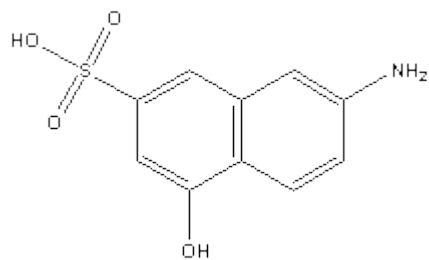


INITIAL TARGETED ASSESSMENT PROFILE

CAS No.	87-02-5
Chemical Name	7-Amino-4-hydroxy-2-naphthalenesulphonic acid
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, hazard assessment of existing chemical substances via environmental exposure has been conducted. If a chemical substance is evaluated as “not biodegradable (persistent)” and “not highly bioaccumulative”, at least, a 28-day repeated dose toxicity and two *in vitro* mutagenicity studies are required as screening studies for hazard evaluation regarding human health. If a chemical is evaluated as having potential of long-term toxicity for human health, the chemical is classified as a Type II Monitoring Chemical Substance. If not, the chemical is of low priority for further action. Type II Monitoring Chemical Substances undergo risk-based management; at first, annual production volumes of those substances are monitored.

7-Amino-4-hydroxy-2-naphthalenesulfonic acid was evaluated as “not biodegradable (persistent)” and “low bioaccumulative” by METI (Ministry of Economy, Trade and Industry, Japan). Biodegradation and bioaccumulation are not part of the targeted assessment and therefore not presented in ITAP. In order to determine whether this chemical is classified as a Type II monitoring chemical substance, the initial hazard assessment of 7-amino-4-hydroxy-2-naphthalenesulfonic acid was conducted for the acute toxicity, repeated dose toxicity and mutagenicity by MHLW (Ministry of Health, Labour and Welfare, Japan) in November 2005.

This targeted assessment document was originally based on the material from the chemical assessment council of MHLW, and the toxicological profile was re-assessed for the OECD Cooperative Chemicals Assessment Programme.

Physical-Chemical Properties

7-Amino-4-hydroxy-2-naphthalenesulphonic acid is an ash gray powder at room temperature. 7-Amino-4-hydroxy-2-naphthalenesulphonic acid decomposes at 180 - 200°C. Partition coefficient between octanol and water (log K_{ow}) is calculated to be -1.39. Vapour pressure is calculated to be 3.27 x 10⁻⁹ Pa at 25 °C. Water solubility is 5,000 mg/L at 20 °C (this value is from Handbook of Environmental Data on Organic Chemicals, 5th edition). Density is 1.3811 g/cm³ at 25 °C. Dissociation constants (pK_a) are calculated to be 3.84 and 9.18

for the -NH₂ functional group and -OH functional group, respectively.

Human Health

No reliable information is available for oral acute toxicity. The oral LD50 of the substance is considered to be greater than 1000 mg/kg bw, as no toxicologically relevant effects were observed at this dose in the 28 day repeated dose toxicity study (see detailed data on the 28 day repeated dose toxicity study, next paragraph). The oral LD50 was reported to be 11500 mg /kg bw in rats as secondary information (supporting information).

A repeated dose oral toxicity study was conducted according to a Guideline for 28-Day Repeated Dose Toxicity Test in Mammalian Species (Chemical Substances Control Law of Japan). In this study, 7-amino-4-hydroxy-2-naphthalenesulfonic acid was administered to male and female rats daily via gavage at 0 (vehicle control: 5% gum arabic solution), 250, 500, or 1000 mg/kg bw/day for 28 days. The test substance did not cause any changes in clinical signs, body weights, food consumption, urinalysis, hematology, blood chemistry or organ weights. There were also no macroscopic or microscopic abnormalities that could be attributed to treatment with the test substance. Based on no toxicological effects, the NOAEL of 7-amino-4-hydroxy-2-naphthalenesulfonic acid was concluded to be 1000 mg/kg bw/day in rats (highest dose tested).

There are three bacterial mutation studies; two were conducted with *Salmonella typhimurium* TA98, TA100, TA1535 and TA1537, or with the foregoing four strains and TA1538 (similar to OECD TG 471), and one was conducted with four strains of *Salmonella typhimurium* and *Escherichia coli* WP2 *uvrA* (similar to OECD TG 471 and 472). 7-Amino-4-hydroxy-2-naphthalenesulfonic acid was positive with metabolic activation in all strains of *Salmonella typhimurium* in two out of three studies, but negative in *E.coli* with and without metabolic activation. In an *in vitro* chromosome aberration test using CHL/IU cells (similar to OECD TG473), 7-amino-4-hydroxy-2-naphthalenesulfonic acid did not induce structural chromosomal aberrations or polyploidy with and without metabolic activation up to concentrations of 1500 µg/mL (assay dissolution limit). However, structural chromosomal aberrations were observed in another study (similar to OECD TG 473), where 7-amino-4-hydroxy-2-naphthalenesulfonic acid was tested up to 4000 µg/mL (carboxymethylcellulose) with S9 mix in CHL cells. Based on these results, 7-amino-4-hydroxy-2-naphthalenesulfonic acid is considered to be genotoxic *in vitro*. No *in vivo* mutagenicity data are available.

Agreed Hazard Conclusions

This chemical possesses properties indicating a hazard for one human health endpoint (*in vitro* genotoxicity) targeted in this assessment.

Available Exposure

Production and/or import volume of 7-amino-4-hydroxy-2-naphthalenesulphonic acid was reported to be 10 – 100 tonnes in the fiscal year 2007 in Japan (the sponsor country). Production volume in the world is not available.

7-Amino-4-hydroxy-2-naphthalenesulphonic acid is used as a feedstock for chemical synthesis and as an intermediate for azo dyes or other kinds of dyes in the sponsor country.