## SIDS INITIAL ASSESSMENT PROFILE

CAS No.	88-60-8
Chemical Name	6- <i>tert</i> -Butyl- <i>m</i> -cresol
Structural Formula	H <sub>3</sub> C CH <sub>3</sub> CH <sub>3</sub> OH

#### SUMMARY CONCLUSIONS OF THE SIAR

#### Human Health

There is no available information on toxicokinetics and metabolism of 6-*tert*-Butyl-*m*-cresol. The LD50 values for acute toxicity of this substance were between 320 and 800 mg/kg in males and between 130 and 320 mg/kg in females for rats, and 580 mg/kg in males and 740 mg/kg in females for mice. This substance is corrosive to skin and eyes in rabbits. But no irritation problem has been reported at any production site where workers wear proper clothing and equipment. In a repeated toxicity study in rats (combined repeat dose and reproduction toxicity screening test [OECD TG 422]), suppression of the body weight and decrease in food consumption were observed in females of the 60 mg/kg group. Liver was the primary organ for toxic effect. Hypertrophy of centrilobular hepatocytes was observed in both sexes of the 60 mg/kg group. Based on the above results, the NOAEL for repeated dose toxicity is considered to be 12.5 mg/kg/day for both sexes.

This substance was not genotoxic in a gene reverse mutation test [OECD TG 471,472]. A chromosomal aberration test in CHL/IU cells [OECD TG 473] was positive for short-term treatment with an exogeneous metabolic activation system. However, a mouse micronucleus assay conducted *in vivo* [OECD TG474] was negative.

A reproductive toxicity study in rats [OECD TG 422] revealed that this substance was toxic to the dams at 60 mg/kg, causing depression of body weight gain and a slight decrease in the number of corpora lutea and implantations. This effect in the dams influenced the outcome of pregnancy, seen as a decrease in the number of live births and depression of weight gain in the offspring. These effects were not seen at 12.5 mg/kg/day. No evidence of gross malformations was observed at any dose. Based on these findings, the NOAEL for reproductive toxicity is considered to be 12.5 mg/kg/day for both female parents and pups. Evidence of malformations was not observed at any dose.

#### Environment

The substance has a solubility in water of 0.42 g/L at 25°C and a vapour pressure of 3.3 Pa at 25°C. The Henry's law constant is 1.3  $Pa \cdot m^3 \cdot mol^{-1}$  at 25°C.

The potential distribution of the substance was estimated using a Fugacity Mackay level III model. The results suggest that the majority of the substance distribute into soil if released to soil or air or equally to each compartment, and into water and sediment if released to the aquatic compartment.

The substance is not readily biodegradable ([OECD TG 301C]; 1% after 28 days). Abiotic degradation by hydrolysis does not occur at pH4, 7 and 9 [OECD TG 111]. The substance has a high logPow (4.11), but the measured BCF is low ([OECD TG 305]; BCF = 41-92 at 10 µg/L and 39-93 at 1 µg/L). The calculated Koc is  $3.2 \times 10^3$ . The acute EC<sub>50</sub> values for algae were 0.900 mg/L and 1.84 mg/L (24to 48hr, i.e. within the exponential growth phase of the

controls) for biomass and growth rate, respectively [OECD TG 203]. The acute  $EC_{50}$  for daphnids was 2.77 mg/L [OECD TG 202] and the  $LC_{50}$  for fish was 2.72 mg/L [OECD TG 203]. The chronic NOEC values for green algae were 0.248 mg/L and 0.622 mg/L for biomass and growth rate, respectively [OECD TG 201]. The chronic NOEC for daphnids was 0.241 mg/L [OECD TG 211, draft April, 1997].

### Exposure

Production volume of the substance is estimated to be ca. 1,500 tonnes/year in Japan. As the substance is used solely as a chemical intermediate of antioxidants, the exposure of the substance is limited to the production and industrial use in Japan. Although the substance is registered in the EU as a flavoring agent, there is no information to confirm the actual usage in the EU.

<u>Consumer exposure</u>: In consideration of the application of the substance (mostly for industrial use as an intermediate to synthesize antioxidants added to polymers and rubbers.), consumer exposure is considered to be negligible because residual contents of the substance in these products is not expected.

<u>Occupational exposure</u>: During production, processing and use, occupational exposure by inhalation and skin contact at the production and industrial use sites is the only case for consideration. The margin of safety for the exposure by inhalation is very high and workers wear proper protective equipment during these operations.

Exposure to the environment: During production, processing and use in Japan, only the aquatic release of the substance at the production site seems to be possible. But the estimated emission amount at the production site where the greatest amount of release is expected, is practically negligible.

# RECOMMENDATION

The chemical is currently of low priority for further work.

# **RATIONALE FOR THE RECOMMENDATION AND NATURE OF FURTHER WORK RECOMMENDED**

The chemical possesses properties indicating a hazard for human health and the environment. Based on data presented by the Sponsor country, exposure to humans and the environment is anticipated to be low, and therefore this chemical is currently of low priority for further work. Countries may desire to investigate any exposure scenarios that were not presented by the Sponsor country.