

## Existing Chemicals Information Sheet

### AMMONIUM LAURYL SULFATE

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CAS No. 2235-54-3

#### General

Ammonium lauryl sulfate (ALS) is an anionic surfactant. By lowering the surface tension of aqueous solutions, surfactants can act as wetting agents by enhancing the spread of water over surfaces.

#### Background

The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) undertook a limited literature search of the available data on the human health effects of sodium lauryl sulfate (SLS). This is an existing chemicals information sheet on the structurally related chemical ALS. It should be noted that a full independent hazard assessment on SLS has not been conducted by NICNAS. The data presented here are from secondary sources and though creditable publications, original publications have not been obtained and it has therefore not been possible to determine the robustness of the reported studies.

#### Data Sources

Data was obtained from the following sources:

1. Cosmetic Ingredient Review (CIR) (1983)
2. International Cosmetic Ingredient Dictionary and Handbook (1997)

#### Identity

Information on identity was obtained from the International Cosmetic Ingredient Dictionary and Handbook, (1997).

There are a large number of synonyms for ALS available in the literature. Those most frequently cited are provided in Table 1.

*Table 1* Frequently cited synonyms for ammonium lauryl sulfate

	<b>Ammonium lauryl sulfate</b>
<b>Commonly used synonyms</b>	Dodecyl ammonium sulfate Sulfuric acid, monododecyl ester, ammonium salt
<b>Structural Formula</b>	$\text{CH}_3\text{-(CH}_2\text{)}_{10}\text{-CH}_2\text{OSO}_3\text{NH}_4$

## Import, Manufacture and Use

Surfactants such as ALS are generally used as surface-active agents for their wetting, foaming, dispersing and emulsifying properties.

Over 100 tonnes per annum of ALS are imported into Australia for use in the manufacture of consumer products such as detergents. ALS is also used as a component of cosmetic and toiletry formulations. Therefore, consumer use of these products would be expected to result in dermal contact.

## Current Regulatory status of Ammonium Lauryl Sulfate in Australia

ALS is **NOT** listed in:

- National Occupational Health and Safety Commission (NOHSC) (1995) *Exposure Standards for Atmospheric Contaminants in the Occupational Environment*
- the NOHSC (1999) *List of Designated Hazardous Substances*
- the National Drugs and Poisons Schedule Committee (September 2003) *Standard for the Uniform Scheduling of Drugs and Poisons*

However, any manufacturer or importer who supplies ALS for use at work is responsible for determining whether it is a hazardous substance in accordance with the National Occupational Health and Safety Commission's *Approved Criteria for Classifying Hazardous Substances*. If hazardous, the manufacturer or importer has a responsibility to classify and label the substance appropriately.

## Data Sources for Human Health Effects

Information on ALS and its formulations was sourced from a CIR report (1983). Established in 1976 by the US-based Cosmetic, Toiletry and Fragrance Association (CTFA) with support from the US Food and Drug Administration and the Consumer Federation of America, the CIR reviews and assesses the safety of ingredients used in cosmetics. Although funded by CTFA, CIR and the review process are independent from CTFA and the cosmetic industry, and the results are published in the open peer-reviewed scientific literature. The CIR report contains several studies, of varying quality, for most human health endpoints. An overview of the data for human health effects is presented below, based on those study summaries adjudged the most robustly reported and/or with methodology most comparable to the appropriate OECD Test Guideline.

## Health and Safety Information on the Chemical

ALS showed low acute oral toxicity in the rat (LD50 value 4700 mg/kg/bw) but is a skin and eye irritant in rabbits. Data on skin sensitisation, chronic exposure, genotoxicity, carcinogenicity and reproductive toxicity are not available.

## Health and Safety Information on Formulations Containing Ammonium Lauryl Sulfate

Information on formulations containing ALS ranging from 0.11 to 15% is available from studies for acute oral toxicity, skin and eye irritation and repeat dermal toxicity in animals, along with skin and eye irritation, and skin sensitisation clinical studies in humans. Together, these data support the findings on ALS that the chemical is of low acute oral toxicity,

and an irritant to the skin and eye in both animals and humans. Data in humans indicate ALS is not a skin sensitiser. In the repeat dermal study in rabbits, 1.75% ALS resulted in skin effects at the site of application but no deaths, reductions in body weight gain, nor treatment related haematology nor histopathology changes (i.e. no systemic toxicity).

### **Human Experience**

The CIR report (1983) contained information on submissions for shampoos containing ALS. It was reported that for shampoo products containing 23%, 25%, 29.2% and 30.9% ALS, with a total combined sales of 6 814 217 units per annum in the USA, there were only 6 safety-related complaints. They included two complaints each of itchy scalp and allergy, and an instance each of damage to hair and eye irritation.

### **Outcome of CIR report (1983)**

The CIR (1983) concluded, “[SLS and] ALS appear to be safe in [cosmetic] formulations designed for discontinuous, brief use followed by thorough rinsing from the surface of the skin. In products intended for prolonged contact with skin, concentrations should not exceed 1%.”

Overall, there are no data in the CIR report (1983) on ALS and its formulations that indicate ALS to be a skin sensitiser, genotoxic, carcinogenic, or a reproductive toxicant. The toxicity of ALS appears to be restricted to skin and eye irritation. Indeed, for chronic toxicity, a dermal study in the rabbit indicates that the primary health effect of ALS appears to be local irritation. However, these health effects are primarily based on the effects of ALS at high doses in studies in laboratory animals. The risk to humans from ALS will depend on the amount of exposure to the chemical. The amounts of ALS used in cosmetics, and hence the potential human exposure, is significantly smaller than that used in animal studies. Consequently, considering the human health effects associated with ALS and potential extensive use in consumer areas, it appears that for consumers and workers, the human health hazards are low.

### **References**

1. Cosmetic Ingredient Review (1983) Final report on the safety assessment of sodium lauryl sulfate and ammonium lauryl sulfate. Journal of the American College of Toxicology. Vol:2(7).
2. The Cosmetic, Toiletry, and Fragrance Association (1997) International Cosmetic Ingredient Dictionary and Handbook, Washington DC, Ed Wenninger J.A and McEwan G.N.
3. National Drugs and Poisons Schedule Committee (2003) Standard for the Uniform Scheduling of Drugs and Poisons, Canberra, ACT, Australian Government Publishing Service.
4. NOHSC (1995) Exposure Standards for Atmospheric Contaminants in the Occupational Environment. Canberra, ACT, Australian Government Publishing Service.
5. NOHSC (1999) List of Designated Hazardous Substances. Sydney, NSW, National Occupational Health and Safety Commission.