This is a provisional English translation of an excerpt from the original full report.

Risk Assessment Report

Di-isodecyl phthalate (DIDP)

(Apparatuses, Containers and Packages)

Food Safety Commission of Japan (FSCJ)
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ABSTRACT

FSCJ conducted a risk assessment of di-isodecyl phthalate (DIDP) (CAS No. 68515-49-1 and CAS No. 26761-40-0) for the revision of the standards and criteria for apparatuses, containers and packages.

The data used in the assessment include pharmokinetics (rats and human), acute toxicity (mice, rats, rabbits and guinea pigs), subacute toxicity (rats and dogs), chronic toxicity and carcinogenicity (mice and rats), reproductive and developmental toxicity (rats) as well as genotoxicity.

These two DIDP products, CAS No. 68515-49-1 and CAS No. 26761-40-0, are prepared from the same starting materials, through an identical olefin oligomeration process, and through similar oxo alcohol manufacturing and phthalate esterification processes. The two products are considered completely interchangeable within the range of uses, and therefore they are considered together in this assessment.

In various animal studies, DIDP demonstrated low acute toxicity. Subacute toxicity and combined chronic toxicity/carcinogenicity studies showed that the liver was a major target of DIDP, and effects included increase in absolute and relative liver weight as well as swelling and vacuolation of hepatocytes. Developmental effects of DIDP in one generation study were skeletal malformation including increases in cervical ribs as well as lowered body weights and decreased survival rate at doses that induced parental toxicity. Reproductive effects were not observed.

FSCJ concluded that DIDP is of no concern for carcinogenicity relevant to human health based on the results from the carcinogenicity study. DIDP has no genototoxicity relevant to human health based on the results from various genotoxicity studies, and therefore, FSCJ considered that the tolerable daily intake (TDI) of DIDP could be established.

Due to the limited literature available on respective epidemiological endpoints, the association between human health effects and exposure levels of DIDP could not be estimated from epidemiological studies.

Hence, FSCJ considered it appropriate to establish the tolerable daily intake (TDI) of DIDP based on the animal data.

Among the studies of subacute toxicity, combined chronic toxicity/carcinogenicity as well as reproductive and developmental toxicity, the lowest no-observed-adverse-effect level (NOAEL) was obtained in a subacute toxicity study in beagles. A NOAEL of 15 mg/kg bw/day was determined based on slight to moderate swelling and vacuolation of hepatocytes in 75 mg/kg bw/day group.

FSCJ specified the TDI of DIDP to be 0.15 mg/kg bw/day by applying an uncertainty factor of 100 (species difference of 10, individual difference of 10) to the NOAEL.