Australian Government

Department of Health and Ageing

NICNAS

Complex Soap TH17

Existing Chemical
Secondary Notification Assessment

Draft Report

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Contents

Preface

This assessment was carried out under the National Industrial Chemicals Notification and Assessment Scheme (NICNAS). This Scheme was established by the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act), which came into operation on 17 July 1990.

The principal aim of NICNAS is to aid in the protection of people at work, the public and the environment from the harmful effects of industrial chemicals.

NICNAS assessments are carried out in conjunction with the Australian Government Department of the Environment, Water, Heritage and the Arts, which carries out the environmental assessment for NICNAS.

NICNAS has two major assessment programs: the assessment of human health and safety and environmental effects of new industrial chemicals prior to importation or manufacture; and the other focussing on the assessment of chemicals already in use in Australia, in response to specific concerns about their health/or environmental effects.

Chemicals that have been assessed as new or existing chemicals may require a reassessment of the risk of the chemical under the secondary notification provisions of the Act.

This assessment report has been prepared by the Director of NICNAS, in accordance with the secondary notification provisions of the Act. Under the Act manufacturers/importers of the chemical are required to notify the Director of new information and apply for assessment. New information can include an increase in quantity imported, the commencement of Australian manufacture, increased environmental exposure, and/or additional information becoming available on hazards.

Applicants for assessment are given a draft copy of the report and 28 days to advise the Director of any errors. Following the correction of any errors, the Director provides applicants and other interested parties with a copy of the draft assessment report for consideration. This is a period of public comment lasting for 28 days during which requests for variation of the report may be made. Where variations are requested the Director's decision concerning each request is made available to each respondent and to other interested parties (for a further period of 28 days). Notices in relation to public comment and decisions made appear in the *Commonwealth Chemical Gazette*.

In accordance with the Act, publication of this report revokes the declaration of this chemical for secondary assessment, therefore manufacturers and importers wishing to introduce this chemical in the future need not apply for assessment. However, manufacturers and importers need to be aware of their duty to provide any new information to NICNAS, as required under Section 64 of the Act.

For the purposes of Section 78(1) of the Act, copies of assessment reports for new and existing chemical assessments are freely available from the web (www.nicnas.gov.au). Summary Reports are published in the *Commonwealth Chemical Gazette* (http://www.nicnas.gov.au/publications/#gazette).

Copies of this and other priority existing chemical reports are available on the NICNAS website. Hard copies are available free of charge from NICNAS from the following address:

NICNAS

GPO Box 58, Sydney,

NSW 2001, AUSTRALIA

Tel: +61 (2) 8577 8800

Fax: +61 (2) 8577 8888

Free call: 1800 638 528

Other information about NICNAS (also available on request and on the NICNAS web site) includes:

- NICNAS Service Charter;
- Information sheets on NICNAS Company Registration;
- Information sheets on the Priority Existing Chemicals and New Chemical assessment programs;
- Safety information sheets on chemicals that have been assessed as Priority Existing Chemicals;
- Details for the NICNAS Handbook for Notifiers; and
- Details for the *Commonwealth Chemical Gazette*.

More information on NICNAS can be found at the NICNAS web site:

http://www.nicnas.gov.au

Other information on the management of workplace chemicals can be found at the web site of Safe Work Australia:

http://www.safeworkaustralia.gov.au/swa/

Overview and Recommendations

Overview

Complex Soap TH17 was assessed as STD/1021 under the NICNAS New Chemicals program in 2002 in the standard notification category. As a result of new information, referred to as new data **(ND)** below, relating to physico-chemical and toxicological properties of Complex Soap TH17 becoming available, Complex Soap TH17 has now been reassessed under the secondary notification provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) relevant to existing chemicals, as more than five years have elapsed since the original assessment.

Complex Soap TH17 belongs to the group of Unknown or Variable Composition, Complex Reaction Products or Biological Materials (UVCB). It is a white solid complex barium salt synthesized in, and never separated from an oil base. It is stable under normal conditions and at high temperature. The overall water solubility of the Complex Soap TH17 UVCB is low. Initial assessment of water solubility by visual examination of undissolved particles indicated solubility of less than 1 g/L. Due to the variable composition of the UVCB, different components have different properties related to the water solubility and partition coefficient. Based on measurements of dissolved carbon content (DOC) overall water solubility was determined to be 219 mg DOC/L at 20^{o}C. The n-octanol/water partition coefficient (log Kow) was estimated to vary between 0.9 and 18 for the different components of the UVCB complex. In addition, new data submitted during the secondary notification assessment demonstrate that water extractability of barium ions from the UVCB complex is low.

Partition coefficient was estimated through Quantitative Structure Activity Relationships (QSAR) and indicated that two main components of Complex Soap TH17 will be immobile in soil while one of the major three components is expected to exhibit higher mobility in soil. Estimates of dissociation constant suggest that Complex Soap TH17 is completely dissociated in the environmentally relevant pH range.

Manufacture and importation

Complex Soap TH17 is not manufactured in Australia. It is introduced as a component (<35%) of a variety of ready-to-use grease products and not in its native state.

Importation volume of Complex Soap TH17 has not exceeded 5 tonnes per annum in the past 4 years.

Uses

Importation and use of Complex Soap TH17 is the same as that notified for the original assessment as a new chemical. The grease products containing the Complex Soap TH17 are used for long term and lifelong lubrication of rolling bearings in sealed components in the automotive industry. Since the introduction of Complex Soap TH17 in 2002, sixteen different products are being introduced. Imported products contain <30% of Complex Soap TH17 as notified in the original assessment except one which contains <35% of the chemical.

More than half of the imported Complex Soap TH17 is used in new automotive, machinery and equipment manufacturing sites and the rest is used in repairs and maintenance.

Health effects

Toxicokinetics data were not available for the assessment of Complex Soap TH17 as a new chemical. During the secondary notification assessment new information was provided. In particular, in vitro Caco-2 cells permeability assay was provided as supporting data for assessment of the bioavailability of this chemical via the oral route. The study report contained reporting errors rendering the study unreliable. In addition, the recovery of the test material at different stages of the study was highly variable, probably due to the low water solubility of Complex Soap TH17 in this aqueous based cell system, which contributed further to the low reliability of the study.

Based on the physico-chemical properties of Complex Soap TH17 which indicate low water extractability of the barium ion component of the UVCB, the bioavailability of this component via the oral route is also considered to be low. This is supported by the low acute oral and dermal toxicity of Complex Soap TH17 experimentally determined to be greater than 2000 mg/kg bw. No acute inhalation data are available.

Complex Soap TH17 was only slightly irritating to the eyes in rabbits and had no irritating or sensitising effects when applied dermally in rabbits and guinea pigs.

Repeated oral treatment of Wister rats with Complex Soap TH17 for 28 days caused no significant toxic effects at the mid-dose level of 150 mg/kg bw/d which was determined to be the no-observed-adverse-effect level (NOAEL). At the lowest-observed-adverse-effect level (LOAEL) of 750 mg/kg bw/d (the high dose), signs of toxicity included: decreases in food consumption and bodyweight gains in high-dose male rats, and decreases of the mean relative spleen and adrenal weights in high-dose female rats.

Complex Soap TH17 was negative in bacterial mutation tests and was not clastogenic in a chromosomal aberration study in Chinese hamster V79 cells. The latter study was hampered by poor solubility, so the concentrations tested were lower than usual for this type of test. No other toxicological studies were available.

Complex Soap TH17 was classified as a hazardous substance following the assessment of this chemical as a new chemical in 2002 (NICNAS, 2002). The assessment indicated a likelihood that barium ions from the Complex Soap TH17 may have similar hazardous effects as soluble barium salts, listed on the Hazardous Substances Information System, with the risk phrases R20/22 (Harmful by inhalation and if swallowed).

Based on the data available at the time of the original assessment and the new data provided for the secondary notification, it is established that Complex Soap TH17 has low acute toxicity and the likelihood of systemic exposure to barium ions from Complex Soap TH17 through the oral route is low.

Based on the available data, Complex Soap TH17 is not classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

Occupational exposure and health risk

The risk to occupational health and safety is low based on the low toxicity profile of Complex Soap TH17 and the limited exposure of workers under the conditions of the occupational settings described by the applicant.

Dermal exposure to products containing Complex Soap TH17 is the predominant route of occupational exposure. The likelihood for exposure is highest for workers at maintenance sites and sites manufacturing new machinery for the automotive industry. Exposure of importation and distribution workers is negligible and is only expected in the unlikely event of breached packaging.

Given that Complex Soap TH17 is not a skin irritant or a skin sensitiser, the risk to workers resulting from contact with this chemical is low. However, repeated or prolonged skin contact with lubricant and grease products should be avoided since human experience has shown that prolonged skin contact with lubricant or grease products may cause skin irritation and/or dermatitis (oil acne or folliculitis).

To further minimise the risk of exposure, personal protective equipment such as gloves, eyewear and protective clothing are reported to be worn when the possibility of exposure to drips and spills exists during the processes of preparation, cleaning and maintenance.

Public exposure and health risk

Complex Soap TH17 is intended for industrial use only and will not be available to the Australian public. Given the likely low exposure of the public and the low toxicity profile of Complex Soap TH17, the risk to public health is considered to be negligible.

Environmental effects

Data were available only for a limited set of environmental toxicity endpoints for Complex Soap TH17. This chemical is not toxic to fish, daphnia and micro-organisms up to the limit of its solubility. Low toxicity was observed in a test with algae below the solubility limit.

Data on bioaccumulation are not available, but due to the limited exposure of the aquatic compartment to Complex Soap TH17, bioaccumulation is not expected.

Environmental exposure and risks

Environmental exposure to Complex Soap TH17 is expected to be low as the majority of the grease containing Complex Soap TH17 will be collected and disposed of by incineration. The wastes resulting from spillage and residual lubricant in import container liners and discarded machinery will also be disposed of in landfill.

Although it is not considered to be readily biodegradable, Complex Soap TH17 is expected to biodegrade to a certain extent in landfill. The high octanol-water partition coefficient calculated for Components II and III of the chemical UVCB and the expected low water solubilities, indicate that they will partition to soil and sediment and be immobile in the environment. The third component of the UVCB, Component I, is moderately soluble, has a low partition coefficient and is potentially mobile in soil. However, as a consequence of its anionic nature it is expected to associate with metal ions on the surface of soil and be immobile.

Based on the expected low environmental exposure to Complex Soap TH17 the risk of adverse effects for the environment is considered to be low.

Recommendations

This section provides the recommendations arising from the secondary notification assessment of Complex Soap TH17. Recommendations are directed principally to

importers of Complex Soap TH17. Implicit in these recommendations is that best practice is implemented to minimise occupational and public exposure and environmental impact.

Recommendations to industry

Recommendation related to occupational controls:

- The following safe work practices should be implemented to minimise occupational exposure during handling of products containing the notified chemical:
  - avoid repeated or prolonged dermal exposure.
  - avoid generation of any oil mist or aerosol of the notified chemical.

- The following personal protective equipment should be used by workers to minimise occupational exposure to products containing the notified chemical:
  - gloves
  - safety eyewear, and
  - protective clothing.

- In the case that any oil mist or aerosol of Complex Soap TH17 is generated at workplaces, the Exposure Standards for oil mist (5 mg/m3, TWA) must be applied (NOHSC, 1995).

Secondary Notification

Under Section 65 of the Act, the secondary notification of Complex Soap TH17 may be required where an applicant or other introducer (importer) of Complex Soap TH17, becomes aware of any circumstances that may warrant a reassessment of its hazards and risks. Specific circumstances include:

a. The use of Complex Soap TH17 has changed, or is likely to change significantly.

b. Manufacture of Complex Soap TH17 has begun, or is likely to begin in Australia.

c. Additional information has become available on the adverse health and/or environmental effects of Complex Soap TH17.

The Director must be notified within 28 days of the introducer becoming aware of any of the above circumstances.

Acronyms & Abbreviations

ATM	Apical transport medium
BTM	basolateral transport medium
bw	bodyweight
C	celsius
$CaCO_3$	calcium carbonate
CAS	Chemical Abstracts Service
d	day
DMSO	Dimethyl sulfoxide
DOC	dissolved organic carbon
E_bC50	median effective concentration (biomass)
EC	European Commission
ECB	European Chemicals Bureau
EC50	median effective concentration
E_gC50	median effective concentration (growth)
EU	European Union
g	gram
GI	gastro-intestinal
GLP	Good Laboratory Practice
h	hour
HBSS	Hanks' Balanced Salt Solution
HPLC	High performance liquid chromatography
ICP-MS	Inductively coupled plasma mass spectroscopy
kg	kilogram
Koc	organic carbon absorption coefficient
K_{ow}	octanol/water partition coefficient
L	litre
LC_{50}	median lethal concentration
LD_{50}	median lethal dose
LOAEL	lowest-observed-adverse-effect level

LOEC	lowest- observed-effect concentration
m^3	cubic metre
mg	milligram
mg/cm^3	milligrams per cubic centimetre
mg/kg bw	milligrams per kilogram bodyweight
mg/kg bw/d	mg/kg bodyweight/day
min	minute
mL	millilitre
µg	microgram
µM	micromolar
MSDS	Material Safety Data Sheet
ND	new data
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NOAEL	no-observed-adverse-effect level
NOEC	no-observed-effect concentration
NOHSC	National Occupational Health and Safety Commission
OECD	Organisation for Economic Cooperation and Development
OECD TG	OECD Test Guideline
Pa	Pascals
PEC	Predicted environmental concentration
PNEC	Predicted no effect concentration
QSAR	quantitative structure-activity relationship
$ThODNH_4$	theoretical oxygen demand calculated on the basis of formation of ammonium
$ThODNO_3$	theoretical oxygen demand calculated on the basis of formation of nitrate
US FDA	United States Food and Drug Administration
UVCB	Substances of unknown or variable composition, complex reaction products or biological material
<	less than

1. Introduction

1.1 Background

Complex Soap TH17 was assessed as a new chemical under Section 23 of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) in the standard notification category and is now listed on the Australian Inventory of Chemical Substances (AICS).

The New Chemicals Assessment Report (STD/1021) was published in August 2002. No experimental data were provided for most of the chemical and physical properties of Complex Soap TH17 for the assessment. Variation of the schedule for data requirements was claimed for vapour pressure, water solubility, hydrolysis as function of pH, partition coefficient, adsorption/desorption, dissociation constant, particle size, flash point, explosive properties and reactivity. These endpoints were either estimated based on QSAR or limited experimental data. In addition no toxicological studies were provided for acute inhalation toxicity and chromosome aberration in vivo.

From the data provided at that time, a hazard assessment was conducted and it was determined that the notified chemical (Complex Soap TH17) would not be classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999). However, Complex Soap TH17 was determined to correspond to the group of soluble barium salts, which is listed on the Hazardous Substances Information System with the risk phrases R20/22 (Harmful by inhalation and if swallowed), and was therefore classified as a hazardous substance and assigned the same risk phrases.

Information on the water solubility of Complex Soap TH17 included a very crude protocol of mixing and visual assessment. Water solubility by this method was determined to be less than 1 g/L. Another test, a simplified flask method and analysis of dissolved organic carbon could not provide information about the solubility or extractability of the barium component of Complex Soap TH17.

Readers are referred to the New Chemicals Full Public Report on Complex Soap TH17 available on the NICNAS website:

http://www.nicnas.gov.au/publications/CAR/new/std/stdFULLR/std1000FR/std1021FR.pdf

Recommendations were made relating to safe work practices, use of personal protective equipment and Material Safety Data Sheet (MSDS). These recommendations were based on the intended use of Complex Soap TH17 as a component of lubricating products in the automotive industry.

Complex Soap TH17 was originally assessed for use as a component of a ready-to-use grease for long term and lifelong lubrication of rolling bearings in sealed components. The use pattern remains the same.

In the period between February 2008 and October 2008, additional information with regard to the barium extractability and toxicokinetic properties in vitro was supplied for Complex Soap TH17. The new data warrant reassessment, and as five

years have elapsed since the original assessment, this chemical is now being assessed as an existing chemical under Section 68A of the Act, covering secondary notifications of existing chemicals.

Data submitted for the original assessment on use, exposure, animal and human toxicity are summarised in this report in the relevant sections. Details of the studies provided for assessment as a new chemical are reproduced in Appendix I. New data submitted for this assessment are discussed in detail and identified by the abbreviation **ND**.

1.2 Declaration

Declaration as a secondary notification was initiated when NICNAS received additional information regarding the water extractability of barium from Complex Soap TH17 and an in vitro study of its toxicokinetic properties. These additional data were not available during its assessment as a new chemical. The information includes:

- an English translation and additional information on technical aspects of a test regarding the water extractability of barium (this information is exempt from publication), and
- Caco-2 cells Permeability Assay.

It was considered that a secondary notification for Complex Soap TH17 was required because the additional information provided have relevance to the hazardous nature of the chemical.

A notice was published in the *Chemical Gazette* of 6 January 2009 (Australian Government, 2009) requiring all persons who introduce Complex Soap TH17 into Australia either by manufacture or import, to apply for secondary notification.

1.3 Objectives

The objectives of this assessment were to review the new information made available since the publication of the 2002 New Chemical Assessment Report, and where appropriate, revise the original assessment to:

- characterise the hazards of Complex Soap TH17 to human health;
- characterise potential occupational, and public exposure to Complex Soap TH17;
- characterise the risks of adverse effects resulting from exposure to workers, and the general public; and
- make appropriate recommendations to control exposures and/or reduce potential health risks for workers and the general public.

No new environmental studies or use patterns were reported for Complex Soap TH17. Hence an environmental assessment was not conducted. The environmental assessment conducted for Complex Soap TH17 as a new chemical has been reproduced here.

1.4 International perspective

Complex Soap TH17 was assessed as a new chemical by the German Competent Authority in the EU. The European Chemical Bureau (ECB) Classification and Labelling section confirmed that no labelling is required for Complex Soap TH17 in the EU and that no EU harmonised classification is proposed. **(ND).**

1.5 Peer review

During all stages of preparation, this report has been subject to internal peer review in NICNAS.

1.6 Applicants

Following the Secondary Notification declaration of Complex Soap TH17, one company applied for assessment of this chemical.

In accordance with the *Industrial Chemicals (Notification and Assessment) Act 1989*, NICNAS provided the applicant with a draft copy of the report for comment during the corrections/variations phase of the assessment. The applicant details are as follows:

KLUBER LUBRICATION (KL) AUSTRALIA PTY LTD

1st Floor, 3 Brand Drive

Thomastown, VIC 3074

2. Chemical Identity, Physical and Chemical Properties

2.1 Chemical identity

Name:	Complex Soap TH17
Chemical Name:	Confidential
Marketing name(s):	Complex Soap TH17 Komplex Seife TH17 Isoflex NBU (formulated grease) Isoflex Topas NB (formulated grease) Staburags NBU (formulated grease) Altemp Q NB (formulated grease).
CAS Number:	Confidential
Molecular Formula	Confidential
Molecular Weight:	Confidential
Structural Formula:	Confidential
Degree of purity:	High
Additives/Adjuvants:	Confidential

2.2 Physical and chemical properties

Physical and chemical data previously assessed by NICNAS for the original assessment of Complex Soap TH17 as a new chemical (STD/1021) is reproduced in this report. New information relating to water extractability of barium from Complex Soap TH17 was provided in confidence to NICNAS. The conclusion from the analysis is presented as new data **(ND)** in this section.

Complex Soap TH17 is a three component UVCB barium salt synthesized in, and never separated from, an oil base.

The physical properties of Complex Soap are given in Table 2.1.

Table 2.1 Physical properties of Complex Soap TH17

Property	Value	Method/Comment
Physical state	White solid	
Specific gravity	1219 kg/m^3 at 20°C	EC Directive 92/69/EEC A.3 Relative Density and OECD TG 109, Density of liquids and Solids.
Melting point	270°C (decomposition)	EC Directive 92/69/EEC A.1 Melting Freezing Temperature and OECD TG 102, Melting point/ Melting Range.
Vapour pressure	$< 8 \times 10^{-8}$ Pa at 25°C	Estimated based on the calculated boiling point and using the Modified Watson Correlation.
Water solubility	Extractability of barium from the Complex Soap in water is very low, <10mg/L (**ND**).	
	Water solubility determined by visual assessment was less than 1 g/L.	
	Water solubility determined by measuring Dissolved Organic Carbon (DOC) was determined to be 219 mg DOC/L at 20°C	Based on EEC directive 92/69, Annex V A6 and OECD TG 105 Water Solubility (DOC measurement).
Partition coefficient (Log Kow)	log Pow = 0.9 (Component I) log Pow = 9.2 (Component II) log Pow = 18 (Component III)	OECD TG 117; HPLC; EEC Publication No. 383, A8
Hydrolysis as a Function of pH:	Not determined	Given the low water solubility of the chemical it was not possible to determine its propensity to hydrolyse.
Adsorption/ Desorption	log K_{oc} = 1.9 (Component I) log K_{oc} = 6.3 (Component II) log K_{oc} = 11.2 (Component III)	Estimated based on octanol/water partition coefficients

Dissociation constant (pKa)	pKa = 4.9 (Aliphatic carboxylic acid) pKa = 22.7 (Amide)	Estimated applying a free energy relationship based on Taft and Hammett correlations.
Particle Size	Not determined	The chemical is synthesised in situ in base oils and will not be isolated from the grease.
Flash Point	Not determined	The chemical is estimated to have very low vapour pressure.
Flammability Limits	Not highly flammable	In contact with the ignition source, the chemical glowed and coloured black. However, the test substance could not sustain a burning reaction.
Autoignition Temperature	315^{o}C	92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Surface Tension	70 mN/m at 20^{o}C	OECD TG 115 Surface Tension of Aqueous Solutions, and EC Directive 92/69/EEC A.5 Surface Tension.

Vapour pressure

Estimated vapour pressure of the lowest boiling point component of the chemical mixture was 8 × 10-8 Pa. A boiling point of 331ºC was calculated for the free acid component utilising Meissner's method. The vapour pressure of this component was calculated to be 1 × 10-4 Pa.

Water solubility (ND)

The experimental data provided for the initial assessment did not include information on the solubility of the entire complex substance but only on the organic carbon component.

New data measuring barium cations extracted from water suspension of Complex Soap TH17 sonicated for 15 minutes and stirred for 48h at room temperature demonstrated that the solubility of the barium component of the Complex Soap TH17 is very low, <10mg/L.

Octanol/water partition coefficient

Solubility of Complex Soap TH17 in both water and octanol was so low that experimental determination of the partition coefficient was not possible. Therefore, the partition coefficient was determined by theoretical fragmentation of the molecule according to the Leo-Hansch method.

Dissociation constant

The dissociation constant was estimated based on applying a free energy relationship based on Taft and Hammett correlations. Based on these Complex Soap TH17 is completely dissociated in the environmentally relevant pH range.

Adsorption/desorption

Estimated through Quantitative Structure Activity Relationships (QSAR) using the relationships log10 Koc = 0.544 log Pow + 1.377 (based on partition coefficient). The adsorption/desorption coefficient indicates that components II and III of the chemical will be immobile in soil. However, Component I is expected to exhibit higher mobility in soil.

Explosive properties

The chemical does not contain any chemically unstable or highly energetic groups that might lead to an explosion.

Reactivity

The chemical does not contain any chemical groups that indicate it might act as oxidising agent.

Physical properties of the grease products containing the Complex Soap TH17

The density of the formulated grease products containing <30% of Complex Soap TH17 is in the range of 800 to 990 kg/m^3. The base oil viscosity at 40°C may range from 20 to 130 mm^2/s, and the drop points are between 170 and >240°C.

3. Manufacture and Use

No new information on use patterns was provided during the secondary notification. The use and maximum importation volume of the chemical is as originally notified for assessment as a new chemical and is reproduced here from the new chemical assessment report.

3.1 Manufacture and importation

Complex Soap TH17 is introduced in Australia as a component of a ready-to-use grease packaged in plastic lined 25 kg pails and 180 kg steel drums.

Fifteen different product types are imported with a Complex Soap TH17 content of <30%. This is the same concentration reported for importation of Complex Soap TH17 in the assessment as a new chemical. Only one new product was introduced in significant volume during 2008 with a Complex Soap TH17 content of <35% **(ND)**.

Maximum importation volume of Complex Soap TH17 in all these products has not exceeded five tonnes per annum in the past four years.

3.2 Uses of Complex Soap TH17

Complex Soap TH17 is a component of a ready-to-use grease used for long term and lifelong lubrication of rolling bearings in sealed components.

More than half of the total quantity of imported Complex Soap TH17 is used in new automotive, machinery and equipment manufacturing sites. The greases containing the Complex Soap TH17 are added via automatic metering devices, dip feed devices or centralised lubrication devices in a closed system during the assembly of automotive components or machine and equipment parts.

Maintenance fitters and other mechanics at maintenance workshops use less than half of the imported Complex Soap TH17. They apply the grease manually by brush, spatula, grease gun or grease cartridge to existing machinery.

4. Occupational Exposure

The occupational exposure assessment is reproduced from the new chemical assessment report (NICNAS, 2002).

4.1 Routes of exposure

Dermal contact is expected to be the main route of occupational exposure. Inhalation exposure is expected to be negligible because the product containing Complex Soap TH17 is highly viscous and therefore has reduced potential to generate aerosols. In addition, Complex Soap TH17 has a very low vapour pressure, so vapour accumulation in the workplace air is unlikely. Eye contact is possible but also unlikely due to the highly viscous nature of grease products.

4.2 Sources of occupational exposure

4.2.1 Importation and distribution

The formulated grease products containing <35% of Complex Soap TH17 are imported from overseas and distributed to end users including car and engine manufacturers, mining sites, engineering sites and maintenance workshops. Transport, storage and distribution of the lubricants should involve little exposure to the chemical, except in the case of an accidental spill.

4.2.2 End users

At the automotive, machinery and equipment manufacturing sites, the grease is applied automatically by automatic drip feeding systems and central automated grease delivery systems. Occupational exposure during the automatic operation is expected to be negligible. Possible occupational exposure may occur when opening the containers, adding the grease into storage containers, and during equipment cleaning and maintenance. These operations generally will last for a short period of time, and dermal contamination would be the main route of occupational exposure.

Maintenance fitters and other mechanics at maintenance workshops apply the grease manually by brush, spatula and grease gun. Dermal exposure may occur during these manual operations. However, the exposure is expected to be infrequent (monthly or yearly) and of short duration (<1 hour), as these products are designed to be long term lubricants.

Workers are reported to wear impermeable gloves, protective eyewear, protective clothing, and safety boots when using the grease repeatedly or for prolonged periods.

4.3 Measures and estimates of occupational exposure

In the assessment of occupational exposure, it is preferable to use measured data for each exposure scenario, however, no measured data are available for Complex Soap TH17 from the Australian industry.

The applicant has provided estimates of the categories and number of workers potentially exposed to Complex Soap TH17 at concentration of <35%.

Category of Worker	Number	Exposure Duration	Exposure Frequency
Importer	8-10	2-3 h/day	10-15 days/year
Distributor		2-3 h/day	<50 days/year
Manufacturing worker	<35		
Maintenance worker	<230	<1 h/time	

4.4 Conclusions

Complex Soap TH17 is imported in pails and drums as a component (<35%) of ready-to-use grease. The exposure for importation and distribution workers is negligible except in the event that the packaging is breached.

More than half of the imported Complex Soap TH17 is used at manufacturing sites. Minimal exposure occurs because the systems for applying the grease are generally enclosed and automated. However, the possibility of exposure to drips and spills exists during the processes of preparation, cleaning and maintenance. Dermal exposure would be the predominant route of occupational exposure to workers during these activities.

Fitters or other mechanics at the maintenance sites apply the grease manually to existing machinery by brush, spatula, grease gun or grease cartridge. Dermal exposure may occur. However, the exposure is considered to be of short duration and intermittent.

5. Public Exposure

Lubricants containing the chemical are not available to the public for domestic use, and public exposure through the intended industrial use is negligible. Significant public exposure to Complex Soap TH17 is unlikely, except in the event of an accidental spill during transport. In the event of an accidental spillage, spills would be collected and placed in suitable containers for disposal. All waste materials would be disposed of in accordance with State regulations for the disposal of oil and grease by licensed oil waste and registered waste drum companies, where the product will be either recycled or incinerated.

6. Environmental Exposure

No new data were provided for assessment of the environmental exposure for the secondary notification assessment of Complex Soap TH17. This section contains relevant information from the assessment of Complex Soap TH17 as a new chemical without changes to the content and formatted to the style of the secondary notification report.

The environment is potentially exposed during all stages of a chemical's life cycle. The four stages, which should be considered separately, are as follows:

- Production (not relevant for this assessment as no production occurs in Australia);
- Processing/formulation (not relevant for this assessment as no processing/formulation occurs in Australia);
- Use of ready-for-use products at multiple sites through Australia; and
- Disposal.

Regardless of the environmental media being assessed for exposure, within the exposure assessment there are three main steps, the ultimate one being to derive predicted environmental concentrations (PECs) in relevant environmental media. These steps are:

1. Release estimation;
2. Consideration of environmental fate and partitioning behaviour (distribution); and
3. PEC derivation.

6.1 Sources of environmental exposure

Complex Soap TH17 is used as a component of ready-to-use grease used at industrial sites throughout Australia.

6.1.1 Release from use of ready-to-use formulated products containing Complex Soap TH17

Based on the pattern of use of products, eventually the entire import volume of Complex Soap TH17 is expected to need disposal.

The chemical in wastes resulting from spillage and residual lubricant in import container liners and discarded machinery would be disposed of in landfill. Similarly, the majority of the used grease containing the chemical would be collected and disposed of by incineration.

6.1.2 Release from wastewater, sewerage systems and landfill

As waste, the majority of the import volume is collected and disposed of by incineration, resulting in the formation of water vapour and oxides of carbon and nitrogen and metal salts in the sludge. A small amount is discarded in landfill through the disposal of plastic drum liners and machinery to which the grease containing Complex Soap TH17 has been applied.

6.1.3 Release due to unintentional incidents

Complex Soap TH17 is imported into Melbourne in plastic lined 25 kg pails and 180 kg steel drums by sea. From the applicant's site in Victoria the grease is transported to various industrial sites throughout Australia.

Release of Complex Soap TH17 during importation, transportation and storage is likely only in the case of an accident. However, in such case spills are likely to be collected and placed in suitable containers for disposal. All waste materials are disposed of in accordance with State regulations for the disposal of oil and grease by licensed oil waste and registered waste drum companies where the product is either recycled or incinerated.

6.2 Fate and transformation processes

6.2.1 Fate

Complex Soap TH17 is not considered to be readily biodegradable under the conditions of a Ready Biodegradability Manometric Respirometry Test (OECD TG 301F). However, it is expected to biodegrade to a certain extent in landfill. The high octanol-water partition coefficient calculated for Components II and III of the Complex Soap TH17 UVCB mixture and the expected low water solubilities indicate that they will partition to soil and sediment and be immobile in the environment. The third component of the mixture, Component I, is moderately soluble, has a low partition coefficient and is potentially mobile in soil. However, as a consequence of its anionic nature it is expected to associate with metal ions on the surface of soil and be immobile.

6.2.2 Persistence and bioaccumulation

Data on the bioaccumulation potential of Complex Soap TH17 were not provided for the assessment. Due to low aquatic exposure Complex Soap TH17 is unlikely to bioaccumulate (Connell 1990).

6.3 Conclusions

Complex Soap TH17 is used as a component of ready-to-use grease, and most of it is collected and incinerated, resulting in the formation of water vapour and oxides of carbon and nitrogen. A small amount is discarded in landfill primarily through the disposal of plastic drum liners. Given that it is not readily biodegradable (<20% over 28 days) and its components have relatively high partition coefficients and low water solubility, Complex Soap TH17 would associate with soil and sediment and slowly degrade over time indicating low exposure to organisms in the environment.

7. Human Health Hazard Assessment

This section contains a short summary of the data relevant to the human health hazard assessment of the chemical. Robust summaries of the data available for the assessment of Complex Soap TH17 as a new chemical are reproduced from the New Chemical report in Appendix 1 of this report without any modification. A detailed description of the new data submitted for the secondary notification is included here.

7.1 Toxicokinetics and metabolism (ND)

Data on metabolism and/or kinetics of Complex Soap TH17 were not available for its assessment as a new chemical.

During the secondary notification assessment new information was provided consisting of a Caco-2 cells in vitro intestinal permeability assay as supporting data for assessment of the bioavailability of the chemical via the oral route. This in vitro assay is used for assessment of intestinal permeability of drug substances as a part of the classification of drug substances within the US FDA Biopharmaceutics Classification System (BCS). Under the BCS system a waiver for in vivo testing of the bioavailability of a new drug formulation can be requested for highly soluble and highly permeable substances in formulation which have rapid or similar dissolution rate as a previously tested formulation.

Caco-2 cells permeability assay utilizes a two compartment system separated by polarized human colon carcinoma cell line monolayer which exhibits absorption properties of human intestine. The integrity of the cell monolayers was confirmed before and after the assay. Apical (200 μL) and basolateral (600 μL) transport medium (ATM and BTM) consisted of Hanks' Balanced Salt Solution (HBSS) adjusted to pH 6.5 and pH 7.4, respectively. Propranolol and Ranitidine were used as reference drugs with high and low permeability, respectively.

The test substance, Complex Soap TH17, or the reference drugs (50 μM final each) were added to the ATM for determination of A to B transport or to the BTM for determination of the B to A transport. Cells were incubated for 120 minutes at 37^0C in orbital shakers in an incubator with 5% CO_2 supplemented atmosphere.

The chemicals in the ATM and BTM were measured at 0 and 120 min at the test facility by LC-MS[1] (reference chemicals) or sent to the sponsor (Klüber Lubrication München KG) for analysis of barium concentration by ICP-MS[2] (test chemical). No GLP compliance report for the study was available.

[1] Liquid chromatography-mass spectrometry
[2] Inductively coupled plasma mass spectroscopy

The average recovery of Complex Soap TH17 from pooled samples at the beginning of the assay was about 60%. Low recovery is most likely due to low solubility of the test chemical and possible adsorption to the cells and the plastic surfaces of the culture plate. Recovery was greater than 100% after the shaking incubation for 120 min at 37^0C. No signs of precipitation of the test chemical was noted at any time or any concentration.

Mean apparent permeability (Papp) and the percent of chemical transported through the cell monolayer are presented in the table below. The authors of the study only calculated % transport through the cell monolayer for the test chemical from an experimental run in which recovery at t_0 was ~60%. The results indicate that apparent permeability A to B is lower than that B to A, which is inconsistent with the % of substance transported in the same time interval (A to B more than B to A). Therefore, values were recalculated using raw data in the report by applying a correction for volume difference in the donor and receptor compartments which had apparently not been done before by the authors and resulted in the inconsistency.

Chemical	Mean P_{app} (10^{-6} cm/s)[a]	Mean P_{app} (10^{-6} cm/s)[b]	% transport[a]	% transport[b]
A → B transport				
Propranolol	35.57	35.5	not reported	42.3
Ranitidine	0.68	0.68	not reported	0.84
Complex Soap TH17	0.94	2.7	1.12	3.36
B → A transport				
Propranolol	70.87	70.9	not reported	28.03
Ranitidine	1.60	1.61	not reported	0.63
Complex Soap TH17	1.82	1.82	0.27	0.67

[a] reported values
[b] recalculated values

Overall, intestinal permeability of Complex Soap TH17 as estimated in this in vitro system appears to be low compared to the reference drugs. It is noted that given the low water solubility of Complex Soap TH17, the HBSS buffered Caco-2 cell system may not be optimal for determining its intestinal permeability.

Considering that bioavailability of a substance is determined by its solubility in addition to the intestinal permeability, the bioavailability of Complex Soap TH17 through GI tract is likely to be low.

7.2 Effects on laboratory animals and other test systems

7.2.1 Acute toxicity

Acute toxicity of Complex Soap TH17 was examined in two reliable studies with rats, after oral and dermal exposure. LD50 for both routes of exposure was found to be greater than 2000 mg/kg bw

No acute inhalation study data were submitted.

7.2.2 Irritation and sensitisation

In an eye irritation study with Complex Soap TH17, two rabbits had Draize scores of 1 and one had a score of 2 for conjunctival redness at one hour after treatment. All other scores were zero. Thus, Complex Soap TH17 is considered to be a slight eye irritant.

Complex Soap TH17 was non-irritant to rabbit skin and was negative to guinea-pigs in a skin sensitisation adjuvant test.

7.2.3 Repeat dose toxicity

In a reliable 28-day oral repeat study with rats, decreases in food consumption and bodyweight gains in high-dose (750 mg/kg bw/d) male rats, and decreases of the mean relative spleen and adrenal weights in high-dose female rats were considered to be treatment-related. No significant histopathological changes were observed at any dose. The no-observed-adverse-effect level (NOAEL) was established as the mid-dose of 150 mg/kg bw/d.

7.2.4 Genotoxicity

Complex Soap TH17 was negative in an Ames test and found not to be clastogenic in a chromosomal aberration study in Chinese hamster V79 cells. However, the latter study was hampered by poor solubility, so the concentrations tested were lower than usual for this type of test. No in vivo genotoxicity data were submitted.

7.2.5 Other end points

No studies were provided to allow assessment of the reproductive toxicity and carcinogenic potential of Complex Soap TH17.

7.3 Effects observed in humans

Information with regard to effects in humans was not available for the assessment of Complex Soap TH17 as a new chemical.

The information submitted from the applicant during the secondary notification did not indicate any adverse effects to humans from the use of Complex Soap TH17 in occupational setting.

7.4 Regulatory classifications based on hazard

This section discusses the classification of the health effects of Complex Soap TH17 according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) which provide mandatory criteria for determining whether a workplace chemical is hazardous.

The classification for health effects is based on experimental studies (animal and in vitro tests). The assessment conducted for STD/1021 determined Complex Soap TH17 to be hazardous and classified it as toxic if swallowed and by inhalation (R20/22) based on presumed similarity to barium salts which are listed as toxic if swallowed and by inhalation (R20/22) in the Hazardous Substances Information System (http://hsis.ascc.gov.au/SearchHS.aspx).

The hazard classification based on the overall data, including the new data **(ND)** provided for the Secondary Notification is presented below.

7.4.1 Physicochemical hazards

No physicochemical hazards are indicated for Complex Soap TH17 or the products that contain it which will be imported in Australia. This chemical does not contain any unstable or highly energetic groups that might lead to an explosion. Also it does not contain any chemical groups that indicate it might act as an oxidising agent.

7.4.2. Health hazards

Acute toxicity

Complex Soap TH17 showed low oral and dermal toxicity in acute rat studies performed according to OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method and OECD TG 402 Acute Dermal Toxicity – Limit Test. No acute inhalation study data were submitted. In addition, Complex Soap TH17 has low water solubility and shows low extractability of barium ions in aqueous solution indicating low bioavailability for the chemical and barium ions in the gastrointestinal tract **(ND).**

Classification: Based on the available data, Complex Soap TH17 is not classified as hazardous for acute toxicity under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

7.5 Conclusions

Based on the available data, Complex Soap TH17 is not considered to be hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

8. Environmental Hazard Assessment

This section contains a short summary of the data relevant to the environmental hazard assessment of the chemical. Robust summaries of the data provided for the assessment of Complex Soap TH17 as a new chemical are reproduced in Appendix 1 of this report without any modification.

No new data were provided for assessment of the environmental hazards for the secondary notification assessment.

8.1 Terrestrial organisms

No data were provided relating to terrestrial vertebrates, invertebrates or plants.

8.2 Aquatic organisms

8.2.1 Amphibians

No data are available

8.2.2 Fish

Acute toxicity test with Zebra Fish *Brachydanio rerio* (OECD TG 203) was conducted using the filtrate of a super saturated stock suspension of Complex Soap TH17. No mortalities were observed. A 96-hour EC50 was not determined but the 96-hour NOEC is expected to be greater than the limit of it solubility.

The data indicate that Complex Soap TH17 is not toxic to fish up to the limit of its solubility.

8.2.3 Aquatic invertebrates

Acute Immobilisation Test (OECD TG 202) with Daphnia species *Daphnia magna* was conducted using the filtrate of a super saturated stock suspension of Complex Soap TH17. No effects were observed at 24 or 48 hours. A 48-hour EC50 could not be determined but the 48-hour NOEC is expected to be greater than the limit of its solubility.

The data indicate that Complex Soap TH17 is not toxic to daphnia up to the limit of its solubility.

8.2.4 Algae

Algal growth inhibition test (OECD TG 201) was conducted with *Scenedesmus suspicatus* using the filtrate of a super saturated stock suspension of Complex Soap TH17. After 72 hours, there was no significant inhibition of algal growth and biomass at the nominal concentrations of 6.25, 12.5 and 25 mg/L. At a nominal

concentration of 50 and 100 mg/L both algal growth and biomass were reduced with E_gC50 at 72 h of >100 mg/L and E_bC50 at 72 h of 85.6 mg/L, respectively.

The data indicate that Complex Soap TH17 had some but not significant toxicity to algae below the limit of its solubility.

8.2.5 Microorganisms

Toxicity of Complex Soap TH17 to microbial activity was examined in Activated Sludge, Respiration Inhibition Test (OECD TG 209) using sludge obtained from sewage treatment plant in Germany. After three hours, activated sludge showed differences in respiration of between –8.5 to –18.6% compared to control. The 3-hour EC50 could not be quantified but is expected to be greater than 1000 mg/L.

The data indicate that Complex Soap TH17 is not toxic to activated sludge microorganisms up to 1000 mg/L in suspension.

8.3 Predicted-no-effect concentrations (PNEC)

Complex Soap TH17 is of low toxicity up to the limit of its solubility and no PNEC was calculated.

8.4 Conclusions

Complex Soap TH17 is not toxic to fish, daphnia and micro-organisms up to the limit of its solubility. However, it shows some toxicity to algae below this limit. Bioaccumulation is not expected due to the limited exposure to the aquatic compartment.

9. Human Health Risk Characterisation

9.1 Critical health effects

Complex Soap TH17 shows no significant systemic toxic effects in animals after acute or repeated treatment. This is consistent with low oral and dermal bioavailability of possibly toxic barium ions dissociating from this complex UVCB.

Complex Soap TH17 shows no significant local toxic effects after topical treatment of the skin and eyes of animals.

9.2 Occupational health risk estimates

Dermal exposure would be the predominant route of occupational exposure to Complex Soap TH17. Although the chemical is neither a skin irritant nor a skin sensitiser, repeated or prolonged skin contact with lubricant and grease products should be avoided since human experience has shown that prolonged skin contact with lubricant or grease products may cause skin irritation and/or dermatitis (oil acne or folliculitis).

The health risk for importation and distribution workers is expected to be negligible except in the event that the packaging is breached.

At sites manufacturing new machinery, exposure is likely to be minimal as the systems are enclosed and automated. However, gloves, eyewear and protective clothing are reported to be worn during the processes of preparation, cleaning and maintenance. With the application of personal protective equipment, the risk of adverse health effects at the manufacturing sites is low.

Fitters or other mechanics at maintenance sites apply the grease manually to existing machinery. Adverse skin effects may ensue if dermal contact is repeated or prolonged.

Overall, there is a low concern for occupational health and safety under the conditions of the occupational settings**.**

9.3 Public health risk estimates

Complex Soap TH17 is not available for use by the Australian public as it is only a component in grease intended for industrial use. Given the likely low exposure of the public and the low toxicity profile of Complex Soap TH17, the risk to public health is considered to be negligible.

9.4 Conclusions

The current conditions of use of Complex Soap TH17 in Australia poses no significant risks for public or worker health.

10. Environmental Risk Characterisation

10.1 Critical environmental effects

Complex Soap TH17 is not toxic to fish, daphnia and micro-organisms up to the limit of its solubility. However, it shows some toxicity to algae below this limit. Bioaccumulation is not expected due to the limited exposure to the aquatic compartment.

10.2 Environmental risk estimates

Complex Soap TH17 is used as a component of ready-to-use grease, and most of it is eventually collected and incinerated, which results in the formation of water vapour and oxides of carbon and nitrogen. A small amount is discarded in landfill primarily through the disposal of plastic drum liners. Here, given it is not readily biodegradable (<20% over 28 days), has a relatively high partition coefficients and low water solubility, the chemical would associate with soil and sediment and slowly degrade over time.

The above considerations indicate minimal risk to the environment when Complex Soap TH17 is used in the manner and levels indicated by the notifier.

10.3 Conclusions

On the basis of the available information, the overall risk to the environment from the use of Complex Soap TH17 is low.

Appendix 1

The toxicological assessment of Complex Soap TH17 as a new chemical is reproduced here without modification.

A.1. TOXICOLOGICAL INVESTIGATIONS

A.1.1. Acute toxicity – oral

Test Substance	Komplexseife TH17
Method	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/Wistar
Vehicle	1% carboxymethylcellulose
Remarks - Method	GLP & QA

Results

Group	Number and Sex of Animals	Dose mg/kg bw	Mortality
1	3 males	2 000	0
2	3 females	2 000	0

LD50	> 2 000 mg/kg bw
Signs of Toxicity	None.
Effects in Organs	None.
Remarks - Results	None.
Conclusion	The notified chemical is of low toxicity via the oral route.
Test Facility	Bioservice Scientific Laboratories GmbH (1999a).

A.1.2. Acute toxicity - dermal

Test Substance	Komplexseife TH17
Method	OECD TG 402 Acute Dermal Toxicity – Limit Test. EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal) – Limit Test.
Species/Strain	Rat/Wistar
Vehicle	1% carboxymethylcellulose
Type of dressing	Semi-occlusive.
Remarks - Method	GLP & QA.

Results

Group	Number and Sex of Animals	Dose mg/kg bw	Mortality
1	5/sex	2 000	0

LD50	> 2 000 mg/kg bw
Signs of Toxicity - Local	None.
Signs of Toxicity - Systemic	None.

Effects in Organs	None.
Remarks - Results	No skin irritation observed.
Conclusion	The notified chemical is of low toxicity via the dermal route.
Test Facility	Bioservice Scientific Laboratories GmbH (1999b).

A.1.3. Acute toxicity - inhalation

No toxicity data were submitted.

A.1.4. Irritation – skin

Test Substance	Komplexseife TH17
Method	OECD TG 404 Acute Dermal Irritation/Corrosion. EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	1% carboxymethylcellulose
Observation Period	72 hours
Type of Dressing	Semi-occlusive.
Remarks - Method	GLP & QA.
Results	The Draize scores for erythema/eschar and oedema were zero for all animals throughout the observation period of 72 hours after treatment.
Remarks - Results	No clinical signs of systemic toxicity were found.
Conclusion	The notified chemical is non-irritating to skin.
Test Facility	Bioservice Scientific Laboratories GmbH (1999c).

A.1.5. Irritation - eye

Test Substance	Komplexseife TH17
Method	OECD TG 405 Acute Eye Irritation/Corrosion. EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Observation Period	72 hours
Remarks - Method	GLP & QA.

Results

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

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

Remarks - Results: Conjunctiva discharge was not observed. At 1 hour, the Draize scores of conjunctival redness for the three animals were 1, 2 and 1, respectively.

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

Test Facility: Bioservice Scientific Laboratories GmbH (1999d).

A.1.6. Skin sensitisation

Test Substance: Komplexseife TH17

Method: OECD TG 406 Skin Sensitisation - Adjuvant test.
EC Directive 96/54/EC B.6 Skin Sensitization - Adjuvant test.

Species/Strain: Guinea pig/DH

PRELIMINARY STUDY: Maximum Non-irritating Concentration:
intradermal: not stated.
topical: 100%

MAIN STUDY

Number of Animals: Test Group: 10 Control Group: 5

induction phase: Induction Concentration:
intradermal injection: 25% (highest applicable concentration).
topical application: 100%

Signs of Irritation: None.

CHALLENGE PHASE

1st challenge: topical application: 100%

Remarks - Method: GLP & QA.

Results

Animal	Challenge Concentration	Number of Animals Showing Skin Reactions after: 1st challenge		
		24 h	48 h	72 h
Test Group	100%	0/10	0/10	0/10
Control Group	100%	0/5	0/5	0/5

Remarks - Results: Historic data of positive controls were provided in the report.

Conclusion	There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
Test Facility	Bioservice Scientific Laboratories GmbH (1999e).

A.1.7. Repeat dose toxicity

Test Substance	Komplexseife TH17
Method	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents. EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral).
Species/Strain	Rat/Wistar
Route of Administration	Oral – gavage.
Exposure Information	Total exposure days: 28 days; Dose regimen: 7 days per week;
Vehicle	1% carboxymethylcellulose
Remarks - Method	GLP & QA.

Results

Group	Number and Sex of Animals	Dose mg/kg bw/day	Mortality
I (control)	5/sex	0	0
II (low dose)	5/sex	30	0
III (mid dose)	5/sex	150	0
IV (high dose)	5/sex	750	0

Mortality and Time to Death
None.

Clinical Observations
A dose-dependent decrease in food consumption and bodyweight gains was observed in treated male rats. The reduced food consumption and bodyweight gain reached statistical significance in the high-dose males.

One male in the group III had diarrhoea for one day.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
There were no treatment-related changes in clinical chemistry, haematology and urinalysis tests.

Pathology
No abnormal findings were observed.

Effects in Organs
The mean relative spleen and adrenal values in females of the group IV were significantly lower than corresponding control group. There were no other treatment-related differences in relative and absolute organ weight for both sexes and any of the groups.

Histopathology
Histopathological examination showed that no differences in incidence or severity between control and treatment groups were considered to be of toxicological significance.

Remarks – Results

The following changes were considered to be treatment-related in the study:

- Decreases in food consumption and bodyweight gain in high-dose male rats.
- Decreases of the mean relative spleen and adrenal weights in high-dose female rats.

Conclusion
The No Observed Adverse Effect Level (NOAEL) was established as 150 mg/kg bw/day in this study, based on the decreases of bodyweight gain and food consumption in high-dose male rats and the mean relative spleen and adrenal values in high-dose female rats.

Test Facility Bioservice Scientific Laboratories GmbH (1999f).

A.1.8. Genotoxicity - bacteria

Test Substance Komplexseife TH17

Method OECD TG 471 Bacterial Reverse Mutation Test.
Plate incorporation procedure & Pre incubation procedure

Species/Strain *S. typhimurium*: TA1535, TA1537, TA98, TA100, TA102
Metabolic Activation System S9-mix
Concentration Range in Main Test a) With metabolic activation: 0 - 5 000 µg/plate.
b) Without metabolic activation: 0 – 5 000 µg/plate.
Vehicle DMSO
Remarks - Method GLP & QA.

Experiment I was an incorporation test, and experiment II was a pre-incubation test.

Results

Metabolic Activation	Test Substance Concentration (µg/plate) Resulting in: Cytotoxicity in Preliminary Test	Cytotoxicity in Main Test	Precipitation	Genotoxic Effect
Absent	>5 000		≥1 000	
Test 1		Not seen	≥1 000	Not seen
Test 2		Not seen	≥1 000	Not seen
Present	>5 000		≥1 000	
Test 1		Not seen	≥1 000	Not seen
Test 2		Not seen	≥1 000	Not seen

Remarks - Results No significant increases in revertant colony numbers of any tested strains were observed following treatment with the notified chemical either in the presence or absence of metabolic activation in both incorporation test and pre-incubation test.

The positive controls induced a distinct increase of induced revertant colonies.

Conclusion The notified chemical was not mutagenic to bacteria under the conditions of the test.

Test Facility Bioservice Scientific Laboratories GmbH (1999g).

A.1.9. Genotoxicity – in vitro

Test Substance	Komplexseife TH17
Method	OECD TG 473 In vitro Mammalian Chromosomal Aberration Test.
Cell Type/Cell Line	Chinese hamster V79 cells
Metabolic Activation System	S-9 mix
Vehicle	DMSO
Remarks - Method	GLP & QA.

Metabolic Activation	Test Substance Concentration (µg/mL)	Exposure Period	Harvest Time
Absent			
Test 1	0, 5*, 50* and 100*	4 h	20 h
Test 2	0, 5*, 50* and 100*	20 h	20 h
Present			
Test 1	0, 5*, 50* and 100*	4 h	20 h

*Cultures selected for metaphase analysis.

Results

Metabolic Activation	Test Substance Concentration (µg/mL) Resulting in: Cytotoxicity in PreliminaryTest	Cytotoxicity in Main Test	Precipitation	Genotoxic Effect
Absent				
Test 1		Not seen	≥5	Not seen
Test 2		Not seen	≥5	Not seen
Present				
Test 1		Not seen	≥5	Not seen

Remarks - Results

The notified chemical did not increase the frequency of aberration in Chinese V79 cells in the presence and absence of metabolic activation.

The positive controls induced a significant increase of cells with structural chromosome aberrations above test laboratory's historic control level.

The study was hampered by the low solubility of the test substance in DMSO and the culture medium.

Conclusion

The notified chemical was not clastogenic to Chinese hamster V79 treated in vitro under the conditions of the test.

Test Facility

Bioservice Scientific Laboratories GmbH (1999h).

A.2. ENVIRONMENT

A.2.1. Environmental fate

A.2.1.1. Ready biodegradability

Test Substance	Complex Soap TH17
Method	OECD TG 301 F Ready Biodegradability: Manometric Respirometry Test.
Exposure Period	28 days
Remarks - Method	Activated sludge was mixed with the test substance to give final concentration of 20 mg/L and with the standard material, aniline at a concentration of 25.3 mg/L. The study was carried out in darkness at 22°C.

Results

Test substance		Aniline	
Day	**Mean % degradation**	**Day**	**% degradation**
14	18.5	14	72.0
28	16.8	28	96.0

Remarks - Results	The aniline standard attained 96% biodegradation after 28 days, indicating the test conditions were valid. After 28 days, the mean biodegradation of the test substance based on $ThODNH_4$ was 16.8% and based on $ThODNO_3$ was 16.2%. Results from the toxicity control indicate that the notified chemical does not have an inhibitory effect on activated sludge micro-organisms.
Conclusion	The notified chemical is not considered to be readily biodegradable under the conditions of OECD TG 301F.
Test Facility	Institut Für Biologische Analytik und Consulting IBACON GmbH (1999i).

A.2.1.2. Bioaccumulation

Data on the bioaccumulation potential of the notified chemical were not provided for this notification. Due to low aquatic exposure the notified chemical it is unlikely to bioaccumulate (Connell 1990).

A.2.2. Ecotoxicological investigations

A.2.2.1. Acute toxicity to fish

Test Substance	Complex Soap TH17

Method	OECD TG 203 Fish, Acute Toxicity Test
Species	Zebra Fish (*Brachydanio rerio*)
Exposure Period	96 h
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	Test solutions were not measured.

Results

Concentration mg/L Nominal	Number of Fish	Mortality 2 h	24 h	48 h	72 h	96 h
0	7	0	0	0	0	0
100	7	0	0	0	0	0

LC50	Not determined
NOEC (or LOEC)	Not determined
Remarks – Results	The definitive studies were conducted on the filtrate of a super saturated stock suspension of the notified chemical at a nominal concentration of 100 mg/L. The results of the definitive study showed that no mortalities were observed at this test substance concentration. A 96-hour EC_{50} for the notified chemical to *Brachydanio rerio* was not determined but the 96 h NOEC is expected to be greater than the limit of it solubility.
Conclusion	The ecotoxicity data indicates the notified chemical is not toxic to fish up to the limit of its solubility.
Test Facility	Institut Für Biologische Analytik und Consulting IBACON GmbH (1999j).

A.2.2.2. Acute/chronic toxicity to aquatic invertebrates [Delete as appropriate]

Test Substance	Complex Soap TH17
Method	OECD TG 202 Daphnia sp. Acute Immobilisation Test
Species	*Daphnia magna*
Exposure Period	48 hours
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	Test solutions were not measured.

Results

Concentration mg/L Nominal	Number of *D. magna*	Number Immobilised 24 h	48 h
0	20	0	0
100	20	0	0

LC50	Not determined
NOEC (or LOEC)	Not determined
Remarks - Results	The definitive studies were conducted on the filtrate of a super saturated stock suspension of the notified chemical at a nominal concentration of 100 mg/L. The immobilisation tests with daphnia were performed in duplicate using 10 daphnids per flask with observations performed at 24 and 48 hours. A 48-hour EC_{50} for the notified chemical to *Daphnia magna* was not determined but the 48 h NOEC is expected to be greater than the limit of it solubility.

Conclusion	The ecotoxicity data indicates the notified chemical is not toxic to daphnia up to the limit of its solubility.
Test Facility	Institut Für Biologische Analytik und Consulting IBACON GmbH (1999k).

A.2.2.3. Algal growth inhibition test

Test Substance	Complex Soap TH17
Method	OECD TG 201 Alga, Growth Inhibition Test.
Species	*Scenedesmus suspicatus*
Exposure Period	72 hours
Concentration Range Nominal	6.25, 12.5, 25, 50 and 100 mg/L
Water Hardness	24 mg $CaCO_3$/L
Analytical Monitoring	Test solutions were not measured

Results

Biomass		**Growth**	
E_bC50 (mg/L at 72 h)	**NOEC (mg/L)**	**E_rC50 (mg/L at 72 h)**	**NOEC (mg/L)**
85.6	50	> 100	25

Remarks - Results	Algae were exposed to the filtrate of a super saturated stock suspension of the notified chemical at a nominal concentration of 100 mg/L under constant illumination and shaking. After 72 h, there was no significant inhibition of algal growth and biomass at the nominal concentrations of 6.25, 12.5 and 25 mg/L. At a nominal concentration of 50 and 100 mg/L both algal growth and biomass were significantly reduced.
Conclusion	The ecotoxicity data indicates the notified chemical shows some toxicity to algae below the limit of its solubility.
Test Facility	Institut Für Biologische Analytik und Consulting IBACON GmbH (1999l).

A.2.2.4. Inhibition of microbial activity

Test Substance	Complex Soap TH17
Method	OECD TG 209 Activated Sludge, Respiration Inhibition Test.
Inoculum	Activated sludge
Exposure Period	3 hours
Concentration Range Nominal	10, 32, 100, 320, 1000 mg/L
Results	The activated sludge study was conducted using sludge obtained from sewage treatment plant in Groβ-Zimmern, Germany. The definitive study was conducted on nominal concentrations of 10, 32, 100, 320 and 1000 mg/L. Amounts of test material (5, 16, 50, 160 and 500 mg) were added to water (284 mL) and sewerage (16 mL) and samples were stirred continuously. The reference material used in the study was 3,5-dichlorophenol. When compared to the control, activated sludge after 3 h experienced differences in respiration of between –8.5 to –18.6%. The 3-hour EC_{50} for the notified substance to activated sludge could not be quantified. However, the 3-hour EC_{50} for the notified substance to

	activated sludge is expected to be greater than 1000 mg/L. The EC50 of the reference substance was 9 mg/L, therefore confirming the suitability of the activated sludge.
EC50	> 1000 mg/L
NOEC	Not determined
Conclusion	The ecotoxicity data indicates the notified chemical is not toxic to activated sludge up to 1000 mg/L in suspension.
Test Facility	Institut Für Biologische Analytik und Consulting IBACON GmbH (1999m).

Glossary

NICNAS uses the IPCS Risk Assessment Terminology (WHO, 2004) glossary which includes Part 1: IPCS/OECD Key Generic Terms used in Chemical Hazard/Risk Assessment and Part 2: IPCS Glossary of Key Exposure Assessment Terminology. The IPCS Risk Assessment Terminology can be accessed at http://www.who.int/ipcs/methods/harmonization/areas/ipcsterminologyparts1and2.pdf

Adverse effect	Change in the morphology, physiology, growth, development, reproduction, or life span of an organism, system or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress, or an increase in susceptibility to other influences.
Assessment	Evaluation of appraisal of an analysis of facts and the inference of possible consequences concerning a particular object or process.
Assessment endpoint	Quantitative/qualitative expression of a specific factor with which a risk may be associated as determined through an appropriate risk assessment.
Chronic exposure	A continuous or intermittent long-term contact between an agent and a target. (Other terms, such as “long-term exposure,” are also used.)
Concentration	Amount of a material or agent dissolved or contained in unit quantity in a given medium or system.
Dose	Total amount of an agent administered to, taken up or absorbed by an organism, system or (sub) population.
Dose-effect relationship	Relationship between the total amount of an agent administered to, taken up or absorbed by an organism, system or (sub) population and the magnitude of a continuously-graded effect to that organism, system or (sub)population Related terms: *Effect Assessment, Dose-Response Relationship, Concentration-Effect Relationship*.
Dose rate	Dose per unit time

Dose-related effect	Any effect to an organism, system or (sub) population as a result of the quantity of an agent administered to, taken up or absorbed by that organism, system or (sub) population.
Dose-response	Relationship between the amount of an agent administered to, taken up or absorbed by an organism, system or (sub) population and the change developed in that organism, system or (sub) population in reaction to the agent. Synonymous with Dose-response relationship. Related Term: *Dose-Effect Relationship, Effect Assessment, Concentration-Effect Relationship*.
Dose-response curve	Graphical presentation of a dose-response relationship.
Dose-response relationship	Relationship between the amount of an agent administered to, taken up or absorbed by an organism, system or (sub) population and the change developed in that organism, system or (sub) population in reaction to the agent. Related Terms: *Dose-Effect Relationship, Effect Assessment, Concentration-Effect Relationship*.
Effect	Change in the state or dynamics of an organism, system or (sub) population caused by the exposure to an agent.
Exposure	Concentration or amount of a particular agent that reaches a target organism, system or (sub) population in a specific frequency for a defined duration.
Exposure assessment	Evaluation of the exposure of an organism, system or (sub) population to an agent (and its derivatives). Exposure Assessment is the third step in the process of Risk Assessment.
Exposure concentration	The exposure mass divided by the contact volume or the exposure mass divided by the mass of contact volume depending on the medium.
Exposure duration	The length of time over which continuous or intermittent contacts occur between an agent and a target. For example, if an individual is in contact with an agent for 10 minutes a day, for 300 days over a one-year time period, the exposure duration is one year.

Exposure period	The time of continuous contact between an agent and a target.
Exposure route	The way an agent enters a target after contact (*e.g.*, by ingestion, inhalation, or dermal absorption).
Exposure scenario	A set of conditions or assumptions about sources, exposure pathways, amount or concentrations of agent(s)involved, and exposed organism, system or (sub) population (i.e. numbers, characteristics, habits) used to aid in the evaluation and quantification of exposure(s) in a given situation.
Fate	Pattern of distribution of an agent, its derivatives or metabolites in an organism, system, compartment or (sub) population of concern as a result of transport, partitioning, transformation or degradation.
Hazard	Inherent property of an agent or situation having the potential to cause adverse effects when an organism, system or (sub) population is exposed to that agent.
Hazard assessment	A process designed to determine the possible adverse effects of an agent or situation to which an organism, system or (sub) population could be exposed. The process includes hazard identification and hazard characterization. The process focuses on the hazard in contrast to risk assessment where exposure assessment is a distinct additional step.
Hazard characterization	The qualitative and, wherever possible, quantitative description of the inherent properties of an agent or situation having the potential to cause adverse effects. This should, where possible, include a dose-response assessment and its attendant uncertainties. Hazard Characterisation is the second stage in the process of Hazard Assessment, and the second step in Risk Assessment. Related terms: *Dose-Effect Relationship, Effect Assessment, Dose-Response* *Relationship, Concentration -Effect Relationship.*
Hazard identification	The identification of the type and nature of adverse effects that an agent has inherent capacity to cause in an organism, system or (sub) population. Hazard identification is the first stage in hazard assessment and the first

	step in process of Risk Assessment
Intake	The process by which an agent crosses an outer exposure surface of a target without passing an absorption barrier, i.e. through ingestion or inhalation.
Margin of exposure	Ratio of the no-observed-adverse-effect level (NOAEL) for the critical effect to the theoretical, predicted or estimated exposure dose or concentration. Related term: *Margin of Safety*
Risk assessment	A process intended to calculate or estimate the risk to a given target organism, system or (sub)population , including the identification of attendant uncertainties, following exposure to a particular agent, taking into account the inherent characteristics of the agent of concern as well as the characteristics of the specific target system. The Risk Assessment process includes four steps: hazard identification, hazard characterization (related term: dose-response assessment), exposure assessment, and risk characterization. It is the first component in a risk analysis process.
Risk characterization	The qualitative and, wherever possible, quantitative determination, including attendant uncertainties, of the probability of occurrence of known and potential adverse effects of an agent in a given organism, system or (sub)population, under defined exposure conditions. Risk Characterization is the fourth step in the Risk Assessment process.
Risk management	Decision-making process involving considerations of political, social, economic, and technical factors with relevant risk assessment information relating to a hazard so as to develop, analyse, and compare regulatory and non-regulatory options and to select and implement appropriate regulatory response to that hazard. Risk management comprises three elements: risk evaluation; emission and exposure control; risk monitoring.
Source	The origin of an agent for the purposes of an exposure assessment.
Target	Any biological entity that receives an exposure or a dose (e.g., a human, human population or a human organ).

Threshold	Dose or exposure concentration of an agent below that a stated effect is not observed or expected to occur.
Time-averaged exposure	The time-integrated exposure divided by the exposure duration. An example is the daily average exposure of an individual to carbon monoxide. (Also called time-weighted average exposure.)
Toxicity	Inherent property of an agent to cause an adverse biological effect.
Uptake (absorption)	The process by which an agent crosses an absorption barrier.

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