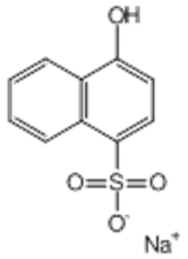
INITIAL TARGETED ASSESSMENT PROFILE

CAS No.	6099-57-6
Chemical Name	1-Naphthol-4-sulfonic acid sodium salt
Structural Formula	

SUMMARY CONCLUSIONS OF THE TARGETED ASSESSMENT

NOTE: The present assessment was targeted to address only the following endpoint(s): Human Health: acute toxicity, repeated dose toxicity and *in vitro* mutagenicity. It cannot be considered as a full SIDS Initial Assessment. Summary information on exposure is also reported here. Other endpoints for human health and the environment have not been presented to OECD member countries, and thus are not included in this profile.

Rationale for targeting the assessment

Under the Japanese Chemical Substances Control Law (CSCL), risk assessment of existing chemical substances has been conducted by the government. The CSCL was amended in 2010 and 2011 and shifted toward risk-based management from hazard-based management. Chemical substances are classified as follows from April 1, 2011: (1) Class I Specified Chemical Substances (persistent, highly bioaccumulative, has long-term toxicity for humans or long-term toxicity for predator animals at higher trophic level), (2) Class II Specified Chemical Substances (has long-term toxicity for humans or flora and fauna in the human living environment, has risk), (3) Monitoring Chemical Substances (persistent, highly bioaccumulative, long-term toxicity unknown), (4) Priority Assessment Chemical Substances (suspected long-term toxicity for humans or flora and fauna in the human living environment, suspected risk) and (5) General Chemical Substances (risk to humans or flora and fauna in the human living environment is sufficiently low).

1-Naphthol-4-sulfonic acid sodium salt is classified as a General Chemical Substance based on degrees of hazard intensity and exposure estimates at the priority assessment meeting.

This targeted assessment document was originally based on the material of the priority assessment meeting provided from the chemical assessment council of Ministry of Health, Labour and Welfare (MHLW), Japan, and the toxicological profile was re-assessed for the OECD Cooperative Chemicals Assessment Programme.

Physical-Chemical Properties

1-Naphthol-4-sulfonic acid sodium salt is white powder at room temperature. As 1-naphthol-4-sulfonic acid sodium salt is a salt of an acid and sodium, 1-naphthol-4-sulfonic acid sodium salt completely dissociates with 1-naphthol-4-sulfonic acid anion and sodium cation in water. Physicochemical properties of 1-naphthol-4-sulfonic acid sodium salt are not available. As EPISUITE calculates the properties for 1-Naphthol-4-sulfonic acid after entering CAS No. 6099-57-6, physicochemical properties of 1-Naphthol-4-sulfonic acid sodium salt could not be estimated. Although no quantitative value is obtained for water solubility, it is expected to be high based on its molecular structure and the estimated value for the acid which is > 2.95×10^5 mg/L at 25 ℃.

Human Health

In a single dose oral toxicity test [OECD TG 401], 1-naphthol-4-sulfonic acid sodium salt was administered by gavage to male and female rats at 0 (vehicle control: water for injection) or 2000 mg/kg bw. In the 2000 mg/kg bw group, soft feces were observed in the early observation period, and the body weight of females was slightly lower than the control on days 8 and 11 after administration. Because no deaths were found in this study, the oral LD_{50} value was concluded to be greater than 2000 mg/kg bw.

A 28-day repeated dose toxicity study was conducted in accordance with the Japanese guideline (similar to OECD TG 407). In this study, 1-naphthol-4-sulfonic acid sodium salt was administered to male and female rats by gavage at 0 (vehicle control: water for injection listed in the Japanese Pharmacopoeia), 100, 300 or 1000 mg/kg bw/day. The test substance did not cause any changes in clinical signs, food consumption, body weight, hematological and blood biochemical parameters, or gross pathological and histopathological findings in any dose group. In the 1000 mg/kg bw/day group, the absolute weight of epididymis was increased by 16%, but this change was considered to be toxicologically insignificant because no changes were found in the gross pathological or histopathological findings in the epididymides. Therefore, the NOAEL for 1-naphthol-4-sulfonic acid sodium salt is considered to be 1000 mg/kg bw/day in this study.

The mutagenicity was evaluated in *Salmonella typhimurium* TA98, TA100, TA1535 and TA1537, and *Escherichia coli* WP2 *uvr*A according to the Japanese guideline (similar to OECD TG 471). In this study, 1-naphthol-4-sulfonic acid sodium salt was negative in all tested strains with and without metabolic activation. In an *in vitro* chromosome aberration test performed according to the Japanese guideline (similar to OECD TG 473), 1-naphthol-4-sulfonic acid sodium salt was negative for structural chromosomal aberration or polyploidy induction in Chinese hamster lung (CHL/IU) cells with and without metabolic activation. *In vivo* genotoxicity data are not available. Based on these results, 1-naphthol-4-sulfonic acid sodium salt is considered to be non genotoxic *in vitro*.

Agreed Hazard Conclusions

This chemical does not possess properties indicating a hazard for human health endpoints targeted in this assessment.

Available Exposure

Production and/or import volume of 1-naphthol-4-sulfonic acid sodium salt was reported to be less than 1,000 tones in fiscal year 2010 in Japan. Production volume in other countries is not available. 1-Naphthol-4-sulfonic acid sodium salt is used as an intermediate for dyes, such as Supramine Red B and Benzo Copper Blue.