# Existing Chemicals Information Sheet

## SODIUM LAURYL SULFATE

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Chemical Abstract Service (CAS) Number: 151-21-3

### General

Sodium lauryl sulfate (SLS) 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) has received a large number of enquiries regarding concern over data on the internet claiming SLS is hazardous to human health. In response to this concern, NICNAS undertook a literature search of the available data on the human health effects of SLS to prepare this existing chemical information sheet. 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. IPCS (International Programme of Chemical Safety) (1997) International Chemical Safety Card
2. Cosmetic Ingredient Review (CIR), 1983
3. OECD (Organisation for Economic Co-operation and Development) (1997) Screening Information Data Set (SIDS) Initial Assessment
4. Hazardous Substances Data Bank (HSDB)
5. International Cosmetic Ingredient Dictionary and Handbook (1997)

### Identity

Information on identity was obtained from the OECD SIDS Initial Assessment Report (SIAR) (1997) and the International Cosmetic Ingredient Dictionary and Handbook (1997).

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

*Table 1* **Frequently cited synonyms for sodium lauryl sulfate**

| | **Sodium lauryl sulfate** |
|---|---|
| **Commonly used synonyms** | Sodium dodecyl sulfate<br>SDS<br>Sulfuric acid, monododecyl ester, sodium salt<br>Lauryl sodium sulfate<br>Sodium N-dodecyl sulfate<br>Lauryl sulfate sodium salt |
| **Structural Formula** | $CH_3$-$(CH_2)_{11}$-O-$SO_3^-Na^+$ |

**Import, Manufacture and Use**

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

SLS has not been reported for listing on the NICNAS High Volume Industrial Chemicals List, a list compiled with industry of industrial chemicals that are manufactured and/or imported in Australia in volumes ≥1000 tonnes/year. However, data obtained from the Hazardous Substances Data Bank (HSDB) indicate the potential for widespread consumer exposure to SLS.

The major uses of SLS listed in HSDB are as a surface-active agent for emulsion polymerisation, in metal processing, detergents and shampoo; emulsifying, foaming, wetting, dispersing agent in creams, lotion and medical preparations; foaming, wetting, and dispersing agent in toothpaste, and emulsifier, whipping agent and surfactant in foods. Some specific examples of SLS use reported are in the preparation of blood samples for red blood cell counts, the electrophoretic separation and molecular weight estimation of proteins, the preparation of sample for dietary fibre content, the characterisation of quaternary ammonium compounds, the electroplating industry (nickel and zinc), and the formulation of injection-moulded explosives. SLS is also reportedly used as a cleansing agent in cosmetics; a whipping aid in dried egg products; food additive (emulsifier and thickener); emulsifier, wetting agent and adjuvant in insecticides; emulsifier and penetrant in varnish and paint remover; anti-foaming agent in solid rocket propellants; model surfactant and reference toxicant in aquatic and mammalian toxicological testing.

The inclusion of SLS as a cleansing agent in cosmetics means that consumer use of these products may result in contact with the general body surface, hair, nails, skin of the hand and face and mucosal surface.

**Current Regulatory Status of Sodium Lauryl Sulfate in Australia**

SLS is **NOT** listed in:

- the National Drugs and Poisons Schedule Committee (September 2002) *Standard for the Uniform Scheduling of Drugs and Poisons*
- the 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*

However, any manufacturer or importer who supplies SLS 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 SLS was sourced primarily from the OECD SIAR (1997). The SIDS program is a voluntary cooperative international testing program that began in 1989, operating under the auspices of the chemicals program within the Environment Health and Safety Division of the OECD. The program focuses on developing base level test information on approximately 600 poorly characterised international High Production Volume (HPV) chemicals. Data are used to "screen" the chemicals and set priorities for further testing or risk assessment/management activities. A HPV chemical is one with a production volume ≥1000 tonnes/year in the EU and 10 000 pounds/year in the US. SLS is deemed a HPV chemical in both the EU and US.

Information on SLS and its formulations is also available 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 numerous studies, of varying quality, for most human health endpoints, and has been used to provide data on those health effects not evaluated in the OECD SIAR (1997).

An overview of the data for human health effects is presented below, based on those study summaries in the OECD (1997) and CIR (1983) reports adjudged the most robustly reported and/or with methodology most comparable to the appropriate OECD Test Guideline. Additionally, a statement on the respiratory irritation of SLS, an endpoint not covered in either the OECD (1997) or CIR (1983) reports, obtained from the International Chemical Safety Card (1997) is included.

**Health and Safety Information on the Chemical**

*Acute Toxicity*

Acute toxicity data in the rat show that SLS is harmful by the oral route ($LD_{50}$ 1200 mg/kg bw), and data in the rabbit and guinea pig show it is harmful by the dermal route ($LD_{50}$ = ~600 mg/kg bw and >1200 mg/kg bw respectively).

*Irritation*

SLS is a skin and eye irritant in rabbits, and skin irritation has been observed in clinical studies in humans. Indeed in the human 4-hour patch test for irritation, SLS is used at 20% as a positive control to identify substances or preparations that would be on the borderline

for classification as irritant. SLS is also reported to irritate the respiratory tract.

*Sensitisation*
No data on skin sensitisation is available in these reviews. However, since OECD Test Guideline methodology for guinea pig skin sensitization predictive tests requires application of 10% SLS at induction to create local irritation for those test materials with no skin irritation potential, it is highly unlikely that SLS is a skin sensitiser as this could create concerns over potential cross sensitisation reactions at challenge with the test material.

*Effects from Repeated Exposure*
Oral (gavage) repeat exposure studies in rats showed the primary effect of SLS to be local irritation of the gastro-intestinal tract, with no effects seen at the 100 mg/kg bw/day dose level.

*Genotoxicity*
SLS was negative in an Ames (bacterial mutation) test, a gene mutation and sister chromatid exchange test in mammalian cells, as well as in an in vivo micronucleus assay in mice. The negative results from in vitro and in vivo studies indicate SLS does not interact with DNA.

*Carcinogenicity*
In the only carcinogenicity study available, SLS was not carcinogenic in Beagle dogs, though the short study duration and limited details provided limit the significance that can be attached to the data.

*Reproductive Toxicity*
No effect on fertility was seen in a study in male mice administered 100 mg/kg bw/day SLS, or on epididymal sperm in male mice administered SLS at a dose producing systemic toxicity: 1000 mg/kg bw/day. In developmental toxicity studies in the mouse and rabbit using doses of 0.2 to 600 mg/kg bw/day, total resorption of foetuses, increased litter loss and/or abortion were seen at 600 mg/kg bw/day in the presence of severe maternal toxicity. At 300 mg/kg bw/day no developmental toxicity was seen, though slight to moderate maternal toxicity was observed. Therefore, SLS is not considered a developmental toxicant, as the developmental effects seen were a secondary non-specific consequence of severe maternal toxicity.

**Health and Safety Information on Formulations Containing Sodium Lauryl Sulfate**
Information on formulations containing SLS at final tested concentrations ranging from 0.21 to 26% is available from studies for acute oral toxicity, and skin and eye irritation in animals, along with skin irritation and sensitisation clinical studies in humans. Together, these data support the findings on SLS that the chemical is of moderate acute oral toxicity, and irritant to the skin and eye in both animals and humans. Data in humans indicate SLS is not a skin sensitiser.

**Human Experience**
The CIR report (1983) contained cosmetic experience submissions for shampoos containing SLS. These data are presented in Table 2.

*Table 2* **Product use and safety-related complaints for SLS formulations**

| % SLS present in shampoo | Sales of shampoo per annum in the USA | Total number of applications of shampoo per annum in USA | Number of safety-related complaints |
|---|---|---|---|
| 10 | 390 000 units | 8 580 000 | No complaints received in 2 years |
| 14.5 | Not reported | 200 000* | A total of 17 complaints over 7 years |
| 30 | 398 000 units | 4 852 620 | One complaint received in 2 years; an allergic/ irritant reaction |

*It was reported that the cumulative total number of uses of the shampoo was 400 000 000.

**Outcome of the SIDS OECD Initial Assessment (1997) and CIR (1983)**

The OECD report (1997) concluded that, *"The human health hazard assessment for SLS shows that at present the substance is of no concern for the general public (consumers) and for workers"* and similarly the CIR report (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 OECD and CIR reports on SLS and their formulations to indicate SLS to be a skin sensitiser, genotoxic, carcinogenic, or a reproductive toxicant. The toxicity of SLS appears to be restricted to acute toxicity and skin and eye irritation. Indeed, for chronic toxicity, an oral study in the rat indicates that the primary health effect of SLS appears to be local irritation. However, these health effects are primarily based on the effects of SLS at high doses in studies in laboratory animals. The risk to humans from SLS will depend on the amount of exposure to the chemical. The amounts of SLS 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 SLS together with data indicating potentially extensive use in both industrial and 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),
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7. NOHSC (1999) List of Designated Hazardous Substances. Sydney, NSW, National Occupational Health and Safety Commission.
8. OECD (1997) OECD Screening Information Data Set (SIDS), Initial Assessment Report Volume 4, Part 2: Sodium Dodecyl Sulfate, Paris, OECD