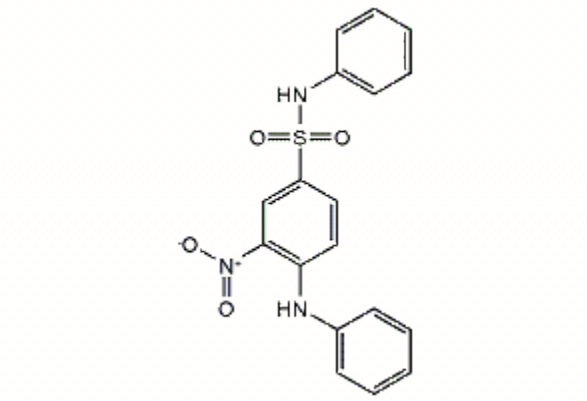
INITIAL TARGETED ASSESSMENT PROFILE

CAS No.	5124-25-4
Chemical Name	Disperse Yellow-42
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.

Disperse Yellow-42 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 Disperse Yellow-42 was conducted for the acute toxicity, repeated dose toxicity and mutagenicity by MHLW (Ministry of Health, Labour and Welfare, Japan) in June 2002 and December 2004.

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

Disperse Yellow-42 is a yellow solid at standard temperature and pressure. The measured value of melting point is 159.85 °C and the boiling point is calculated to be 536.07 °C by MPBPWIN. The measured partition coefficient between octanol and water (log Kow) is 4.60. The density is estimated to be 1.3786 g/cm^3 at 25 °C. The vapour pressure is calculated to be 2.02×10^{-8} Pa at 25 °C by MPBPWIN. The measured water solubility is 0.2 mg/L at 25 °C.

Human Health

An acute oral toxicity study in rats was conducted according to OECD TG 401 under the principles of GLP. No death or toxicologically significant clinical sign were observed at 2000 mg/kg bw. Therefore, the oral LD_{50} value was estimated to be greater than 2000 mg/kg bw for both sexes in rats.

A repeated dose oral toxicity study was conducted following a Guideline for 28-Day Repeated Dose Toxicity Test in Mammalian Species (Chemical Substances Control Law of Japan) under the principles of GLP. In this study, Disperse Yellow-42 was administered to rats via gavage at 0 (vehicle control: 0.5% sodium carboxymethylcellulose solution), 100, 300 and 1000 mg/kg bw/day for 28 days. No death or clinical signs of toxicity were observed, and no adverse effects were found in terms of body weight, urinalysis, hematology or blood biochemistry in any group. In urinalysis, the yellowish color of urine was observed at 100 and 1000 mg/kg bw/day, but this was considered to be attributed to the color of the test substance. The relative liver and spleen weights were increased at 1000 mg/kg bw/day in females. Histopathological examination revealed centrilobular hypertrophy of hepatocytes in 3/5 males given 1000 mg/kg bw/day, but no histopathological changes were observed in the spleen. After the 14-day recovery period, centrilobular hypertrophy of hepatocytes was observed in 1/5 male in the 1000 mg/kg bw/day group, but no significant changes were found in the liver and spleen weight. Based on the hepatocyte hypertrophy in males and increased relative liver and spleen weights in females at 1000 mg/kg bw/day, the NOAEL of Disperse Yellow-42 in this 28-day study was concluded to be 300 mg/kg bw/day in both sexes.

In a bacterial mutation study using *Salmonella typhimurium* and *Escherichia coli* [OECD TG 471], Disperse Yellow-42 was negative with or without metabolic activation. In an *in vitro* chromosome aberration test using CHL/IU cells [OECD TG 473], Disperse Yellow-42 induced structural chromosomal aberrations after 6 hr short-term treatment with metabolic activation. Polyploidy was not induced in any treatment group. Based on these results, Disperse Yellow-42 is considered to be genotoxic *in vitro*.

Agreed hazard conclusions

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

Available Exposure

Production and/or import volume of Disperse Yellow-42 in Japan (sponsor country) was reported to be less than 1,000 tonnes in the fiscal year 2010 according to the notification of annual manufactured and/or imported quantities under Chemical Substances Control Law. Production and/or import volume of Disperse Yellow-42 in the United States was less than 500,000 pounds (227 tonnes) according to 2006 Inventory Updated Reporting. Production volume in the world is not available.

Disperse Yellow-42 is mainly used for dyeing and printing of polyester and its fabrics. Disperse Yellow-42 is used as a disperse dye in the sponsor country.