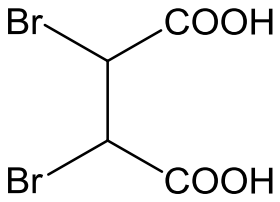
INITIAL TARGETED ASSESSMENT PROFILE

CAS No.	526-78-3
Chemical Name	2,3-Dibromosuccinic acid
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. 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.

2,3-Dibromosuccinic acid was evaluated as "not biodegradable (persistent)" and "moderately 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 the ITAP. In order to determine whether this chemical is classified as a Type II monitoring chemical substance, the initial hazard assessment of 2,3-dibromosuccinic acid was conducted for the acute toxicity, repeated dose toxicity and mutagenicity by MHLW (Ministry of Health, Labour and Welfare, Japan) in October 2006.

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

Physical-chemical properties

2,3-Dibromosuccinic acid has *D*-form, *L*-form *DL*-form and *meso*-form because of its stereo structure. 2,3-Dibromosuccinic acid is a crystalline solid at standard temperature and pressure. Melting points are 167 °C (*DL*-form), 157–158 °C (*D*-form) and 270–273 °C (*meso*-form). The *L*-form is decomposed at 157–158 °C; the *meso*-form is also reported to be decomposed at 255–256 °C. The partition coefficient between octanol and water (log K_{ow}) is -0.21. The vapour pressure is calculated to be 5.52×10^{-4} Pa at 25 °C. The water solubility is 20 g/L at 17 °C (*meso*-form or *DL*-form). The dissociation constant of pKa1 = 1.4 and pKa2 = 3.4 shows that 2,3-dibromosuccinic mainly exists under its anionic form at environmental pH values. Compositions of isomeric forms in the tested substance were not specified in the following studies.

Human Health

An acute oral toxicity study was conducted under OECD TG 401 in compliance with GLP. The oral LD_{50} value

was more than 2000 mg/kg bw for both sexes in rats. No deaths or clinical signs of toxicity were observed.

A repeated dose oral toxicity study in rats was conducted following a Guideline for 28-Day Repeated Dose Toxicity Test in Mammalian Species (Chemical Substances Control Law of Japan). In this study, 2,3-dibromosuccinic acid was administered via gavage at 0 (vehicle control: 0.5% sodium carboxymethyl cellulose solution), 20, 140 or 1000 mg/kg bw/day for 28 days. There were no treatment-related deaths and no toxicological effects in either sex. Based on the findings, the NOAEL for this 28-day repeated dose toxicity study is considered to be 1000 mg/kg bw/day (the highest dose tested) for both sexes.

In a bacterial mutation study using *Salmonella typhimurium* and *Escherichia coli* (Japanese Guideline, in compliance with GLP using a buffered solution), 2,3-dibromosuccinic acid was negative with or without metabolic activation when tested up to a cytotoxic concentration. In an *in vitro* chromosome aberration test using CHL/IU cells (Japanese Guideline, in compliance with GLP), 2,3-dibromosuccinic acid was also negative with or without metabolic activation. Based on these results, 2,3-dibromosuccinic acid is not considered to be genotoxic *in vitro*.

Agreed hazard conclusions

This chemical has a low hazard profile for the human health endpoints (acute toxicity, repeated dose toxicity, gene mutations and chromosomal aberrations) targeted in this assessment.

Available Exposure information

The production volume of 2,3-dibromosuccinic acid in Japan (sponsor country) is not known. 2,3-Dibromosuccinic acid is used as a raw material in the production of pharmaceutical products, antiseptic agents and fungicides in the sponsor country.