred to the filling line by stainless steel dedicated pipeline and the filling of containers is largely an automated process with little or no worker interaction. Local exhaust ventilation is provided. Exposure to the formulated product containing the notified chemical may occur in the event of packaging equipment malfunction or leaking of the product from defective pipes or fittings. Plant operators wear protective clothing, gloves and safety glasses.

Preventative maintenance and repairs are carried out on the production line and the use of the line to package different products requires slight modifications between batches. The lines are rinsed between batches to remove any residual formulated product.

The final product is packaged in HDPE bottles and EVA sachets, which are packaged in cardboard boxes and palletised for transport. Exposure to the notified chemical in the form of the formulated product is not expected during transport or retail handling except in the unlikely event of an accident where the packaging may be breached.

5.4. Release

RELEASE OF CHEMICAL AT SITE

The notified chemical will be transported from the dock to one site at Villawood NSW, from where it is transferred from the bulk import containers (200 L drums & 20 000 L isotainer) by pipe to storage tanks. No release of the notified chemical is anticipated during transport and storage, except in the event of an accidental spill. The MSDS contains procedures for dealing with spills.

During formulation at the site, the product is pumped from storage containers to the main tank for mixing with water and other ingredients before repackaging. It is estimated that 3.5% of finished product, containing 12-14% notified chemical, may go to waste during formulation when the mixing equipment and pipelines are cleaned with hot water. This equates to about 2.3 tonnes of notified chemical per year. The wash water is collected in pits, transferred to a storage tank, and then mixed with other wash water containing both anionic and non-ionic detergent. The esterquats are inactivated

in the tanks by the anionic detergents, which combine to form insoluble salts. The wastes from this process are collected, treated by applied soil technology and used in landfarming.

RELEASE OF CHEMICAL FROM USE
Most of the notified chemical will be used in domestic laundries that normally drain to the sewer. As such, most of the imported volume of the chemical could be released into the aquatic environment.

5.5. Disposal

The 200 L drums are warmed and drained during processing. The empty drums are collected by an authorised company (name provided) who clean the drums for recycling. The waste water from the drum cleaning process is treated in accordance with EPA regulations and used in landfarming.

5.6. Public exposure

It is not expected that the public will be exposed to the notified chemical in its pure form except in the unlikely event of accidental spillage. The notified chemical will be reformulated for use in household fabric softeners at a concentration of 12-14% in 500 mL to 1.5 L packages. The consumer may be directly exposed to the fabric softeners and similar products for example during use as a fabric softener in automated washing machines. Skin contact may occur during pouring of the chemical or from residual product present on the lid or neck of the bottle.

The consumer will also be exposed to the proportion of notified chemical which remains attached to the fabric, however, the notified chemical will be firmly fixed to the cotton textile fibres.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa Off-white semi-solid paste.

Melting Point 32.8 ºC

METHOD Not stated
Remarks
TEST FACILITY Not stated

Boiling Point 90 ºC at 101.3 kPa

METHOD Not stated
Remarks
TEST FACILITY Not stated

Density 960 kg/m^3 at 40ºC

METHOD Not stated
Remarks
TEST FACILITY Not stated.

Vapour Pressure <1 kPa at 20ºC

METHOD Not stated
Remarks
TEST FACILITY Not stated

Water Solubility <20 mg/L at 20ºC

METHOD Not reported
Remarks The notifier indicated that water solubility is very difficult to determine due to the chemical's surfactant properties.
TEST FACILITY

Hydrolysis as a Function of pH Not determined

Remarks The pH of a 5% solution of the chemical is 2-4. The notified chemical is stable below about pH 4.5. The chemical contains ester linkages that are expected to undergo hydrolysis quickly above pH 4.5 to 5 (Garcia *et al*., 2000).

Partition Coefficient (n-octanol/water) Not determined

Remarks The notified chemical is a quaternary ammonium surfactant. As such, it is not possible to measure the partition co-efficient and get meaningful results.

Adsorption/Desorption Not determined

Remarks The notified chemical is expected to undergo ion exchange in the environment and to adsorb strongly to clays and organic matter.

Dissociation Constant Not determined

Remarks The chemical is expected to dissociate completely in water at a concentration <20 mg/L. At concentrations >20 mg/L, the chemical is expected to aggregate, form a dispersive solution, and then precipitate.

Particle Size Not determined

Remarks Paste is not expected to form particles of respirable size.

Flash Point 35 ºC

METHOD Pensky Martin closed cup method
Remarks Test pressure not provided
TEST FACILITY Not stated.

Flammability Limits Not determined

Remarks Expected to be combustible but not flammable

Autoignition Temperature Not applicable

Explosive Properties None

Reactivity Stable and non- reactive at normal temperatures and conditions.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral	LD50 > 5000 mg/kg bw, low toxicity
Rabbit, skin irritation	Irritating
Rabbit, skin irritation (20% notified chemical in water)	Not irritating
Rabbit, eye irritation	Irritating
Rabbit, eye irritation (20% notified chemical in water)	Not irritating
Guinea pig, skin sensitisation - adjuvant test	Inadequate evidence of sensitisation.
Guinea pig, skin sensitisation – non-adjuvant test	Non-sensitising
Skin Sensitisation – Human Repeated Insult Patch Test	Non-sensitising
Rat, Oral – gavage repeat dose toxicity - 90 days.	NOAEL 300 mg/kg
Genotoxicity - Bacterial Reverse Mutation	Non mutagenic
Genotoxicity – in vivo Mammalian Erythrocyte Micronucleus Test	Non genotoxic
Skin Compatibility – Burckhardt Test -	Good compatibility

7.1. Acute toxicity – oral

TEST SUBSTANCE — Stepantex VS 90

METHOD — EEC Directive 84/449/EEC B1
- Species/Strain: Rat/Sprague-Dawley
- Vehicle: None; test substance as supplied.
- Remarks - Method

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	2000	0/10
2	5/sex	5000	0/10

- LD50: > 5000 mg/kg bw
- Signs of Toxicity: A slight decrease in the spontaneous activity of the animals treated at the dose level of 5000 mg/kg was observed for a few hours after treatment and was accompanied with a slight decrease in body weight gain by the males.
- Effects in Organs: The macroscopic examination revealed no abnormalities in the animals sacrificed at the end of the study.
- Remarks - Results

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

TEST FACILITY — Centre International de Toxicologie (1991a)

7.2. Acute toxicity – dermal
No data provided – variation claimed

7.3. Acute toxicity - inhalation
No data provided – variation claimed

7.4.1 Irritation – skin

TEST SUBSTANCE — Stepantex VS 90

METHOD — EEC Directive 84/449EEC B4

Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	None; test substance as supplied
Observation Period	15 days
Type of Dressing	Semi-occlusive.
Remarks - Method	

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	2.67	2	0.33	3	15 days	0/D
Oedema	2	2.0	0.33	4	6 days	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.
D = Desquamation

Remarks - Results	Cutaneous reactions which were slight in one animal and marked in 2 animals were observed after the application of the test substance. The cutaneous lesions consisted of erythema (scores 1 to 3) and oedema (scores of 1 to 4).

CONCLUSION — The notified chemical is irritating to skin.

TEST FACILITY — Centre International de Toxicologie (1991b).

7.4.2 Irritation – skin

TEST SUBSTANCE — Stepantex VS 90 (20% in water)

METHOD — EEC Directive 84/449EEC B4

Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	Water
Observation Period	4 days
Type of Dressing	Semi-occlusive.
Remarks - Method	

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0.7	0	0	1	2 days	0
Oedema	0	0	0	0	N/A	0

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

Remarks - Results	No cutaneous reactions were observed in the animals one hour after removal of the dressing. Slight erythema was noted in one animal after 24 and 48 hours but had disappeared by 72 hours.

CONCLUSION — The 20% solution of the notified chemical is slightly irritating to skin.

TEST FACILITY Centre International de Toxicologie (1991c).

7.5.1 Irritation - eye

TEST SUBSTANCE Stepantex VS 90

METHOD EEC Directive 84/449/EEC B5
Species/Strain Rabbit/New Zealand White
Number of Animals 3
Observation Period Up to 8 days
Remarks - Method Observation period varied between test animals. Observation ceased once animals recovered and ceased to show any signs of irritation.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	1.7	1.0	2.0	2	7 days	0
Conjunctiva: chemosis	2.0	1.3	3.0	3	6 days	0
Corneal opacity	0.7	0.3	1.7	2	7 days	0
Iridial inflammation	0	0	1	1	4 days	0

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

Remarks - Results Following instillation of the test substance, marked and moderate conjunctival reactions were observed. An irritation of the iris was observed in one animal after 24, 48, and 72 hours. Corneal opacity which was slight in 2 animals or moderate for 72 hours in one animal was observed on an area less than half or less than one quarter of the cornea. All the ocular lesions had resolved between day 4 and day 8.

CONCLUSION The notified chemical is irritating to the eye.

TEST FACILITY Centre International de Toxicologie (1991d).

7.5.2 Irritation - eye

TEST SUBSTANCE Stepantex VS 90 (20% in water)

METHOD EEC Directive 84/449/EEC B5
Species/Strain Rabbit/New Zealand White
Number of Animals 3
Observation Period 4 days
Remarks - Method

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	0	0.3	0	1	1 day	0
Conjunctiva: chemosis	0	0	0	0	1 day	0
Corneal opacity	0	0	0	0	1 day	0
Iridial inflammation	0	0	0	0	1 day	0

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

Remarks - Results	A slight redness of the conjunctiva was observed in all 3 test animals one hour after instillation of the test substance. This redness was associated with slight chemosis in one animal. A slight enanthema persisted in one animal after 24 hours. No reactions were noted after 48 and 72 hours.
CONCLUSION	The 20% aqueous solution of the notified chemical is slightly irritating to the eye.
TEST FACILITY	Centre International de Toxicologie (1991e).

7.6.1 Skin sensitisation – Maximisation method

TEST SUBSTANCE	Stepantex VS 90
METHOD	OECD TG 406 Skin Sensitisation – Maximisation method.
Species/Strain	Guinea pig/Pirbright white
PRELIMINARY STUDY	Maximum Non-irritating Concentration: intradermal: All concentrations used found to be irritating (0.5% - 3%) topical: 2%
MAIN STUDY	
Number of Animals	Test Group: 20 (female) Control Group: 10 (female)
INDUCTION PHASE	Induction Concentration: intradermal injection 0.5% topical application 5.0%
Signs of Irritation	Weak dermal reactions were observed in the test animals following intracutaneous induction. All but 3 control animals showed no effects. Following the epicutaneous induction the test animals showed weak to moderate, and weak skin reactions 1 and 24 hours respectively after application. Control animals however also showed weak skin reaction at both times.
CHALLENGE PHASE	
1st challenge	Topical application: 2%
RESULTS	Nearly all guinea pigs, test and control animals, exhibited dermal reactions after retreatment. Additionally nearly 90% of the control animals demonstrated weak skin reactions following the epicutaneous induction. Irritation is believed to be effect of the vehicle rather than the test substance.

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*			
		1st challenge		*2nd challenge*	
		24 h	*48 h*	*24 h*	*48 h*
Test Group	0.2%	19/20	19/20	N/A	N/A
Control Group	0.2%	10/10	10/10	N/A	N/A

Remarks - Results	The observed effects are interpreted as irritation effects rather than sensitisation effects. Such irritating effects would mask any sensitisation effects if they were present.
CONCLUSION	No conclusions can be drawn from this study with regard to the sensitising potential of the notified chemical.

TEST FACILITY	Henkel KGaA (1991a).

7.6.2 Skin sensitisation – Beuhler method

TEST SUBSTANCE	Stepantex VS 90
METHOD	OECD TG 406 Skin Sensitisation – Beuhler Test
Species/Strain	Guinea pig/Pirbright white
PRELIMINARY STUDY	Maximum Non-irritating Concentration: Epicutaneous:5%
MAIN STUDY	
Number of Animals	Test Group: 10 (female) Control Group: 10 (female)
INDUCTION PHASE	Induction Concentration: Epicutaneous application: 15.0%
Signs of Irritation	Six test animals showed slight to moderate effects on the exposed skin area 1 hour after termination of the third induction. After 24 hours 9 test animals demonstrated slight to strong effects. Control animals showed no dermal alterations on the treated skin areas at any time.
CHALLENGE PHASE	
1st challenge	Topical application: 5%

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after challenge.*			
		Left Flank		*Right flank*	
		24 h	*48 h*	*24 h*	*48 h*
Test Group	5%	4	6	7	4
Control Group	5%	3	2	2	2

Remarks - Results	Weak skin alterations were observed in some test animals and controls 24 and 48 hours after termination of the retreatment. Observed slight irritations following retreatment are interpreted as irritation effects rather than sensitisation effects.
CONCLUSION	The test substance is non-sensitising on the skin of guinea pigs based on the results of the Buehler test.
TEST FACILITY	Henkel KGaA (1991b).

7.7. Repeat dose toxicity

TEST SUBSTANCE	Stepantex VS 90
METHOD	OECD TG 408 Repeated Dose 90-Day Oral Toxicity Study in Rodents.
Species/Strain	Rat/Sprague-Dawley
Route of Administration	Oral – gavage. Dose – 0, 100, 300, 1000 mg/kg/day
Exposure Information	Total exposure days: 90 days; Dose regimen: 5/ days per week; Post-exposure observation period: 35 days.

Vehicle	Not known
Remarks - Method	Summary data only available.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	10M/10F	0	0
II (low dose)	10M/10F	100	0
III (mid dose)	10M/10F	300	0
IV (high dose)	10M/10F	1000	1
V (control recovery)	5M/5F	0	0
VI (high dose recovery)	5M/5F	1000	0

Mortality and Time to Death

One male of the 1000 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.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Clinical Chemistry:

Significantly increased alanine transferase (ALT) levels were detected in animals at 1000 mg/kg/day at week 6. Increased calcium was also detected in males at week 6. Increased ALT persisted at week 13. Other significant findings at week 13 in females were increased alkaline phosphatase (AP) and cholesterol at 1000 mg/kg/day and increased creatinine at 100 mg/kg/day and 1000 mg/kg/day. Significantly increased potassium in males at 300 mg/kg/day and 1000 mg/kg/day was evident.

Haematology

Increased platelet counts were observed at week 6 in males at 300 mg/kg/day. Decreased cell volumes were observed at week 13 in females.

Pathology - microscopic

At 1000 mg/kg/day the bladder indicated increased desquamation, localised regressive changes in the epithelium to focal epithelium denudation without inflammatory reaction in the submucous area. Kidney, renal pelvis and urethra were free of corresponding changes, therefore, the bladder epithelium effects may be due to local irritation.

The mucous membrane of the omasum of some animals in the 1000 mg/kg/day group showed results of a local irritation in the form of thickening of the mucous membrane, inflammatory infiltration in the submucosa and isolated ulceration.

Remarks – Results

At 1000 mg/kg/day, effects related to treatment were observed in the liver (elevated ALT) and the effects secondary to treatment (local irritation) were observed in the bladder and omasum. Increases in potassium, chloride, creatine, and calcium content were not considered to be substance related, as the content values are comparable with historic control animal values.

CONCLUSION

The No Observed Adverse Effect Level (NOAEL) was established as 300 mg/kg bw/day in this study.

TEST FACILITY Henkel KGaA (1991c)

7.8. Genotoxicity - bacteria

TEST SUBSTANCE Stepantex VS 90

METHOD OECD TG 471 Bacterial Reverse Mutation Test.

Species/Strain	*Salmonella typhimurium*: TA1538, TA1535, TA1537, TA98, TA100.
Metabolic Activation System	Aroclor 1254–induced S9 mix.
Concentration Range in Main Test	a) With metabolic activation: 6.25 - 1600 µg/plate. b) Without metabolic activation: 6.25 - 1600 µg/plate.
Vehicle	Tween 80 in distilled water.
Remarks - Method	The assay was performed in two independent experiments, both with and without metabolic activation by S9 mix. In the second experiment with the strain TA 1538 with S9-mix small colonies were observed in control plates and treated plates, independently of tested concentrations. Therefore the experiment was repeated and only the repeated experiment was reported.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in PreliminaryTest	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent	200	400	Not noted	None observed
Present	5000	1600	Not noted	None Observed

Remarks - Results	Stepantex VS 90 did not induce any reverse mutations in the absence of rat liver enzymes (without S9-mix), nor did it induce any reverse mutations in the presence of Aroclor 1254-induced S9-mix. 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.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Henkel KgaA (1989).

7.9. Genotoxicity – in vivo

TEST SUBSTANCE	Stepantex VS 90
METHOD	OECD TG 474 Mammalian Erythrocyte Micronucleus Test.
Species/Strain	Mouse/CFW 1
Route of Administration	Oral – gavage .
Vehicle	Distilled. water
Remarks - Method	

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
Negative Control	6M/6F	0	24
Positive Control	6M/6F	10 mg/kg (CP)	24
Test Group	6M/6F	5000 mg/kg	24
Test Group	6M/6F	5000 mg/kg	48
Test group	6M/6F	5000 mg/kg	72

CP = cyclophosphamide.

RESULTS

Doses Producing Toxicity	No mortality was observed during either the range finding study or the micronucleus test. 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.
Genotoxic Effects	No increase in the frequency of micronucleated cells was observed in the test groups at any sampling time. The positive control substance, cyclophosphamide, induced a statistically significant increase in the number of micronucleated cells in both sexes.
CONCLUSION	The notified chemical was not clastogenic in this in vivo micronucleus assay under the conditions of the test.
TEST FACILITY	Henkel KGaA (1990a).

7.10. Skin sensitisation – human volunteers

TEST SUBSTANCE	Dehyquart F75
METHOD	
Study Design	Human Repeated Insult Patch Test
Study Group	88 volunteers; comprised of males and females
Vehicle	Distilled water
Induction Procedure	Induction concentrations: 0.5%, 1.0%, 2.0%. Nine repeat applications of the test substance (0.4 mL, 24 exposure, applied via an occlusive patch) at 3 applications/week for 3 weeks., to the same skin area on the upper arm. Negative control was purified water.
Rest Period	2 weeks
Challenge Procedure	1.0% active ingredient applied to upper arm of each subject.
Remarks - Method	Stotts (1980)
RESULTS	
Remarks - Results	HEDSET data only available. No dermal reactions indicative of sensitisation to the test substance or negative control following challenge at 48 and 96 hours post-application.
CONCLUSION	The notified chemical was non-sensitising under the conditions of the test.
TEST FACILITY	Pharmaco UK Ltd, 1995

7.11. Human Skin Compatibility

TEST SUBSTANCE	Stepantex VS 90
METHOD	Open epicutaneous application (Burckhardt, 1964)
Study Group	20 male and female volunteers aged 19 – 53 years (average 36.6)
Vehicle	Water
Remarks - Method	Stepantex VS 90 was applied at concentrations of 5%, 10%, 20% and 50% aqueous solution. A 5% solution is first applied to the left arm of the volunteers to an area of 3 cm in diameter on the skin of the inner surface of the forearm. The application is repeated each 30 seconds for 30 minutes. The other concentrations are then applied in increasing order and in similar fashion on the right arm.
RESULTS	
Remarks - Results	During application to the left arm 1 of 20 volunteers showed a slight erythema after 16 minutes of exposure that disappeared 10 minutes after the end of the application. No reaction was observed during or after application to the right arm.
CONCLUSION	Stepantex VS 90 is considered to possess a very good skin compatibility in all tested concentrations under the conditions of the test.
TEST FACILITY	Henkel KGaA (1991d).

7.12. MTEA

Degradation of Stepantex Esterquat occurs via the scission of the ester bond in the esterquat molecule by aerobic and anaerobic processes resulting in the formation of fatty acids and the degradation intermediate Methyl-triethanol-ammonium, ion (MTEA). In addition to the toxicological data on the notified chemical and its analogues, the notifier supplied information relating to the toxicity, toxicokinetics and pharmacology of MTEA.

7.12.1 Subchronic Oral Toxicty in Rat: 90 Day Study

TEST SUBSTANCE	MTEA
METHOD	OECD TG 407 Repeated Dose 90 day Oral Toxicity Study in Rodents.
Species/Strain	Rat/Sprague-Dawley
Route of Administration	Oral – drinking water
Exposure Information	Total exposure weeks: 90 days; Dose regimen: 7 days per week – Ad libitum; Post-exposure observation period: 35 days
Vehicle	Not known
Remarks - Method	. Doses used: 0%, 0.12%, 0.39% and 2.0%.
RESULTS	Summary data only available. Diarrhoea was observed in male rats receiving the highest concentration (1.6%). This equates to 351.4 mg/kg for males and 438.2 mg/kg for females. There were no other significant findings reported.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as 351.4 mg/kg for males and 438.2 mg/kg for females in this study.

TEST FACILITY	Biodynamic Inc. (1991).

7.12.2 Toxicokinetics

Elimination following intravenous administration

The elimination rate of MTEA in urine, faeces, and expired CO2 was observed in rats over a 72 hour period using orally intravenously administered radioactively labelled MTEA.
The main excretion route was the urinary route with about 96% eliminated in the 3 day period. Small amounts were also excreted via the faeces and CO_2. Most of the administered substance (approximately 90%) was eliminated within the first 24 hours.

Intestinal Absorption and Excretion following oral administration

The elimination rate of MTEA in urine, faeces, and measurement of radioactivity in the inner organs of rats was observed over a 72 hour period using orally administered, radioactively labelled MTEA.
Low doses of the compound (1 mg/kg) yielded elimination (recovery) rate of 92.7% for female rats and 100% for male rats in the first 3 days. High doses (100 mg/kg) yielded the elimination rate of 93.1% for female animals and 94.6% for male animals in the first 3 days. The data indicated that MTEA is rapidly excreted mainly in the faeces and the urine with most of the radioactive material being excreted within the first 24 hours. The recovery of radioactive material in the carcasses of test animals was low at 0.98%.

Pharmacokinetics

Pharmacological investigation of MTEA indicated no significant effect on blood pressure in the cat following the intravenously administered dose of 10 mg/kg. The intravenous injection of 56 mg/kg to the rat was found to significantly reduce blood pressure with a NOEL for the study of 18.7 mg/kg. Investigations into the ganglion-blocking effect in the cat indicate effects evident at 30 mg/kg with a NOEL of 10 mg/kg in this study. Pharmacological investigations conducted with dogs demonstrated significant reduction in the blood pressure by intravenously administered doses of 16.25 mg/kg to 65 mg/kg. The NOEL was established as 4.884 mg/kg. No reduction in arterial blood pressure was observed following the oral administration of MTEA and the NOEL in this study was 326 mg/kg.

8. ENVIRONMENT

8.1. Environmental fate

The notifier provided a number of summary reports on the biodegradability of Stepantex VS 90. These data are summarised below. An additional more detailed report on five substances, including Stepantex X7747B, was included, indicating between 61-84% degraded after 15 days and 72.5-89.6% degraded after 28 days. It is unclear, however, whether the pass level was reached within the specified 10-day window after reaching 10% degradation. While the test substance, Stepantex X7747B, is closely related to Stepantex VS 90 (mainly C_{16} and C_{18}), it is not the same product, and hence the details of this test are not included.

8.1.1. Ready biodegradability

TEST SUBSTANCE	Stepantex VS 90
METHOD	EEC-Directive 84/449 Annex V, Part C: Closed Bottle Test (= OECD TG 301 D)
Inoculum	Municipal sewage
Exposure Period	30 days
Auxiliary Solvent	Yes. The test material was evaporated from solvent (type not reported) prior to its introduction in the test.
Analytical Monitoring	Biological Oxygen Demand (BOD), Chemical Oxygen Demand (COD)
Remarks - Method	A mineral medium containing 2 and 5 mg/L of the test substance was inoculated with effluent from a sewage treatment plant and the oxygen concentrations measured after 5, 15, and 30 days. In addition, the concentration of nitrite and nitrate were determined to correct the BOD values for nitrification-caused oxygen consumption.

RESULTS

Concentrations	*Day 30: % BOD/COD*
2 mg/L	67-88
5 mg/L	>73

Remarks - Results	The results are corrected for oxygen consumption caused by nitrification. No information was provided for reference substance or controls.
CONCLUSION	The test substance is stated to be readily biodegradable according to the 60% BOD/COD criteria. However, without more details it is unclear whether the additional criteria of 60% degraded within the 10 day window after an initial 10% degradation was met.
TEST FACILITY	Henkel KGaA (1988a)

8.1.2 Ultimate Biological Degradation

TEST SUBSTANCE	Stepantex VS 90

METHOD BOD – test for insoluble substances (BODIS). Modified RDA-Blok Test (Blok, 1979).

Remarks - Method A mineral medium was inoculated with a mixed bacterial inoculum, stabilized for 1 week and then spiked with 100 mg COD/L of test substance. The test vessels were shaken continuously for the 28-day test period to assure steady state oxygen partitioning between the liquid and gas phases. The degradation was measured weekly by determining BOD in the aqueous phase. The total oxygen uptake was calculated from dissolved oxygen concentrations (DOC) divided by the saturation value (normal conditions) and multiplied by the total oxygen content (TOC).

RESULTS

Remarks - Results The percentage BOD/COD after 28 days was 87-100%.

CONCLUSION The test substance is ultimately biodegradable.

TEST FACILITY Henkel KGaA (1990b).

8.1.3 Biological Degradation in a Model Sewage Treatment Plant

TEST SUBSTANCE Stepantex VS 90

METHOD Decree concerning the degradation of anionic and nonionic surfactants in detergents and cleaning agents, Part 2 Confirmatory Test; Bundesgesetzblatt, 1977, Part 1, January 30 1977.

Remarks - Method This test was performed to determine the primary biodegradability of the notified chemical in an activated sludge model plant. The test substance was added at 10 mg/L DSBAS together with synthetic sewage (from a sewage treatment plant) as influent to a small (laboratory scale) sewage treatment plant. The concentration of the test substance (DSBAS) in the effluent was measured after the exposure period. Note: DSBAS (disulfine blue active substance) is an analytical parameter specific for cationic surfactants.

RESULTS

Remarks - Results At a test concentration of 10 mg/L DSBAS in the influent, a removal of 93% DSBAS occurred during the 3 hour test period.

CONCLUSION There is expected to be >90% removal of the test substance from biological sewage treatment plants.

TEST FACILITY Henkel KGaA (1990c).

8.1.4 Biological Degradation: Coupled Units Test

TEST SUBSTANCE Stepantex VS 90

METHOD EEC-directive 79/831 Annex VIII, Part C. Activated Sludge Simulation Test, Coupled units test (corresponding to OECD TG 303A).

Remarks - Method The test substance (22.3 active ingredient (a.i.)/L) was added to synthetic sewage influent in a laboratory scale activated sludge unit. A second control unit received only the sewage sludge. There was daily exchange of supernatant liquid from the settling vessels of the two units. The substance specific carbon removal rate was determined from the

	difference in the mean concentrations of DOC between the test and control effluents, which was compared with the carbon (C) concentrations of the test substance in the influent.
RESULTS	
Remarks - Results	Over the 6 hour test period, 89 ±7% of carbon was eliminated from the test unit in which 10 mg C/L (22.3 a.i./L) was added.
CONCLUSION	The carbon removal efficiency was high, and it was concluded that removal was mainly due to biodegradation.
TEST FACILITY	Henkel KGaA (1990d).

8.1.5 Anaerobic degradation

TEST SUBSTANCE	Stepantex VS 90
METHOD	ECETOC, Technical Report No. 28, Evaluation of Anaerobic Biodegradation, June 1988.
Remarks - Method	The test substance (50 mg active substance/L) was inoculated in airtight vessels with sludge from the anaerobic digester of a municipal sewage treatment plant and incubated for 6 weeks. The amount of methane and carbon dioxide produced from degradation was determined by measuring the gas pressure in the headspace of the test vessel. The concentration of dissolved inorganic carbon (DIC) in the digester liquid was also measured at the end of the test. The extent of degradation was determined from the net gas production and DIC formation (i.e. gas/DIC in test vessel minus gas/DIC in the controls).
RESULTS	
Remarks - Results	At the end of the 6-weeks, the extent of degradation (CO_2 + CH_4) was 101 ±13% (P = 95%).
CONCLUSION	The substance is degradable under anaerobic conditions.
TEST FACILITY	Henkel KGaA (1988b)

8.1.6. Bioaccumulation

No data were provided on bioaccumulation. The bioaccumulation potential of the notified chemical and its main degradation product is expected to be low owing to its high biodegradability and the low bioaccumulation factor of other quaternary ammonium surfactants (Steber, undated).

8.2. Ecotoxicological investigations

The notifier provided a number of full and summary reports on the ecotoxicity of Stepantex VS 90. These data are summarised below. The notifier also provided ecotoxicity data for the class of compounds know as esterquats, and for the subclasses of esterquats, called esteramines, of which the notified chemical is included, however, these data are not included in the following summary.

8.2.1. Acute toxicity to fish (1)

TEST SUBSTANCE	Stepantex VS 90 (full report)
METHOD	OECD TG 203 Fish, Acute Toxicity Test - semi-static conditions.
Species	Golden Orfe (*Leuciscus idus*)

Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	14ºd H (~250 ppm $CaCO_3$)
Analytical Monitoring	
Remarks – Method	Following a preliminary test, 10 fish were exposed in a definitive test to concentrations of 1.0, 1.4, 1.9, 2.6, 3.6, 5.1, 7.1 and 10 mg/L of test substance. The test water was renewed after 48 hours. Test concentrations were determined every 24 hours from 3 representative samples by photometric analysis. The LC_{50} was determined by calculating the geometrical average of the LC_0 and LC_{100}. Controls containing isopropanol were also included because the test substance was in a solution of isopropanol.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality %*			
Nominal	*Actual*		*24 h*	*48 h*	*72 h*	*96 h*
Control		10	0	0	0	0
Control		10	0	0	0	0
1.0	1.1 (0 hours), 0.52 (48 hours)	10	0	0	10	10
1.4		10	0	0	0	0
1.9		10	0	0	0	0
2.6		10	0	0	0	0
3.6		10	0	0	0	0
5.1	5.8 (0 hours), 4.6 (48 hours)	10	70	70	70	70
7.1		10	100	100	100	100
10	13.1 (0 hours)	10	100	100	100	100

LC50	5.1 mg/L at 96 hours (C.I., not provided).
LC0	3.6 mg/L
Remarks – Results	No fish mortalities occurred in the controls. In the preliminary test, no animals died when exposed to concentrations of 1 mg/L or below, while all animals died when exposed to the 10 and 100 mg/L test solutions. In the definitive test, after 24 hours of exposure, the LC_0 was around 3.6 mg/L, and the LC_{100} was 7.1 mg/L. After 48 hours of exposure and until the end of the test, these endpoints remained constant, however, one fish died in the 1.0 mg/L sample after 72 hours. No reasons are provided for the mortalities in the lowest concentrations but not in the intermediate concentrations
CONCLUSION	The test substance is moderately toxic to fish (Mensink *et al*. 1995).
TEST FACILITY	International Bio Research (1989)

8.2.2 Acute Toxicity to Fish (2)

TEST SUBSTANCE	Stepantex VS 90 (summary report)
METHOD	EEC Directive 84/449, Annex V, Part C: method for the determination of ecotoxicity. C.1. Acute toxicity for fish.
Remarks - Method	Ten fish (species not reported) per test concentration were exposed to the test substance in water (concentrations not reported). The test solutions were renewed daily. The number of dead fish was observed at 6, 24, 48, 72 and 96 hours. The LC50 was calculated from the log of LC0 × LC100.

RESULTS

Remarks - Results	The 96 h LC0 was 2.5 mg/L active ingredient (2.8 mg/L product), the LC100 was 3.6 mg/L active substance (4 mg/L product), and the 96 h

	LC50 was 3.0 mg/L active substance (3.3 mg/L product). The product is defined as Stepantex VS 90, the active ingredient is defined as pure esterquat.
CONCLUSION	The test substance is moderately toxic to fish (Mensink *et al*. 1995).
TEST FACILITY	Henkel KGaA (1990e)

8.2.3. Subacute Toxicity to Fish

TEST SUBSTANCE	Stepantex VS 90 (full report)
METHOD	OECD TG 204 (adopted April 4, 1984): prolonged toxicity, dynamic test in 14 days flow through test.
Remarks - Method	Ten fish *(Brachydanio rerio)* per concentration were exposed in a flow through test to 0.5, 1.0, 2.0, 4.0, 5.0 6.0 and 8.0 mg/L of the test substance for 14 days and visible symptoms of toxicity were recorded daily. The test medium was changed at a rate of 1L/h. A toxicity reference substance, $K_2Cr_2O_7$ was used to validate the sensitivity of fish stock.
RESULTS	
Remarks - Results	No sublethal effects were observed. The 14-day LC0 was 4 mg/L Stepantex VS 90, the LC50 was 4.9 mg/L and the LC100 was 6 mg/L. The subacute NOEC was determined to be 4 mg/L. These results are very similar to those obtained after 96 h.
CONCLUSION	The test substance is very slightly toxic in terms of the chronic value (Mensink *et al* 1995).
TEST FACILITY	Institute National de Recherche Chimique Applique (1990).

8.2.4 Acute Toxicity to Daphnia (1)

TEST SUBSTANCE	Stepantex VS 90 (summary report)
METHOD	German standard methods for the examination of water, waste water and sludge; bio assays (group L); determination of the effects of substances in water on small crustaceans (daphnia-short-time-test) (L11); DIN 38412 Part 11.
Remarks - Method	Ten test animals (*Daphnia*) per concentration were exposed to different concentrations of the test substance (concentrations not reported) for up to 48 hours. The percentage of animals unable to swim was determined after 24 and 48 hours.
RESULTS	
Remarks - Results	The EC0 was determined to be 32 mg/L of product (28.8 mg a.i./L); the EC50 was 87 mg/L product (78.3 mg a.i./L), and the EC100 was 180 mg/L product (162 mg a.i./L).
CONCLUSION	The test substance is slightly toxic to *Daphnia* (Mensink *et al* 1995).
TEST FACILITY	Henkel KGaA (1990e)

8.2.5 Acute toxicity to Daphnia (2)

TEST SUBSTANCE	Stepantex VS 90 (Full report)
METHOD	AFNOR Standards for chemical products (reference: NF T90-301) to test *Daphnia magna* mobility inhibition.
Species	*Daphnia magna*
Exposure Period	24 hours
Auxiliary Solvent	Not reported
Water Hardness	Not reported
Analytical Monitoring	PH, O_2 concentrations
Remarks - Method	Seven replicates of 20 Daphnia were exposed to test concentrations of 10, 16, 26, 40, 65 and 100 mg/L of Stepantex VS 90 for 24 hours. A biological sensitivity test was also conducted using potassium dichromate as the test substance, which resulted in an EC_{50} of 1.10 mg/L.

RESULTS

Concentration mg/L		*Number of D. magna*	*% Immobilised*
Nominal	*Actual*		*24 h [acute]*
Control		20	5
10		20	10
16		20	50
26	Not measured	20	90
40		20	100
65		20	100
100		20	100

RESULTS

Remarks - Results	The results indicate between 5% and 100% of daphnia were immobilised, i.e. 5% immobilised at the lowest test concentration (10 mg/L) and 100% at the three highest test concentrations (40-100 mg/L). The 24 h EC_{50} was determined to be 16.10 mg/L (95% C.I. = 13.95-18.53 mg/L).
CONCLUSION	The test substance is slightly toxic to Daphnia (Mensink *et al*. 1995).
TEST FACILITY	LMD SA (1989a)

8.2.6 Acute toxicity to Daphnia (3)

TEST SUBSTANCE	Stepanquat T (Full report)
METHOD	AFNOR Standards for chemical products (reference: NF T90-301) to test *Daphnia magna* mobility inhibition.
Species	*Daphnia magna*
Exposure Period	24 hours
Auxiliary Solvent	Not reported
Water Hardness	Not reported
Analytical Monitoring	pH, O_2 concentrations
Remarks - Method	Seven replicates of 20 daphnia were exposed to 6 test concentrations of Stepanquat T between 1.8 and 8.7 mg/L, and a control. A biological sensitivity test was performed using potassium dichromate as the test substance, which resulted in an EC_{50} of 1.25 mg/L. The EC_{50} values were determined by probit analysis.

RESULTS

Concentration mg/L		*Number of D. magna*	*% Immobilised*
Nominal?	*Actual?*		*24 h [acute]*

Control	0	20	0
1.8	500	20	10
2.5	700	20	15
3.2	830	20	45
4.5	1000	20	60
5.8	1200	20	75
8.7	1450	20	100

Remarks - Results: The test report states that the exposure concentrations were between 1.8 and 8.7 mg/L, while the annexe (which is referred to on the same page as the reported test concentrations) indicate test concentrations were between 500 and 1450 mg/L, while in the section on test conditions, these higher concentrations are attributed to the reference substance potassium dichromate. The 24 h IC50 reported in the results section is 919.07 mg/L (CI = 816.21-1034.91 mg/L). This endpoint is clearly not derived from the exposure concentrations reported on the same page in the results section, but is more in line with the concentrations reported in the annexe for Stepanquat, and also with the concentrations attributed in the section on test conditions to potassium dichromate.

CONCLUSION: The test report was too confusing to conclude the toxicity of Stepanquat T to *Daphnia*. It is not clear how closely related Stepanquat T is to Stepantex VS.

TEST FACILITY: LMD SA (1989b)

8.2.7 Chronic Toxicity to Daphnia

TEST SUBSTANCE: Stepantex VS 90 (summary report)

METHOD: Draft method: Prolonged toxicity test with *Daphnia magna* (Determination of the NOEC for reproduction rate, mortality and the moment of the first appearance of descendants; 21 d), Texte Umweltbundesamt 16/84.

Remarks - Method: Twenty animals (5 per test vessel) were exposed to different concentrations (not specified) of the test substance in a semi-static test in which the test solution was changed three times per week. For the evaluation of endpoints, the lethal effects, the number of juvenile organisms, and the first appearance of descendents were evaluated.

RESULTS

Remarks - Results: The 21-day NOEC was 3 mg/L product (2.7 mg a.i./L), the FOEC (first observed effects concentration) was 10 mg/L product (9 mg a.i./L).

CONCLUSION: The test substance is very slightly toxic to *Daphnia* (Mensink *et al* 1995) in terms of chronic exposure.

TEST FACILITY: Henkel KGaA (1990e)

8.2.8 Algal growth inhibition test

TEST SUBSTANCE: Stepantex VK 90 (full report)

METHOD: OECD TG 201 Alga, Growth Inhibition Test (1984).
- Species: *Scenedesmus subspicatus*
- Exposure Period: 72 hours
- Concentration Range: 0 (control), 1.0, 5.0 and 10 mg/L

Nominal Concentration Range Actual	Not reported
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	Cell concentrations, pH.
Remarks - Method	Three replicates (6 for controls) containing 10^4 cell/mL were exposed to each test concentration of test substance. Test temperatures were maintained at 23°C ±2. Illumination intensities were maintained at 6000 lux. Increases in pH values over the test period did not exceed 0.5 pH units. Potassium dichromate was used as the reference substance. Cell concentrations in each flask were determined at 24, 48, and 72 hours by cell counter. The endpoints were calculated by comparisons of the area under the growth curve between controls and replicates.

RESULTS

Effects	Growth: 10 mg/L at 72 hours (0% inhibition) Biomass: 10 mg/L at 72 hours (8.44% inhibition)
Remarks - Results	The 72 h ErC_{50} for $K_2Cr_2O_7$ was 0.2 mg/L and the EbC_{50} was 0.79 mg/L. Cell concentrations in the blank controls increased by a factor of greater than 16 in the control over the exposure period.
CONCLUSION	The test substance had no inhibitory effects on cell growth rates, but had a minor inhibitory effect on biomass growth.
TEST FACILITY	Institute National De L'Environment Industriel et des Risques (1994).

8.2.9 Subacute/chronic toxicity to algae

TEST SUBSTANCE	Stepantex VS 90 (summary report)
METHOD	German standard methods for the examination of water, waste water and sludge; bio assays (group L); determination of the inhibitory effects of water constituents on green algae (*Scenedesmus)* cell multiplication inhibition test) (L9); DIN 38412 Part 9 (= OECD TG 201).
Remarks - Method	*Scenedesmus subspicatus* was exposed to various concentrations (not specified) of the test substance for a 96-hour period. The chronic effects were determined by measuring the turbidity of the algal suspension at the end of the exposure period. No other details were provided.

RESULTS

Remarks - Results	The NOEC was 0.3 mg/L product (0.27 mg a.i./L), the 96 h EC10 was 1.6 mg/L product (1.4 mg a.i./L), and the EC50 was 2.0 mg/L product (1.8 mg a.i./L).
CONCLUSION	The test substance is moderately toxic (acute) to green algae (Mensink *et al* 1995). The reason for this very different result to the fully reported test above using the same algal species is unclear.
TEST FACILITY	Henkel KGaA (1990e)

8.2.10 Inhibition of microbial activity

TEST SUBSTANCE	Stepantex VS 90 (summary report)
METHOD	German standard methods for the examination of water, waste water and

sludge; bio assays (group L); Determination of the inhibitory effects of waste water on the oxygen consumption of *Pseudomonas putida* (L27); DIN 38412 Part 27, draft January 1990.

Remarks – Method: The oxygen consumption of a bacterial suspension in the presence of glucose and without test substance was determined and compared to the consumption of bacterial suspensions containing various concentrations (not specified) of the test substance.

RESULTS

NOEC: 30 mg/L product (27 mg a.i./L)

FOEC: 100 mg/L product (90 mg a.i./L)

Remarks – Results

CONCLUSION: No adverse effects toward bacterial activity in sewage treatment plants are expected up to 20-25 mg/L of test substance.

TEST FACILITY: Henkel KGaA (1990e)

8.2.11 Subacute/chronic toxicity: Bacteria

TEST SUBSTANCE: Stepantex VS 90 (summary report)

METHOD: German standard methods for the examination of water, waste water and sludge; bio assays (group L); Determination of the inhibitory effects of water constituents on bacteria (*Pseudomonas* cell multiplication inhibition test) (L8); DIN 38412 Part 8, draft April 1989.

Remarks - Method: The test organism, *Pseudomonas putida*, was incubated in nutrient solution in the presence of different concentrations (not specified) of test substance. After 16 hours, the turbidity of the bacterial suspension was determined. The effect concentration of the test substance was determined photometrically.

RESULTS

Remarks - Results: In one test, the 16 h EC0 was 1.0 mg/l product (0.9 mg a.i./L), the EC10 was 1.3 mg/L (1.2 mg a.i./L). In a second test, the EC0 was 3.0 mg/L product (2.7 mg a.i./L) and the EC10 was 3.9 mg/L (3.5 mg a.i./L). According to the report, the difference between the two test results corresponds to one gradation step of the concentrations tested and may reflect the intrinsic variability in the biological tests.

CONCLUSION: The 16 h NOEC is in the range 0.9 to 2.7 mg/L.

TEST FACILITY: Henkel KGaA (1990e; 1991e).

8.2.12. Subacute/chronic toxicity: Biocenosis (microcosm)

TEST SUBSTANCE: Stepantex VS 90 (summary report)

METHOD: Guhl W. (1987).

Remarks - Method: The microcosm system is a multi-species system consisting of a number of different species of bacteria, algae, protozoans and small multicellular organisms. The organisms are exposed in a flow-through system to different concentrations of test substance for the duration of 3 weeks. The test is evaluated by comparing quantitative and qualitative biotic indices (not specified) of the biocenoses present in the test vessels and controls.

	The effects evaluation covers acute and chronic effects toward a number of different species and their interspecific interactions.
RESULTS	
Remarks - Results	3-week NOEC = 0.15 mg a.i./L, FOEC = 0.2 mg/L.
CONCLUSION	No negative effects toward biocenosis were observed at a concentration of 0.15 mg/L.
TEST FACILITY	Henkel KGaA (1990f)

8.2.13. Complex systems simulation: STP to river water – Subsequent *Daphnia* test

TEST SUBSTANCE	Stepantex VS 90 (summary report)
METHOD	Modification of the OECD Confirmatory Test (sewage treatment plant sumulation model). Schoberl P (1991). Tenside Surf. Det. 28: 6 and Daphnia multi-generation tests.
Remarks - Method	Artificial sewage with (10 mg/L) and without the test article was dosed continuously into a model sewage treatment plant. To obtain full nitrification in the STP, the concentration of the artificial sewage in the plant influent was reduced by 50% and the hydraulic retention time was doubled to 6 hours. *Daphnia* were exposed to the diluted or undiluted plant effluent (i.e. with 1 and 4 parts tap water to simulate dilution by receiving water) for a period of 6-7 weeks, a period covering the lifetime of the parent and 3 consecutive filial generations. The *Daphnia* reproduction rate of each generation was compared with a corresponding control without the test substance.
RESULTS	
Remarks - Results	There was no measurable difference in the reproduction rate of *Daphnia* between the controls or the animals exposed to 10 mg/L of the plant effluent either diluted or undiluted.
CONCLUSION	No chronic effects toward *Daphnia* are expected from residual test compound or its degradation products when exposed to it in sewage effluent.
TEST FACILITY	Henkel KGaA (1990f).

8.2.14. Complex systems simulation: STP to river water – Cascade Model

TEST SUBSTANCE	Stepantex VS 90 (summary report)
METHOD	Guhl W. (1987).
Remarks - Method	Artificial sewage with and without the test article was dosed continuously into a model sewage treatment plant for a 4-month period. The plant effluent was diluted with 1 and 4 parts tap water to simulate dilution in the receiving water. The effluent was continuously added to the top vessel of a cascading system. The cascade system consisted of 25 vessels arranged one upon another so that the diluted plant effluent passes through all vessels at a rate of 50 L per 24 hours. Six trophic levels were present in the cascade system, bacteria, blue-green algae, microalgae, protozoa, and small multicellular organisms. The effects were evaluated based on a comparison of the qualitative and quantitative biotic indices (not specified) in the control and dosed units.

RESULTS

Remarks - Results	After the continuous addition of 33 mg/L of test substance (corresponding to 15 mg C/L) to the plant effluent, no significant differences were observed in biocenotic parameters between the treated systems and the control over the test period, except in one of the 25 vessels. The effects were not described. A parameter "K" describing the similarity of the biotic systems, was provided as follows: vessel 1: K = 0.71, vessels 2-25: K = 0.8. The limit of no effect was K ≥ 0.8.
CONCLUSION	It was concluded that even at the unrealistically high STP influent concentrations used in the test, no significant effects on biocenosis of a model river system occurred. Consequently, neither the test compound nor its degradation products are expected to negatively influence aquatic life in river systems at realistic STP influent concentrations.
TEST FACILITY	Henkel KGaA (1990f)

8.2.15. Earthworms

TEST SUBSTANCE	Stepantex VS 90 (summary report)
METHOD	Draft method: Toxicity test with the earthworm *Eisenia foetida* (Savigny) 1826 in artificial soil. (LC50, 14 days), Umweltbundesamt 3/1984 (Corresponding to OECD TG 207).
Remarks - Method	Adult earthworms (*Eisenia foetida*) were exposed to different concentrations of test substance in artificial soil for 14 days. After 7 and 14 days, the contents of the test vessels were spread and the number of surviving worms counted. No other information on the test procedures or conditions was provided.

RESULTS

Remarks - Results	14 d LC0 > 1000 mg/product (or > 900 mg a.i./kg soil).
CONCLUSION	No acute toxicity of the compound to earthworms was observed at the maximum concentration level tested.
TEST FACILITY	Henkel KGaA (1990e)

8.2.16. Subacute/chronic toxicity: Terrestrial plants (growth)

TEST SUBSTANCE	Stepantex VS 90 (summary report)
METHOD	EEC-Ringtest Protocol C(21)3: Higher plant (June 1986), corresponding to OECD TG 208.
Remarks - Method	Varying concentrations (not specified) of up to 1000 mg/product (or > 900 mg a.i./kg) were incorporated into soil into which seeds were sown. The number of seedlings to emerge was recorded and after at least 2 weeks (exact period not specified), the plants were harvested and weighed. The condition of the plants including any stunting, chlorosis, or necrosis was also visually assessed. The EC50 is the concentration at which the change in emergence is 50% of the controls.

RESULTS

Remarks - Results	Oats (*Avena sativa*) EC0 > 900 mg a.i./kg Tomato (*Lycopersicum esculentum*) EC0 > 900 mg a.i./kg

	Radish (*Raphanus sativus*) EC0 > 270 mg AS /kg, EC50 >900 mg a.i./kg
CONCLUSION	The compound has a low toxicity toward the growth of terrestrial plants with an NOEC between 270 and > 900 mg/kg.
TEST FACILITY	Henkel KGaA (1990e)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Usage patterns in domestic and industrial laundries indicate that almost all of the notified chemical in fabric conditioners and softeners could be released into the environment via the municipal sewer at end use, except for about 3% lost during formulation, which is expected to be treated for landfarming.

Based on predicted import volumes up to 500 tonnes may be released into the sewer during use of the finished fabric conditioners. Usage is expected to occur nation wide, such that release will occur in a diffuse manner. The notified esterquat is readily biodegradable, and consequently, biodegradation will significantly reduce the amount of chemical released in sewage effluent. In the closed bottle tests, between 70 and 100% of Stepantex was degraded. In the coupled units and model STP tests, aerobic degradation by sewage microorganisms resulted in over 90% removal. Anaerobic degradation also resulted in about 87-100% removal. High (70-100%) anaerobic biodegradation levels of esterquats, and no toxic effects on anaerobic bacteria, were also reported at levels up to 300 mg/L (Garcia *et al*. 2000). The notified chemical is not expected to be volatile, however, there is likely to be some partitioning of the chemical to solids in the sewer owing to its surfactant properties, which would also reduce exposure concentrations.

A high proportion of the notified chemical is also expected to adsorb to the fabric during the wash cycle. According to information provided by the notifier, the amount of adsorption differs with the type of fabric. Loosely woven fabrics, such as wool, adsorb more of the compound than do tightly woven fabrics, owing the greater surface area available for adsorption. Synthetic fabrics adsorb more than natural fibres such as cotton because they have a greater distribution of negative charges. The notifier estimates an adsorption rate of 50-80% for fabrics available on the Australia market. Most of the esterquat, adsorbed to cloth in the first wash, will eventually be removed from the fibres in subsequent wash cycles, where it is expected to hydrolyse in the wash water (ie. at pH >5.0). Under neutral to alkaline conditions the ester bonds in the molecule hydrolyse quickly to yield fatty acids and a small hydrophilic quaternary compounds (Garcia *et al*. 2000).

Given the above considerations, we have calculated a worst-case daily predicted environmental concentration (PEC), making the following assumptions:

- product use is spread over the whole population (19.5 million);
- release occurs evenly over 365 days;
- water use is 200 L per person per day;
- 85% is degraded in the washing machine/sewer.
- 50% adsorption

The resulting PEC for the notified esterquat in sewage effluent is 19.9 µg/L per day [((500 × 0.756 × 0.5)/365 tonnes × 15%)/200 L X 19.5 million]. It is expected that this exposure concentration would be further reduced by dilution in receiving waters.

Esterquats decompose into non-surface active fragments through cleavage of the ester bonds via either chemical or microbial processes (Garcia *et al*. 2000). Degradation of Stepantex results in the formation of an intermediate product, tris(hydroxymethyl)methylammonium-cation (MTEA), which is also a by-product contained in Stepantex. The degradate is soluble in water

and not adsorbed to sewage sludge (Anon. 1991). However, it is also readily biodegradable, with >80% removal in the Zahn-Wellens test, 70-100% removed in the OECD screening test, and 76-94% removed in the CO_2 evolution test (Puchta *et al* 1993).

Approximately 2.3 tonnes per year of the notified chemical in liquid waste will be applied to soil in landfarming. Prior to landfarming, the notified chemical is pre-treated with anionic and non-ionic detergents during which it hydrolyses to form a salt. Once applied to soil, the degradation products are expected to be utilised by microorganisms and biodegraded.

9.1.2. Environment – effects assessment

A number of acute and chronic toxicity endpoints are available for Stepantex Esterquat. Some of these are summarised below:

Acute	**LC/EC50**
Fish	3 mg/L
Daphnia	87 mg/L
Bacteria	>100 mg/L
Algae (96 h)	1.8 mg/L
Algae (72 h)	>10 mg/L
Earthworm	>1000 mg/L

Subacute/chronic	**EC0/NOEC**
Fish (14 d)	4 mg/L
Daphnia (21 d)	3 mg/L
Bacteria	90 mg/L
Terrestrial plants	>270 mg/L

Data were also provided for complex biocenosis microcosm tests, which indicated no effects on a range of organisms at concentrations of 0.15 mg/L, as well as a complex simulation system which showed no effects after the continuous adding of 33 mg/L of test substance.

The predicted no effects concentration (PNEC) for acute toxicity using the most sensitive species (algae) and a safety factor of 100 is 0.018 mg/L. A safety factor of 100 is recommended by the OECD when acute data for each of the three trophic levels is available.

Data are available for the acute toxicity of MTEA. Puchta *et al* (1993) report the following acute no effects concentrations (EC0): fish 300 mg/L, Daphnia 180 mg/L and bacteria >10,000 mg/L. These data indicate MTEA is significantly less toxic than the parent compound.

9.1.3. Environment – risk characterisation

Almost all of the notified chemical in fabric conditioners and softeners could be released into the environment via the municipal sewer when washing machines are emptied. We have calculated a PEC in the sewer of 0.0186 mg/L per day, which assumes 50% adsorption to fabric, hydrolysis in the wash, and 85% biodegradation in the sewer. It is expected that this exposure concentration would be further reduced by dilution in receiving waters. We assume a conservative dilution ratio of 10:1 for oceans, and no dilution for a river, resulting in a PEC of about 0.002 mg/L for release into oceans, but no change to the PEC in rivers.

The notified chemical is moderately acutely toxic to fish and algae, and slightly or very slightly toxic to other aquatic organisms. The PEC/PNEC ratio, assuming no dilution in receiving waters, is 1.03, using algae as the most sensitive species. This value is close to 1 suggesting a moderate risk (concentrations of concern = Q>1) to aquatic organisms in riverine environments where dilution is minimal, but no concern in marine environments. However, a complex microcosm test showed no effects at 0.15 mg/L about an order of magnitude higher than the PNEC, indicating the conservative nature of this risk assessment methodology. The degradate MTEA is also less toxic than the parent compound, and is expected to have a significantly lower PEC/PNEC ratio and lower aquatic risk.

Liquid waste, containing the notified chemical, which is used in landfarming is not expected to present a risk to soil fauna or plants because it is treated and destroyed prior to application. In

any case, the chemical was not toxic to earthworms exposed to concentrations >1000 mg/kg soil and had a low toxicity to a range of plant species.

The level of biotic elimination of the notified chemical in sewage treatment facilities and soil under both aerobic and anaerobic conditions is expected to be high, and would continue in the receiving waters and soil. Thus, the 85% removal rate used to calculate the PEC in the sewer is likely a conservative estimate. The expected low concentrations in the natural environment is supported by monitoring data collected from surface and ground water in the Netherlands and France where, at the time of monitoring, esterquats had been used for at least a decade. Results showed concentrations of MTEA of <10 ppb (793 samples), with most samples below the detection limit (5 ppb). Similar studies in Germany showed similar results (Puchta *et al*. 1993). As such, the notified chemical is not expected to pose a significant risk to the environment at the current maximum import volumes.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Stepantex Esterquat is imported as a component of Stepantex VT 90 in 200L drums or 20000L isotainer. Stepantex VT 90 is classified as a dangerous good due to the flammability of the isopropanol. As dangerous goods packaging is required to comply with the requirements of the Australian Dangerous Goods Code (FORS, 1998), the likelihood of exposure to workers involved in the importation, storage and transport of Stepantex VT 90 is considered low, even in the event of an incident such as a truck accident during transport or forklift accident during warehousing.

Workers responsible for the transfer of material from the drum/isotainer to the storage tank may be exposed by skin contact to small amounts of the product containing the notified chemical if hoses and hose-fittings contain residues which may be released on disconnection and movement of hoses. Research and development and quality control personnel responsible for confirming the integrity of the delivered Stepantex VT 90 may also be exposed to undiluted Stepantex VT 90, however, the quantities are expected to be small.

The formulation of the final product containing 12-14% Stepantex VT 90 and the transfer of this formulation takes place within an enclosed series of tanks and pipes. The entire formulation is controlled remotely from a computer terminal providing little opportunity for exposure to workers involved in this process.

Workers operating on the factory floor may be exposed dermally to a 12 –14% concentration of the notified chemical in the formulated product in the unlikely event of leakage from defective piping or fittings. Incidental skin exposure may also occur should packaging of finished products be ruptured or leaking.

The production lines are rinsed between batches and before preventative maintenance and modifications performed by maintenance staff. The likelihood of exposure of these workers to significant concentrations of Stepantex Esterquat is therefore considered low.

Once finished products have been packaged, packed in cartons, and palletised, there is little risk of exposure to workers involved in the outbound warehousing and transport of the products. Retail workers involved in the stocking of supermarket shelves or sales may be exposed to the consumer product containing 12-14% of the Stepantex VT 90 should dropped containers rupture or leak, however these occasions are considered infrequent and the likelihood of exposure is considered low.

The most likely opportunity for significant exposure to the notified chemical therefore occurs during the transferring of Stepantex VT 90 to the storage tank and to a lesser extent the packaging of the formulated products.

9.2.2. Public health – exposure assessment

The public are not expected to come into contact with the notified chemical in its most concentrated form, as even in the event of an accident, the packaging requirements of Stepantex

VT 90 as a dangerous good should prevent release from the containers or isotainer.

The likelihood of consumers being exposed to the 12-14% concentration of Stepantex VT 90 as it occurs in consumer products during shopping/purchasing is considered low.

The consumer may be directly exposed to the fabric softeners and similar products during use, as the fabric softener will be used predominantly in automated washing machines. Some dermal exposure may be experienced during pouring of the chemical or from residual product present on the lid or neck of the bottle.

Ocular exposure as a result of splashing of the notified chemical is not expected due to the high viscosity of the consumer product. Incidental ocular exposure through transfer of the notified chemical from contaminated hands is possible but s likely to be infrequent.

The consumer will also be exposed to the proportion of notified chemical which remains attached to the fabric following washing and it is estimated that up to 0.08% fabric weight of the notified chemical remains on the washed garments. Given the low concentration of notified chemical remaining on the fabric, and the fact that the notified chemical will be firmly fixed to the cotton textile fibres, the level of exposure to the notified chemical through the wearing of washed clothing is considered low.

The most significant scenario for exposure to the notified chemical therefore occurs during the pouring of the product and removal/replacement of the container cap.

9.2.3. Human health - effects assessment

The notified chemical was found to be of low acute oral toxicity with LD_{50} for the rat determined to be > 5000 mg/kg. Acute dermal toxicity studies were not conducted, however on the basis of the data supplied for acute oral toxicity, the notified chemical is not expected to be acutely toxic by the dermal route. Inhalation studies were also not carried out as the notified chemical exists as a paste and is not expected to be an inhalation hazard.

Dermal irritation studies using Stepantex VS 90 demonstrated slight to marked effects with erythema ranging from slight to moderate and oedema formation ranging from slight to severe. Based on these results Stepantex Esterquat causes skin irritation of sufficient concern to be classified as a skin irritant (NOHSC, 1999). Skin irritation was markedly reduced using a 20% preparation of Stepantex VS 90 in water with only one animal displaying slight erythema after 24 and 48 hours but recovering after 72 hours. At 20% aqueous solution of Stepantex VS 90 is not considered to be a skin irritant.

Eye irritation studies using Stepantex VS 90 demonstrated moderate to marked conjunctival reactions. Irritation to the iris was observed in one animal for 3 days and slight to moderate corneal opacity was apparent in 3 animals. The score for conjunctival effects obtained in the study meets the criteria for classification as an eye irritant (NOHSC, 1999). Eye irritation studies using a 20% preparation of Stepantex VS 90 failed to produce any significant effects.

The results of an adjuvant skin sensitisation study using Stepantex VT 90 are confounded by the presence of moderate to strong erythema and/or oedema observed in the majority of control animals at challenge. Using the Beuhler method for determination of skin sensitisation slight reactions were observed in some test animals however these effects were interpreted as irritational effects rather than sensitisation effects. The notified chemical is determined to be non-sensitising on the skin of guinea pigs based on the results of the Beuhler test using Stepantex VS 90. A human repeat insult test using Dehyquart F75, also a quaternary fatty acid ester but differing in its mix of fatty acids to the notified chemical, did not demonstrate dermal reactions indicative of sensitisation to the test substance. The notified chemical was also shown to be compatible with skin in an open epicutaneous application on human volunteers.

Repeat dose oral toxicity in a 90 day gavage study using Stepantex VS 90 established a NOAEL of 300 mg/kg/day. Effects observed in concentration above 300 mg/kg/day included:

- increased ALT;

- increased platelet counts and decreased cell volumes (300mg/kg/day);
- increased desquamation in the bladder and localised regressive changes to focal denudation of epithelium in the submucosal area;
- irritation of the mucous membrane of the omasum.

No genotoxic effects were observed either *in vitro* using a Bacterial Reverse Mutation Test or *in vivo* using the mammalian erythrocyte micronucleus test.

Stepantex Esterquat is readily degraded by the cleavage of the ester linkages to give fatty acids and the main degradation intermediate, MTEA. While no data is available on the toxicokinetics of the notified chemical, the toxicokinetics of this degradation intermediate have been studied. MTEA was found to be almost completely excreted within 3 days of administration by both the oral and intravenous route in rats. In pharmacological investigations for MTEA in a variety of laboratory animals, effects on blood pressure were observed only at high doses (8mg/kg).
Long term oral toxicity studies for the degradation product found MTEA to also be of low toxicity with a NOEL of 0.096% when administered *via* drinking water.

Hazard Classification
On the basis of results of dermal Irritation and eye Irritation studies using Stepantex VS 90, Stepantex Esterquat is classified as an Irritant (Xi) R36/38 Irritating to the eyes and skin, in accordance with the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

9.2.4. Occupational health and safety – risk characterisation

Workers responsible for the transfer of material from the drum/isotainer to the storage tank and quality control workers responsible for testing of the incoming material may be exposed to small amounts of Stepantex VT 90 which contains 75.6% of the notified chemical. Stepantex VS 90 is irritating to the skin and eyes and therefore exposure to small amounts may be sufficient to cause injury to exposed workers. Therefore impervious gloves, protective clothing, and chemical goggles are recommended during these operations.

Incidental exposure to the notified chemical in the form of the final products (12-14%) may occur in the event of leaks from the production line or in the event of a ruptured or leaking package during the packaging process. At these concentrations however, the aqueous solution containing the notified chemical is non-irritating to the eyes and skin. Therefore, the OHS risk associated with these activities is therefore assessed as low. Nevertheless, all workers in the factory area should wear safety glasses, gloves, and protective shoes at all times.

The likelihood of exposure during import, storage and transport of Stepantex VT 90 is considered negligible and therefore the health risk is low. The risk to workers associated with the transport storage and handling of consumer goods containing the notified chemical is considered to be low due to the low likelihood of exposure. The formulation of products containing the notified chemical is computer controlled with little potential for exposure to workers performing the formulation remotely from computer terminals. The risk associated with the formulation of products is therefore considered low. As the rinsing of the pipelines in between packaging of different Colgate-Palmolive batches is carried out before any modification or routine maintenance is carried out, any remaining Stepantex Esterquat will be at insignificant concentrations and the OHS risk associated with these activities is considered negligible.

The OHS risk associated with the notified chemical is considered low based on the information provided regarding the operational processes involved, and the engineering controls in place.

9.2.5. Public health – risk characterisation

The notified chemical is classified as a hazardous substance due to its irritating effects on skin and eyes. A 20% solution of the Stepantex VS 90 (15% notified chemical) does not however exhibit significantly irritating effects on the skin and eyes of rabbits although irritating effects were seen in some test animals. The notifier indicates that the final concentration of Stepantex VS 90 in the final product is 12-14%.

The risk to public health associated with the notified chemical in washing water or on washed clothes is not considered due to the low concentration of the notified chemical involved

Therefore, given the low potential for exposure to the notified chemical during consumer use, and the low irritancy of the final products used by consumers, the public risk associated with the notified chemical is considered low. Nevertheless, consumers should avoid splashing due to possible eye irritation.

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

10.1. Hazard classification

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

- Irritant (Xi) R36/38 Irritating to eyes and skin

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio; the chemical is not considered to pose a risk to the marine aquatic environment, but represents a moderate risk to riverine aquatic environments where dilution by receiving waters is reduced. However, when taking into account the high degradability of the chemical and conservative nature of the risk assessment methodology, the risk is considerably reduced.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is low concern to occupational health and safety under the conditions of the occupational settings described.

10.3.2. Public health

There is low concern to public health provided consumers are not in contact with the undiluted consumer formulations for extended periods.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the product containing the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994a). It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

The label for the product containing the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994b). Hazardous substances which are imported from overseas may be labelled in accordance with overseas requirements. The label provided contains equivalent information to that advised in the National Code of Practice, including the appropriate risk and safety phrases, and it is not necessary to relabel the imported product. The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

REGULATORY CONTROLS

Hazard Classification and Labelling

- The NOHSC Chemicals Standards Sub-committee should consider the following health, hazard classification for the notified chemical:
  - R36/38 Irritating to eyes and skin

- Products containing more than 20% notified chemical must carry the following risk and safety directions on the label:
  - R36/38 Irritating to eyes and skin
  - S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice
  - S28 After contact with skin, wash immediately with plenty of soap suds
  - S 37 Wear suitable gloves
  - S 39 Wear eye/face protection

- The product Stepantex VT 90 containing the notified chemical should be classified as follows under the ADG Code:
  - Class 3 Packaging Group II

- Suppliers should label the product containing the notified chemical Stepantex VT 90 as a Class 3 dangerous good and the risk and safety phrases listed above.

CONTROL MEASURES

Occupational Health and Safety

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

  - Standard Operating Procedures (SOPs) should be documented for the process of transferring products containing the notified chemical from isotainers and drums. SOPs should refer to the MSDS of the product and outline PPE requirements.
  - Induction and supervision of contractors such as transport workers should be carried out to ensure the above SOPs are followed.
  - Standard operating procedures should be documented for the process of quality control of products containing the notified chemical. SOPs should refer to the MSDS of the product and outline PPE requirements

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

  - Protective clothing
  - Chemically resistant gloves or gauntlets
  - Chemical goggles or safety glasses

  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 Stepantex Esterquat are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999), workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Public Health

- The following measures should be taken by the manufacturer of consumer products containing the notified chemical to minimise public exposure to the notified chemical:
  - Advice on the label of products containing the notified chemical should include

information on the possibility of dermal and eye irritation to sensitive individuals and recommend washing of skin and eyes immediately following exposure to the undiluted product.

Environment

Disposal

- The notified chemical should be disposed of through licensed waste contractors and in accordance with EPA regulations.

Emergency procedures

- Spills/release of the notified chemical should be contained with an absorbent material such as dry earth or sand and placed in sealable containers for disposal. Spills should not be allowed to enter drains or waterways.

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 sub-section 64(2) of the Act:
   - if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

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