File No: STD/1189

13 April 2006

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Quartamin BTC 131

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health and Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment and Heritage.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at:

Library
Australian Safety and Compensation Council
25 Constitution Avenue
CANBERRA ACT 2600
AUSTRALIA

To arrange an appointment contact the Librarian on TEL + 61 2 6279 1162 or email ascc.library@dewr.gov.au

This Full Public Report is available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

Street Address:	334 - 336 Illawarra Road MARRICKVILLE NSW 2204, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

Director
NICNAS

TABLE OF CONTENTS

FULL PUBLIC REPORT

Quartamin BTC 131

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Henkel Australia Pty. Limited (ABN 82 001 302 996)
20 Rodborough Rd
Frenchs Forest NSW 2086

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical identity (Chemical name, other names, CAS. Number, Molecular Formula, Structural Formula. Molecular Weight, Spectral Data)
Composition (Purity, identity of toxic or hazardous impurities, % weight of toxic or hazardous impurities, non-hazardous impurities, identity of additives/adjuvants, % weight of additives/adjuvants)
Import Volume
Identity of Sites

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Physico chemical data: Melting Point/Boiling point; Specific gravity/Density; Vapour pressure; Water solubility; Hydrolysis as a Function of pH; Partition Co-efficient; Absorption/Desorption; Dissociation Constant; Particle size; Flash point; Flammability limits; Autoignition temperature; Explosive properties; Reactivity
Acute Inhalation toxicity
Genetic toxicity

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
Submitted a notification advice covered by the cosmetic exemption under section 21(4) of the *Industrial Chemicals (Notification and Assessment) Act 1989*. CE/46 (2005)

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Quartamin BTC 131 (imported chemical)
Extra Care Pearl Shimmer Colour Mask (finished product)
Extra Care Pearl Shimmer Repair Mask (finished product)

METHODS OF DETECTION AND DETERMINATION

METHOD	IR
Remarks	Spectra available

3. COMPOSITION

DEGREE OF PURITY
< 80%

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. The notified chemical will be imported by sea as Quartamin BTC 131 as a paste formulation (< 80% notified chemical) in 60 L high density PE (HM-HDPE) drums.

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

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

USE
The notified chemical will be used as a component (< 1.5% notified chemical) of hair care products.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Sydney, New South Wales

IDENTITY OF MANUFACTURER/RECIPIENTS
Hair care formulator(s)

TRANSPORTATION AND PACKAGING
The imported paste product (Quartamin BTC 131) containing < 80% notified chemical will be shipped in 60 L open top high density PE (HM-HDPE) drums. The imported product will be transported from the dockside to hair-care formulator(s) for storage and formulation into finished hair care products.

The finished hair care products will be packaged into small sealed consumer-size 300 mL plastic bottles. The plastic bottles will be sealed with plastic closures and packed into cardboard cartons before being transported by truck or van to end-users (hair salons, retail outlets) Australia-wide.

5.2. Operation description

Formulation
During formulation of hair care products, an operator will open the drums, connect pumping equipment to the drums and dose the required amount of the notified chemical into a mixing vessel. The drum of raw material will be heated to ~80ºC prior to pumping. Other ingredients will also be added and the mixture is blended in either an open or closed mixing vessel. Mixing operation will be automated. Prior to packaging, sampling and quality testing of the hair products are carried out by quality assurance (QA) workers in the laboratory. The final formulated products will be transferred by an automated pump system into a storage tank connected to a multiple-head filler machine and automatically dispensed into push-on cap 300 mL plastic bottles. The concentration of the notified chemical in the finished hair care products will be a maximum of 1.5%.

The bottled products will be sealed with plastic closures and packed in cardboard cartons. The finished and packaged hair care products will be transported, typically by road, to distribution warehouses for supply, as required, to retail outlets for consumer-use and for sale to professional hair-care workers. Maintenance and cleaning workers will be involved in cleaning equipment

End-use
Retail workers will handle the finished products in the retail packaging. Professional hair care workers will apply the finished products.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Transporting and warehousing	5-10	2-3 hours/day	50 days/year
Operators	20-50	8 hours/day	230 days/year
Laboratory technicians	2	2-3 hours/day	230 days/year
Maintenance	3	2-3 hours/day	10 days/year
Hair salon and retail outlet workers	>1000	1 hour per day	200-240 days per year

Exposure Details
Import, Transport and Storage
Warehousing and distribution of the notified chemical involves loading, unloading, moving and storing the imported product and packaged hair care products. Exposure to workers involved in the importation, storage and transport of the imported product (< 80% notified chemical) is not expected except in the event of an accidental spill.

Formulation
Dermal and accidental ocular exposure to the notified chemical (< 80%) may occur during opening of the drums, dosing the required amount of the notified chemical into a mixing vessel and connecting and disconnecting transfer and filling lines. Exposure to the finished product (< 1.5% notified chemical) will most likely occur during packaging and unitising of finished consumer products.

Inhalation exposure is not likely as the notified chemical is imported as a paste formulation.

The mixing vessels are enclosed and the filling machines are automated and fitted with local exhaust ventilation. Workers are expected to wear overalls, face mask, safety glasses and/or safety shoes and impervious gloves.

Quality Control/Maintenance
Dermal exposure and accidental ocular to small quantities of the notified chemical (< 80%) may occur during sampling and testing or during machine maintenance and cleaning. Workers are expected to wear laboratory coats, safety glasses and rubber gloves.

End-Use
Dermal and accidental ocular exposure to up to 1.5% notified chemical may occur in hair care professionals, e.g., hair dressers, where the services provided involve the application of personal care products. In addition, retail and distribution workers may be exposed to up to 1.5% notified chemical in the event of an accidental breach of packaging.

Intermittent dermal exposure to hairdressers is likely to occur when applying the hair care products to the hair of customers in salons, as gloves will probably not be used for this process. Based on similar uses, the notifier indicated that the quantity of notified chemical used per application is estimated to be approximately 5 grams per application. Repeated exposure may occur through use of the product on different customers. Some accidental ocular exposure may occur. The low concentration of the notified chemical in the hair care products (< 1.5%) will reduce the exposure of hairdressers.

5.4. Release

RELEASE OF CHEMICAL AT SITE
The notified chemical will be transported from the dockside to the formulation site, where it will be stored and formulated into hair care products. Environmental release from the formulation process will be low. During the formulation of hair care products the estimated annual losses of notified chemical are:

Spills	less than	1%	< 30 kg
Equipment cleaning	max	3%	90 kg
Import container residual	less than	1%	< 30 kg
Total Annual Loss			< 150 kg

All the reformulation waste will be treated in an on-site treatment plant. It will be neutralised and the solids removed for landfill and the liquid effluent discharged to trade waste.

RELEASE OF CHEMICAL FROM USE

Following application of hair care products, almost all of the notified chemical will be washed from hair and released to sewer. The end use containers are expected to be disposed of with normal household garbage to landfill. The residues of notified chemical remaining in these bottles are expected to be 2% or up to 60 kg/annum.

5.5. Disposal

Residual chemical in containers is expected to account for less than 2% per annum of total imported notified chemical.

Import containers are expected to be disposed of to drum recyclers, where any residual notified chemical will be removed and thermally decomposed in high temperature incinerators. End use containers are expected to be disposed of as domestic waste to landfill.

5.6. Public exposure

The notified chemical will be used in the formulation of hair care products, which will be available to the general public. Public exposure will be widespread and will result through the use of personal care products containing < 1.5% notified chemical. Members of the public will make dermal contact and possibly accidental ocular contact with products containing the notified chemical.

Typical use profile is estimated as follows:

Product	*Amounts (g)/Task*	*Use Frequency (tasks per day)*	*Total exposure (g per day)*
Shampoo	8	1	8
Rinse off conditioner	14	0.28	3.9
Leave-in conditioner	12.4	0.28	3.5

In a worst-case scenario, exposure to the notified chemical could be up to 0.23 g/day for the above three applications as the effects of exposure from above application can be additive.

Since the hair care product will be stored and used in a domestic environment, there is the possibility of accidental ingestion by a child.

Public exposure to the imported product (up to 80% notified chemical) during transport, storage and retail distribution is unlikely unless the packaging is accidentally breached.

6. PHYSICAL AND CHEMICAL PROPERTIES

Information below was retrieved from the suppliers' Material Safety Data Sheet (MSDS) for Quartamin BTC 131

Appearance at 20°C and 101.3 kPa White to yellowish paste

Melting Point/Freezing Point 50°C

Remarks Melting point for Quartamin BTC 131 cited in MSDS

Boiling Point ≈ 100 °C

Remarks Boiling point for Quartamin BTC 131 cited in MSDS. Decomposition is expected at high temperatures.

Density 970-1010 kg/m^3 at 25°C

Remarks Density for Quartamin BTC 131 cited in MSDS

Vapour Pressure 2.4×10^{-3} kPa at 20°C

Remarks Based on water content of Quartamin BTC 131. The notified chemical will not be volatile due to it quaternised form.

Water Solubility 0.1 g/L at 25ºC

Method A semi-quantitative method involving serial dilutions of Qartamin BTC 131. The % light transmission of each dilution was measured using spectrophotometery.

Remarks A 20% solution was mixed at 25 and 60ºC for 2 hours with stirring and then diluted with water from 25 ºC to lower concentration.
Relatively poor transmittance was observed at 1 g/L and above, indicating dispersion (microdroplettes) of notified chemical in solution. However, 98 to 100% transmittance was observed from 0.1 g/L, indicating the solubility of the notified chemical.

Hydrolysis as a Function of pH Not Determined

REMARKS The chemical contains ester linkages that are expected to undergo hydrolysis under extreme temperature and conditions.

Partition Coefficient (n-octanol/water) Not Determined

Remarks The notified chemical is quaternary ammonium surfactant. As such, it is not possible to measure the partition coefficient and get a meaningful result.

Adsorption/Desorption Not Determined

Remarks The notified chemical is an active surfactant, therefore, it is expected to bind readily to, or be associated with soil and sediments.

Dissociation Constant Not determined

Remarks The notified chemical contains a quaternary ammonium group which is expected to be fully dissociated in water throughout the environmental pH range of 4 to 9.

Particle Size Not applicable, Quartamin BTC 131 is in paste form.

Remarks Test not conducted. Paste is not expected to form particles of desirable size.

Flash Point > 100ºC

METHOD Open cup (Cleveland) (Full test report not provided).

Remarks Flash point is based on Quartamin BTC 131 cited in MSDS

Flammability Limits Not expected to be flammable

Autoignition Temperature Not expected to autoignite.

Explosive Properties Not expected to be explosive.

Reactivity

Remarks Quartamin BTC 131 is stable under normal conditions. Hazardous decomposition products are carbon oxides, nitrogen oxides, halogenated compounds and hydrogen chloride.

7. TOXICOLOGICAL INVESTIGATIONS

The notifier submitted toxicological reports and summaries, some of which were not according to OECD protocols. The notifier has submitted genotoxicity studies for 2 analogues of similar structures.

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral	Low toxicity, LD50 > 2000 mg/kg bw
Rabbit, acute dermal	Low toxicity, LD50 > 9ml/kg bw
Rat, acute inhalation	Not determined
Rabbit, skin irritation	Moderately irritating
Rabbit, eye irritation	Non-irritating
Guinea pig, skin sensitisation - Guinea pig maximisation test by Magnusson and Kligman	No evidence of sensitisation.
Rat, oral repeat dose toxicity - 28 days.	NOEL > 200 mg/kg bw/day
Genotoxicity – Ames Test	Non mutagenic
Genotoxicity – in vitro Chinese hamster lung fibroblasts (V79 cells)	Non genotoxic
Genotoxicity – *in vitro*, based on analogue data:	Non mutagenic

7.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 401 Acute Oral Toxicity – Limit Test.
Species/Strain	Rat/Wistar
Vehicle	Water
Remarks – Method	No deviation from protocol Administration by gavage (5 mL/kg)

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/male	2000	Nil
2	5/female	2000	Nil

LD50	> 2000 mg/kg bw
Signs of Toxicity	No mortalities occurred and no signs of systemic toxicity were observed during the 14-day observation period. All animals showed body weight gain during the study period.
Effects in Organs	Macroscopic examination of all animals at the end of the study revealed no gross abnormalities.
Remarks – Results	
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	NOTOX C.V. (1987)

7.2. Acute toxicity – dermal

TEST SUBSTANCE	Notified chemical (Summary only provided)
METHOD	Not known
Species/Strain	Rabbit/New Zealand White
Vehicle	Undiluted
Type of dressing	
Remarks – Method	The test was conducted by exposing a large surface of the skin to 0 (control), 5, 10 or 100% of the material in an amount of 9 ml/kg body weight of the rabbits during 24 hours. Each of the doses was applied to 2 male and 2 female rabbits. In each dose group one male and one female

received material on intact skin, while the other male and female was treated on the superficially damaged skin. After exposure, the animals were observed for a period of 14 days. Body weights and intake of food and water were recorded. At day 14 blood samples were collected for examination of haematological parameters. The animals were then sacrificed and examined for gross pathological changes.

RESULTS

LD50	> 9 ml/kg bw
Signs of Toxicity - Local	One rabbit in the lowest dose group and one of the controls were reported dead from causes unrelated to treatment. No deaths occurred in the intermediate-, and high dose group. After the 24-hour exposure period only one top-dose rabbit showed signs of skin irritation. General health condition, gain in body weight, intake of food and water did not show any treatment related changes.
Signs of Toxicity - Systemic	Haematology did not show any treatment-related changes.
Effects in Organs	No gross changes attributable to the test material were observed.
Remarks – Results	

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

TEST FACILITY CIVO Institutes TNO (1981)

7.3. Acute toxicity – inhalation

There was no acute inhalation toxicity test submitted. However, given that the notified chemical is a paste and of low vapour pressure, inhalation exposure is not considered a significant route of exposure.

7.4. Irritation – skin

TEST SUBSTANCE Notified chemical

METHOD FDA standards (patch-test technique on the abraded and intact skin)

Species/Strain	Rabbit/New Zealand White
Number of Animals	12
Vehicle	None (administered undiluted)
Observation Period	72 hours
Type of Dressing	Occlusive.
Remarks – Method	An amount of 0.5 g of the test substance is applied on the intact or abraded skin under a surgical patch. The patches are fixed to the application site by means of adhesive tape and the entire trunk of the rabbits is wrapped with an impervious material to maintain the test patches in position and to retard evaporation of volatile substances. Six rabbits are treated on the intact skin, the other 6 on the abraded skin. After an exposure of 24 hours the patches and the test substance applied are removed and the resulting skin reactions are evaluated by the method of Draize. A second reading was made 48 hours later (72 hours after application) using the CIVO-grading system based on the effects seen on scaliness and/or necrosis.

RESULTS

Intact skin

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Erythema/Eschar	3	3	72 hr	2
Oedema	1	1	72 hr	1

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

Abraded skin

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Erythema/Eschar	2	2	72 hr	1
Oedema	0.7	1	24 hr	0

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

Remarks – Results: Test substance caused slight to moderate skin irritation. Its dermal effects generally consisted of very slight or well-defined erythema, very slight oedema and slight scaliness.

CONCLUSION: The notified chemical is moderately irritating to the skin and is classified under the NOHSC Approved Criteria for Classifying Hazardous Substances.

TEST FACILITY: CIVO Institutes TNO (1981a)

7.5. Irritation – eye

TEST SUBSTANCE: Notified chemical

METHOD: FDA standard
Species/Strain: Rabbit/New Zealand White
Number of Animals: 6
Observation Period: 48 hours
Remarks – Method: 0.1 mL of the test substance is allowed to fall on the everted lower lid of one eye of each rabbit; the upper and lower eye lid are then carefully closed and subsequently held together for at least one second before releasing, to prevent loss of the test substance. The other eye, remaining untreated, serves as a control. The eyes are examined at 24, 48, 72 hours and 7 days after instillation of the test substance.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	0.08	1	24 hr	0
Conjunctiva: chemosis	0.08	1	24 hr	0
Corneal opacity	0	0	-	0
Iridial inflammation	0	0	-	0

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

Remarks – Results: Test substance caused slight conjunctivitis in one out of 12 rabbits. After 48 hours these lesions had cleared up.

CONCLUSION: The notified chemical is slightly irritating to the eye.

TEST FACILITY: CIVO Institutes TNO (1981a)

7.6. Skin sensitisation

TEST SUBSTANCE: Notified chemical

METHOD: Guinea pig maximisation test by B. Magnusson and AM Kligman (1970) in Allergic Contact Dermatitis in the Guinea pig: identification of contact allergens", published by C.C. Thomas, Springfield, Illinois, USA.
Species/Strain: Guinea pig/albino Hartley/Dunkin
PRELIMINARY STUDY: Maximum Non-irritating Concentration:

Intradermal injection: 1% v/v in 0.9% w/v sterile saline
Topical application: undiluted test substance

MAIN STUDY

Number of Animals induction phase: Test Group: 10 males Control Group: 10 males
Induction Concentration:
Intradermal: Intradermal injections of Freund's complete adjuvant both alone and mixed with test substance, 1% v/v in 0.9% w/v sterile saline elicited dermal irritation.

Signs of Irritation: Slight dermal irritation was observed following intradermal injection of test substance, 1% v/v in 0.9% w/v sterile saline alone. Slight dermal irritation was seen following the topical application of undiluted test substance.

CHALLENGE PHASE

1st and 2nd challenge: topical application: Test substance, 10% + 2% v/v in distilled water

Remarks – Method

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*			
			1st challenge	*2nd challenge*	
		24 h	*48 h*	*24 h*	*48 h*
Test Group					
	2%	*0/10*	*0/10*	*0/10*	*0/10*
	10%	*1/10*	*0/10*	*0/10*	*0/10*
Control Group					
	2%	*0/5*	*0/5*	*0/5*	*0/5*
	10%	*0/5*	*0/5*	*0/5*	*0/5*

Remarks – Results

First Challenge application with test substance, 10% v/v in distilled water:
Slight erythema was seen in two guinea pigs (616 and 620) at the 24 hours reading only. In one case this was restricted to a small area of the challenge site. No dermal reactions were observed in the remaining 8 guinea pigs (for guinea pigs from 611 to 620).
For the treated control animals (guinea pigs from 621 to 625), no dermal reactions were seen in any of the 5 treated control animals during the 72 hours observation period.

First challenge application with test substance,, 2% v/v in distilled water (for test animals from 611-620)
No dermal reactions were seen in any of the 10 test animals.
Treated control animals (guinea pigs from 621 to 625), no dermal reactions were observed.

Second challenge application with test substance, 10% v/v in distilled water
No dermal reactions were seen in any of the 10 test animals (guinea pigs from 611 to 620)
Treated control animals , no dermal reactions were observed (guinea pigs from 626 to 630)

Second challenge application with test substance, 2% v/v in distilled water
No dermal reactions were seen in any of the 10 test animals (guinea pigs from 611 to 620)
Treated control animals , no dermal reactions were observed (guinea pigs from 626 to 630)

CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	Hutingdon Research Centre (1979)

7.7. Repeat dose toxicity

TEST SUBSTANCE	Notified chemical
METHOD	Sub Acute (4 week) Oral Toxicity Study
Species/Strain	SPF rats (Cpb:WU; Wistar Random)
Route of Administration	Oral – diet.
Exposure Information	Total exposure days: 28 days;
Remarks – Method	The concentrations of the test substance in the diets were 0 (control), 400, 2000 or 10,000 ppm.

RESULTS

Group	*Number and Sex of Animals*	*Dose/Concentration <units>*		*Mortality*
		Nominal	*Actual*	
I (control)	10 per sex	0	0	0/20
II (low dose)	10 per sex	400	0	0/20
III (mid dose)	10 per sex	2000	0	0/20
IV (high dose)	10 per sex	10,000	0	0/20
V (control recovery)				
VI (high dose recovery)				

Mortality and Time to Death

No death or abnormalities of conditions or behaviour were observed.

Clinical Observations

Mean body weights were significantly decreased in the top-dose group, in male only. Food intake was diminished in the top-dose group in males throughout the study, whereas females were no dose-related differences between the various test groups and controls. Food efficiency was slightly diminished in the top-dose group in males throughout the study and in females of the top-dose group only in one week. Water intake figures were slightly diminished in the top-dose group in males only.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Haemoglobin concentration did not show any outstanding differences amongst the control and test groups.
At autopsy no abnormalities were observed that could be ascribed to the ingestion of the test compound. Microscopic examination of the kidneys revealed an increased incidence of tubular nephrosis in male rats of the top-dose group, as compared to controls.
In females, a high incidence of tubular nephrosis was found in all groups. No other renal or hepatic abnormalities were found that could be attributed to the test compound.

Effects in Organs

The absolute weights of the kidneys of females were slightly increased in the top-dose.

Remarks – Results

The growth depression observed in the top-dose group (10,000 ppm) in males was accompanied by decreased food intake and food efficiency. Therefore, this finding in males is attributed to a toxic action of the test substance.
The increase in the relative weight of the kidneys in females at 10,000 ppm and the increased incidence of tubular nephrosis in the kidneys of males in this group suggest a slight nephrotoxic action of the test compound.
No treatment-related variation in the incidence of tubular nephrosis was found in females. However, the

incidence in female control rats was higher than in control groups of other oral toxicity studies with rats of the same strain and age.
The increase in the relative weight of the liver in females at 10,000ppm was not accompanied by treatment-related lesions. Therefore, the liver enlargement may be considered the expression of an adaptive phenomenon rather than of a toxic action of the test compound.
Since none of the criteria was adversely affected at the lower-dose levels of 400 or 2000 ppm, it is concluded that 2000 ppm was the no-toxic-level. This level is equivalent to a nominal intake of approximately 200 mg test substance/kg bw/day.

CONCLUSION
The No Observed Effect Level NOEL was established as 200 mg/kg bw/day in this study, based on decreased food intake and effect in the kidneys at the next higher dose level.

TEST FACILITY	CIVO Institutes TNO (1981b)

7.8. Genotoxicity – bacteria

TEST SUBSTANCE	Notified chemical
METHOD	Ames, et al. (1975) Methods for detecting carcinogens and mutagens with the Salmonella/mammalian microsome mutagenicity test.
Species/Strain	*S. typhimurium*: TA1538, TA1535, TA1537, TA98, TA100.
Metabolic Activation System	Liver fraction (S9 mix) from rats pretreated with Aroclor 1254
Concentration Range in Main Test	a) With metabolic activation: 0.5 - 50 µg/plate. b) Without metabolic activation: 0.5 -50 µg/plate.
Remarks – Method	No significant protocol deviations.
RESULTS	
Remarks – Results	Incorporation of the test product at levels up to 5 mg/plate did not increase the numbers of histidine revertants in any of the five tester strains, either in the presence or in the absence of the liver microsome activation system.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	CIVO Institutes TNO (1980)

7.9.(a) Genotoxicity – in vitro

TEST SUBSTANCE	Notified chemical
METHOD	Cleaver, JR. Radiation Research 37, 334 (1969)
Species/Strain	
Cell Type/Cell Line	V79 line of Chinese hamster lung fibroblasts
Metabolic Activation System	Liver fraction (S9 mix) from rats pretreated with Aroclor 1254
Remarks – Method	Dose selected 125 - 500 µg/ml
RESULTS	There was slight increase in the percentage of cells undergoing repair in the dose range 12.5 - 50µg/ml, both in the presence and absence of metabolic activation. However, these results were marginal and could not be confirmed in the repeat experiment.
Remarks – Results	A significant increase in the percentage of cells undergoing repair synthesis was generally noted although Analyst 1 tended to detect these increases qualitatively rather than quantitatively. All three analysts were able to unambiguously identify the positive control agents used in this experiment.

CONCLUSION	The notified chemical was not clastogenic to Chinese hamster lung fibroblasts (V79 cells) treated in vitro under the conditions of the test.
TEST FACILITY	Huntingdon Research Centre (1981)

7.9. Genotoxicity – in vitro

TEST SUBSTANCE	Two analogues
METHOD	Information was extracted from: Chapter 5 on Cationic Surfactants from the Danish Report on *"Environmental and Health Assessment of Substances in Household Detergents and Cosmetic Detergent Products, 2001".*
CONCLUSION	Analogue 1 was studied in *in vitro* short-term tests to detect potential mutagenic effects. Cultures of Syrian golden hamster embryo cells were used for an *in vitro* bioassay. No *in vitro* transformation of hamster embryo cells was induced and analogue 1 was not mutagenic in *Salmonella typhimurium.* No mutagenic effects or genetic damages were indicated in a survey of nine-short-term genotoxicity tests with both analogues.
TEST FACILITY	Danish EPA (2001)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE: Notified Chemical

METHOD: OECD TG 301 D Ready Biodegradability: Closed Bottle Test.
- Inoculum: Influent and effluent from a STP
- Exposure Period: 28
- Auxiliary Solvent:
- Analytical Monitoring: Oxygen electrode
- Remarks - Method: Four different concentrations of notified chemical were tested for each sampling date. During test period the pH of the test solution was 3.6 and the concentration of dissolved oxygen was 8.92 mg/L.
No reference solution was used.

	Test substance	
Day	*mg/L*	*% Degradation*
5	22	2
	7.63	6
	4.37	5
	2.93	20
15	15.2	31
	6.24	75
	3.89	63
	2.45	55
28	10.8	44
	5.79	65
	3.42	76
	2.45	72

- Remarks - Results: The notified chemical achieved > 70% biodegradation after 28 days only on the lowest concentrations. However, only at 4 and 6 mg/L was the 10 day criteria, ie > 60% degraded once 10% has been reached, met. Therefore it can not be classified as being readily biodegradable.

CONCLUSION: The test substance is not considered readily biodegradable.

TEST FACILITY: Krachtwerktuigen (1991)

8.1.2 Bioaccumulation

No bioaccumulation data is available. The potential to bioaccumulate is expected to be low due to the charge stage of the quaternary ammonium functional group.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE: Notified Chemical

METHOD: OECD TG 203 Fish, Acute Toxicity Test – limit test
EC Directive 92/69/EEC C.1
- Species: Rainbow Trout
- Exposure Period: 96 hours
- Auxiliary Solvent: Tetrahydrofuran
- Water Hardness: 50 mg $CaCO_3$/L
- Analytical Monitoring:
- Remarks – Method: The study was performed on one test concentration of 100 mg/L plus one

control and one solvent control (including 100 µL/L auxiliary solvent).

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
100	100	20	0	0	0	0	0
Control		20	0	0	0	0	0

LC50 > 100 mg/L at 96 hours.
NOEC ≥ 100 mg/L at 96 hours.
Remarks – Results There were no mortalities or adverse reactions to exposure in 20 fish exposed to a test concentration of 100 mg/L for a period of 96 hours. The test solution was a direct dispersion in water with the aid of shielded propeller stirrers and the addition of tetrahydrofuran (100 µL/L)

CONCLUSION The notified chemical is not toxic to Rainbow Trout up to it limit of its solubility.

TEST FACILITY SafePharm Laboratories (1993).

8.2.1. Acute toxicity to fish

TEST SUBSTANCE Notified Chemical

METHOD Dutch Test Guideline NEN 6504 Fish, Acute Toxicity Test – semi static
Species Guppy (*Poecilia reticulata*)
Exposure Period 96 hours
Auxiliary Solvent
Water Hardness
Analytical Monitoring
Remarks – Method The fish are exposed to various concentration of the test substance for a period of 96 hours with removal after 48 hours. During test period the pH of the test solution ranged from 8.1 to 8.3 and the concentration of dissolve oxygen varied from 8.4 to 8.6 mg/L.
Test substance was LB 776 = notified chemical.

Concentration mg/L		*Number of Fish*	*Mortality*			
Nominal	*Actual*	*Number of Fish*	*24 h*	*48 h*	*72 h*	*96 h*
3.2		Not stated	0	0	0	0
5.2		Not stated	0	0	0	0
10		Not stated	10	10	20	20
18		Not stated	100	100	100	100
32		Not stated	100	100	100	100

LC50 > 10, < 18 mg/L at 24 hours.
NOEC 5.6 mg/L at 96 hours.
Remarks – Results Mortality was observed from 24 hours at a concentration of 10 mg/L. There are no indications of how test solutions were prepared or whether they were clear.

CONCLUSION The notified chemical is harmful to *Poecilia reticulata* under the test conditions.

TEST FACILITY Krachtwerktuigen (1990)

8.2.2. Acute/chronic toxicity to aquatic invertebrates

TEST SUBSTANCE Notified Chemical

METHOD

Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	
Water Hardness	210 mg $CaCO_3$/L
Analytical Monitoring	
Remarks - Method	The test was carried out in duplicate, 25 animals per vessel. The conditions of the animal were assessed after 24 and 48 hours. Two experiments were conducted. The first experiment tested concentrations between 3.2 to 320 mg/L. Because the conditions of the animal were worst than that of the animal without notified chemical, a second test was conducted at concentration between 0.32 to 3.2 mg/L. The test solutions were prepared by adding calculated amounts of a 1% or 0.1% solution of notified chemical in distilled water to reconstitute test water in the test vessels. The mixture was stirred, both solutions and the dilution of reconstituted test water were turbid, but were reasonably homogeneous (the more concentrated solutions were more turbid). In both experiments, 0.1% and 1% solution, were turbid, but reasonable homogeneous. The O_2 concentration was lower at higher notified chemical concentration.

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0		50	0	0
0.32		50	0	0
0.56		50	0	0
1		50	0	0
1.8		49	0	0
3.2		48	0	3
5.6		48	0	0
10		49	0	0
32		50	0	0
56		49	0	0
100		49	0	0
180		50	0	0
320		50	46	48

LC50	> 180 mg/L and < 320 mg/L at 48 hours
NOEC (or LOEC)	0.56 mg/L at 48 hours
Remarks - Results	It was difficult to estimate the influence of the notified chemical on *Daphnia magna*. The conditions of the *Daphnia magna* became gradually less good with increasing concentration, without quantifiable effects. Two-non quantifiable effects were evident: • The colour of the animals changed increasingly from red-brown (normal) to pale or colourless with the increase concentration of the notified chemical. • The animals swimming behaviour became less and less normal. The animals swam slower and laid in the bottom most time. Concentrations higher than 320 mg/L were not tested, since the viscosity of such a solution was rather high for small animals. Unfavourable effects appeared at 10 mg/L. Immobilization appears to be greater than 18 mg/L and less than 320 mg/L. The report stated that the animals exposed to concentrations in the range 1 to 5.6 mg/L were probably worse than the control. Concentrations of 0.56 mg/L and lower seemed to have not effect on the conditions of the animals.

CONCLUSION	The notified chemical is toxic to *Daphnia magna* under the test conditions. This may be a physical effect caused by insoluble material.
TEST FACILITY	TNO (1980)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified Chemical
METHOD	OECD TG 201 Alga, Growth Inhibition Test- limit test. EC Directive 92/69/EEC C.3 Algal Inhibition Test.
Species	*Scenedesmus subspicatus*
Exposure Period	72 hours
Concentration Range	Nominal: 100 mg/L
Auxiliary Solvent	
Water Hardness	Not stated
Analytical Monitoring	Haemocytometer and light microscope.
Remarks - Method	Following a preliminary range finding test, *Scenedesmus subspicatus* was exposed to an aqueous dispersion of the test material at a concentration of 100 mg/L (six replicate flasks) for 72 hours under constant illumination and shaking at temperature of 24±1ºC. Samples of algal population were removed daily and cell concentration determined for each control and treatment group.

Biomass		*Growth*	
E_bC50 (95% CL) mg/L (0-24 h)	*NOEC* mg/L	*E_rC50 (95% CL)* mg/L (0-24 h)	*NOEC* mg/L
> 100	100	> 100	100

Remarks - Results	The data clearly shows that neither the growth nor biomass of *Scenedesmus subspicatus* was affected by the presence of the test material over the 72 hours exposure period.
CONCLUSION	The notified chemical does not reduce biomass or inhibit specific growth of algal cells at 100 mg/L.
TEST FACILITY	SafePharm Laboratories (2003).

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified chemical will not be manufactured in Australia. The notified chemical will be imported and reformulated in Australia to be used as a component (< 1.5% notified chemical) of hair care products. The finished product containing the notified chemical will be sold to end-users (hair salons, retail outlets) Australia-wide. Nearly all of the notified chemical may potentially be disposed of to sewer after use, with only small quantities, including that proportion remaining as residual in containers and major spills, being disposed of to landfill.

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

Process or Dilution Factor	Notified Chemical
Typical notified chemical use expected per day	8.22 kg
Number of day used	365 days
Australian population	20 million people

Water consumed average	200/L/person
STP daily Volume	4000 ML
Concentration in effluent from sewage treatment plant	2.05 µg/L
Predicted environmental concentrations (PECs) in receiving waters	
Ocean (Dilution Factor 1:10)	
PEC	0.21 µg/L
River (Dilution Factor 1:1)	
PEC	2.05 µg/L

The water solubility test results indicate that large proportion of the notified chemical would partition into the water column. However, as it is designed to be a surface active chemical, therefore, it is expected to bind readily to or be associated with soil and sediments.

The potential for bioaccumulation is also low due to the charge stage. However, as it is designed to be a surface active, it can bind to fish, or daphnia skin and/or gills.

9.1.2. Environment – effects assessment

The results of the aquatic toxicity tests are listed below.

Organism	*Duration*	*End Point*	*mg/L*
Fish	96 h	LC_{50}	> 100
Fish		LC_{50}	> 10 - < 18
Daphnia	48 h	LC_{50}	> 180 - < 320
Algae	0-72 h	E_bC_{50}	> 100
		E_uC_{50}	> 100

Using the lowest value of > 10 mg/L and a safety factor of 100 (based on 3 experimental results) for fish/*Daphnia*/algal acute toxicity endpoints, a Predicted No Effect Concentration (PNEC) for aquatic ecosystems of > 0.10 mg/L is estimated.

9.1.3. Environment – risk characterisation

The Risk Quotient PEC/PNEC in marine water is < 1 indicating a low risk to the aquatic environment.

	Location	PEC* µg/L	PNEC µg/L	Risk Quotient (RQ)*
Notified Chemical	Ocean outfall	0.21	> 100	< 0.002
	Inland River	2.05	> 100	< 0.02

*The worst-case PEC and the RQ values calculated assuming the notified chemical is not removed during the wastewater treatment process.

The resulting risk quotient (RQ = PEC/PNEC) values for the aquatic environment, assuming that the chemical is not removed in the communal STP, is less than 1 for marine and freshwater environment indicating no concern.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Formulation

Dermal and possibly ocular exposure to the notified chemical could occur during the transfer of the mixture to the blending vessel. The estimated dermal exposure is 336 mg/day, based on EASE model using reasonable worst case defaults for the exposure scenario 'manual addition of liquids' (European Commission, 2003) and assuming the notified chemical is present at concentration of 80%. Therefore, for a 70 kg worker and a 100% dermal absorption factor,

systemic exposure is estimated to be 4.8 mg/kg bw/day. Exposure would be limited by the use of engineering controls such as pumping equipment and personal protective equipment.

Following formulation of the end use products, exposure to the notified chemical is expected to be very low due to the low concentration of the notified chemical (< 1.5%) and the expected use of PPE.

End use
Workers may be exposed to the notified chemical during final application of the formulated cleaning/cosmetic products or during their addition to water if dilution is required. Although the level and route of exposure will vary depending on the method of application and work practices employed, exposure is considered to be low due to the low concentration of the notified chemical (< 1.5%).

9.2.2. Public health – exposure assessment

Since the notified chemical will be in products sold to the general public, widespread public exposure to the notified chemical at a concentration up to 1.5% is expected. Based on exposure to a range of household, personal care and cosmetic products in Europe (SDA, 2005), public exposure (dermal) to the notified chemical through use of a wide range of products containing the notified chemical, is estimated to be 0.03 mg/kg bw/day, assuming a bodyweight of 60kg, a 100% dermal absorption factor, a concentration of 1.5% and that product usage (amount used per use and frequency of use) is similar in Australia to Europe. This estimate is considered to be an overestimate as it assumes all products (household, personal care and cosmetic) used by one person contain the notified chemical and uses the maximum 'product amount used' from the range in the dataset.

Based on exposure to a range of household, personal care and cosmetic products in Europe (SDA, 2005), maximum single product use exposure is expected for the products: shampoos and hair conditioners. Exposure to the notified chemical in these products assuming a bodyweight of 60kg, a 100% dermal absorption factor, a concentration of 1.5% and that product usage (amount used per use and frequency of use) is similar in Australia to Europe, is as follows:

Shampoos: 0.02 mg/kg bw/day
Hair conditioners: 0.01 mg/kg bw/day

If the notified chemical is used in baby care products, a child's exposure is estimated to be 0.05 mg/kg bw/day assuming a bodyweight of 15kg, a 100% dermal absorption factor, a concentration of 1.5% and that product usage (amount used per use and frequency of use) is similar in Australia to Europe. Since products containing the notified chemical are stored and used in a domestic environment, there is the possibility of accidental ingestion by a child.

9.2.3. Human health – effects assessment

The notified chemical indicated a low acute toxicity profile by oral and dermal route, substantiated by an LD50 of > 2000 mg/kg in rat and LD50 > 9ml/kg bw in rabbit, respectively. The notified chemical is moderately irritating to skin of rabbit and is non-irritating to the rabbit eye. The notified chemical was not a skin sensitiser in the Guinea pig maximisation test. Oral 28-day repeat dose toxicity showed a NOEL of > 200 mg/kg bw/day. The notified chemical was not mutagenic in the Ames test and non-genotoxic in *in vitro* Chinese hamster lung fibroblasts (V79 cells). Analogue data also showed that is was non-mutagenic in *in vitro* genotoxicity studies.

The notified chemical at a concentration of > 80% meets the criteria for classification as a skin irritant, according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

The appropriate risk phrases are:

R38: Irritating to skin

The appropriate safety phrases are:
S37: Wear suitable gloves

9.2.4. Occupational health and safety – risk characterisation

Reasonable worst-case exposure to the notified chemical during formulation was estimated to be 4.8 mg/kg bw/day. Based on a NOAEL of 200 mg/kg bw/day, derived from a 28-day rat oral study the margin of exposure (MOE) is calculated as 42. MOE greater than or equal to 100 are considered acceptable to account for intra- and inter-species differences. As the exposure using reasonable worst case defaults is expected to be an overestimate of exposure (see section 9.2.1), the risk of systemic effects using modeled worker data is acceptable for formulation workers.

Following formulation of the end use products, exposure is expected to be very low and as such the risk to workers is also considered to be low.

9.2.5. Public health – risk characterisation

Based on a NOAEL of 200 mg/kg bw/day, derived from a 28-day rat oral study the margin of exposure (MOE) from a number of exposure scenarios is calculated as follows:

Product(s) used	*Adult/Child*	*Estimated Exposure <mg/kg bw/day>*	*MOE*
Wide range of household, personal care and cosmetic products.	Adult	0.03	7000
Shampoos	Adult	0.02	10000
Hair conditioners	Adult	0.01	20000
Baby care product	Child	0.05	4000

MOE greater than or equal to 100 are considered acceptable to account for intra- and inter-species differences. As the all the calculated MOEs are > 100, the risk to public health is considered to be low.

Since products formulated with the notified chemical will be stored and used in a domestic environment, there is also the possibility for children to be exposed to the notified chemical by accidental ingestion. However, as the notified chemical is considered to be of low acute toxicity and given the low concentration of the notified chemical in the formulated products, the risk of lethal effects as a result of accidental ingestion is considered to be low.

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

10.1. Hazard classification

The notified chemical at a concentration of > 80% meets the criteria for classification as a skin irritant, according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

The appropriate risk phrases are:
R38: Irritating to skin

The appropriate safety phrases are:
S37: Wear suitable gloves

and

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

For skin irritation, the notified chemical should be classified as irritant category 2.

For environmental purposes the notified chemical should be classified as chronic category 3.

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio:

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

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

10.3.2. Public health

There is Negligible Concern to public health when used in the proposed manner.

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 2003). 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 labels for the products containing the notified chemical provided by the notifier were in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC 1994). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- No specific engineering controls, work practices or personal protective equipment are required for the safe use of the notified chemical itself, however, these should be selected on the basis of all ingredients in the formulation. Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.
- A copy of the MSDS should be easily accessible to employees.
- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with

provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified chemical should be disposed of in incinerators or to authorised landfill.

Emergency procedures

- Spills/release of the notified chemical should be handled by physical containment, collection and subsequent disposal by thermal decomposition in an incinerator or to authorised landfill.

12.1. Secondary notification

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

(1) Under Section 64(2) of the Act:
  – if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

13. BIBLIOGRAPHY

CIVO Institutes TNO (1980) Evaluation of Quartamin BTC 131 in the Salmonella/Microsome Mutagenicity test. Final Report October 1980 Study B80/64-21 for DSM, Geleen, Netherlands. CIVO Institutes TNO, Division for nutrition and food research TNO, 3700 AJ zeist, Netherlands (Unpublished report provided by notifier).

CIVO Institutes TNO (1981). Quartamin BTC 131: Acute dermal toxicity in rabbits. CIVO Institutes TNO, Division for nutrition and food research TNO, 3700 AJ zeist, Netherlands (Unpublished report provided by notifier).

CIVO Institutes TNO (1981a). Quartamin BTC 131: Primary skin irritation and eye irritation tests in Albino rabbits. Final Report February 1981. Study for DSM, Geleen, Netherlands. CIVO Institutes TNO, Division for nutrition and food research TNO, 3700 AJ zeist, Netherlands (Unpublished report provided by notifier).

CIVO Institutes TNO (1981b). Sub-acute (4-week) oral toxicity study with Quartamin BTC 131 in rats. Final Report January 1981 Study V 81.035/201722 for DSM, Geleen, Netherlands. CIVO Institutes TNO, Division for nutrition and food research TNO, 3700 AJ zeist, Netherlands (Unpublished report provided by notifier).

Danish EPA (2001) Environmental and Health Assessment of Substances in Household Detergents and Cosmetic Detergent Products. Environment Project No. 615 2001. Miljø-og Energi-ministeriet, Danmark. (http://www.mst.dk/udgiv/publications/2001/87-7944-596-9/pdf/87-7944-597-7.pdf

European Commission (2003) Technical Guidance Document on Risk Assessment in Support of Commission Directive 93/67/EEC on Risk Assessment for New Notified Substances and Commission Regulation (EC) No 1488/94 on Risk Assessment for Existing Substances and Directive 98/8/EC of the European Parliament and of the Council Concerning the Placing of Biocidal Products on the Market – Part I. Institute for Health and Consumer protection, European Chemicals Bureau, European Communities.

HSIS (2006), National Occupational Health and Safety Commission, Hazardous Substances Information System. <http://www.nohsc.gov.au/applications/hsis/>. Accessed 2006 03 February 2006.

Hutingdon Research Centre (1979). Screening test for delayed contact hypersensitivity with Quartamin BTC 131 in the Albino Guinea Pig, Final Report April 1979. Study 10353/D5/79 for Chem-Y, Bodegraven, Holland. Hutingdon Research Centre, Hutingdon, Cambridgeshire England (Unpublished report provided by notifier).

Hutingdon Research Centre (1981). An assessment of DNA repair synthesis in mammalian cells following exposure to Quartamin BTC 131. Final Report March 1981 Study 1/81101 for DSM, Geleen, Netherlands. Hutingdon Research Centre, Hutingdon, Cambridgeshire England (Unpublished report provided by notifier).

Krachtwerktuigen (1991). Closed bottle test for Quartamin BTC 131. Final Report December 1991 Study 91.2026 for Chem-Y Emmerich. Krachtwerktuigen, 3818 HJ Amersfoort – Regentesselaan 2 (Unpublished report provided by notifier).

Krachtwerktuigen (1990). Determination of the acute toxicity of Quartamin BTC 131 to fish with Poecilia reticulata *(Lebistes reticulatus)*. Final Report January 1990 Study 89.1414-V for Chem-Y Emmerich. Krachtwerktuigen, 3818 HJ Amersfoort – Regentesselaan 2 (Unpublished report provided by notifier).

NOHSC (1994) National Code of Practice for the Labelling of Workplace Substances [NOHSC:2012(1994)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (2003) National Code of Practice for the Preparation of Material Safety Data Sheets, 2nd edn [NOHSC:2011(2003)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (2004) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

NOTOX C.V. (1987). Quartamin BTC 131: Acute oral toxicity study in the rat, Final Report October 1987. Study 0682/884 for Chemische Fabrik CHEM-Y GmbH D 4240 EMMERICH F.R.G. NOTOX C.V., 5231 DD's-Hertogenbosch, The Netherlands (Unpublished report provided by notifier).

SafePharm Laboratories Ltd (1993) Acute toxicity to Rainbow Trout. Final Report July 1993 Study 590/11 for Chmische Fabrik Chem-Y Gmbh. SafePharm Laboratories, D-4240 Emmerich 1, Republic of Germany (Unpublished report provided by notifier).

SafePharm Laboratories (2003). Quartamin BTC 131: Algal inhibition test. Final Report September 2003 Study 309/228 for Kao Corporation S.A. Barcelona Spain. SafePharm Laboratories Limited, Shardlow Business Park, Shardlow, Derbyshire, DE72 2GD (Unpublished report provided by notifier).

SDA (2005) Exposure and Risk Screening Methods for Consumer Products Ingredients. Washington, The Soap and Detergent Association.

TNO (1980) The acute toxicity of Quartamin BTC 131 for *Daphnia magna.* Final Report November 1980 Study CL 80/123 for DSM, Geleen, Netherlands. Organisation for Industrial Research, TNO, 2600 AE delft (Unpublished report provided by notifier).

United Nations (2003) Globally Harmonised System of Classification and Labelling of Chemicals (GHS). United Nations Economic Commission for Europe (UN/ECE), New York and Geneva.