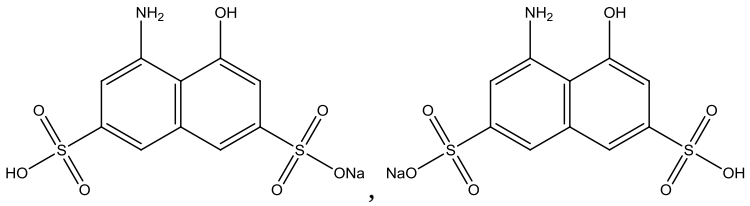
INITIAL TARGETED ASSESSMENT PROFILE

CAS No.	5460-09-3
Chemical Name	Monosodium 4-amino-5-hydroxynaphthalene-2,7-disulphonate
Structural Formula	

SUMMARY CONCLUSIONS OF THE TARGETED ASSESSMENT

NOTE: The present assessment is 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. Nevertheless, the conclusions for the endpoints addressed have been agreed by member countries and may be used for hazard and risk assessment. Results on other endpoints may be relevant for hazard and risk assessment but have not been addressed in the assessment.

Rationale for targeting the assessment

Under the Japanese Chemical Substances Control Law, hazard assessment of existing chemical substances has been conducted. If a chemical substance is evaluated as "not biodegradable (persistent)" and "not highly bioaccumulative", at least, a 28-days 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.

Monosodium 4-amino-5-hydroxynaphthalene-2,7-disulphonate was evaluated as "not biodegradable (persistent)" and "moderately bioaccumulative" by the METI (Ministry of Economy, Trade and Industry), Japan. Biodegradation and bioaccumulation are not parts of the targeted assessment and therefore not presented in the ITAP. In order to determine whether this chemical is classified as a Type II monitoring chemical substance, the initial hazard assessment of monosodium 4-amino-5-hydroxynaphthalene-2,7-disulphonate was conducted for the acute toxicity, repeated dose toxicity and mutagenicity by the MHLW (Ministry of Health, Labour and Welfare), Japan, in December 2006.

This targeted assessment document was originally based on the material from the chemical assessment council of MHLW, and the toxicological profile was reassessed for the OECD HPV chemical programme.

Physical-chemical properties

Monosodium 4-amino-5-hydroxynaphthalene-2,7-disulphonate is a light brown powder with water solubility of 11,400 mg/L at 20 °C. It is thought that sodium ion of this chemical is dissociated from thesulfonate group in water. The melting point is more than 380 °C. A calculated partition coefficient between octanol and water (Log K_{ow}) is -2.3 for the free acid. A calculated vapour pressure is 9.8×10^{-22} Pa at 25 °C

Human Health

Monosodium 4-amino-5-hydroxynaphthalene-2,7-disulphonate administered orally caused no effects at a dose of 2000 mg/kg bw in rats and the oral LD_{50} was greater than 2000 mg/kg bw in both sexes (OECD TG 401).

In a repeated dose oral toxicity study in rats following the Guideline for 28-Day Repeated Dose Toxicity Test in

Mammalian Species (Chemical Substances Control Law of Japan), monosodium 4-amino-5-hydroxynaphthalene-2,7-disulphonate was administered via gavage at 0 (vehicle control: 1 w/v% methylcellulose), 30, 100, 300, or 1000 mg/kg bw/day for 28 days. There were no adverse effects on any observations including body and organ weights, blood and urine analyses, and microscopic examination of the liver and kidney. Based on the results, the NOAEL for repeated dose oral toxicity was 1000 mg/kg bw/day in both sexes.

In a bacterial mutation study using four strains of *Salmonella typhimurium* and an *Escherichia coli* WP2 *uvr*A strain (OECD TG 471), monosodium 4-amino-5-hydroxynaphthalene-2,7-disulphonate was negative with or without metabolic activation. In an *in vitro* chromosome aberration test using Chinese hamster lung (CHL/IU) cells (OECD TG 473), monosodium 4-amino-5-hydroxynaphthalene-2,7-disulphonate was also negative with or without metabolic activation.

Agreed hazard conclusions

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

Available Exposure information (not part of the targeted assessment)

Total volume of production and import of monosodium 4-amino-5-hydroxynaphthalene-2,7-disulphonate in Japan (sponsor country) was estimated to be in the range of 100 – 1,000 tonnes in the fiscal year of 2007. Total volume of production and import in USA was 0.5 to 1 million pounds (227 – 454 tonnes) in 2006 according to IUR information by the US-EPA. Worldwide production volume was not obtained. Monosodium 4-amino-5-hydroxynaphthalene-2,7-disulphonate is used as an intermediate for azo dyes and dye mordants. No other use information was obtained in Japan.