



Australian Government
Department of Health and Ageing
NICNAS

Complex Soap TH17

*Existing Chemical
Secondary Notification Assessment*

Draft Overview and Recommendations

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°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 Wistar 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).