

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

Risk Assessment Report

2-deamino-2-hydroxymethionine Mn (Mintrex®Mn) (Feed Additives)

Food Safety Commission of Japan (FSCJ)
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ABSTRACT

FSCJ conducted a risk assessment of manganese bis (2-hydroxy-4-methylthio butyrate) (CAS No. 292140-32-0), a feed additive, based on documents prepared by an applicant for designation of a new feed additive.

For manganese bis (2-hydroxy-4-methylthio butyrate) (Mn-(HMTBa)₂) as a feed additive, the acceptable daily intake (ADI) has not been specified in Japan.

Orally ingested Mn-(HMTBa)₂, which is a manganese chelate of HMTBa, is thought to be absorbed from digestive tract as HMTBa and manganese. Methionine metabolized from HMTBa and manganese are used in our body.

Previously FSCJ has assessed human health risks of HMTBa which are given to animals, and concluded that it is unlikely that human beings will take excessive amount of methionine derived from veterinary medicinal products or feed additives through food consumption. FSCJ has also specified TDI of manganese to be 0.18 mg/kg bw/day, based on the NOAEL of 0.18 mg/kg bw/day which was estimated from tolerable upper intake level of manganese for a Japanese adult (11 mg /day) reported in “Development of Dietary Reference Intakes for Japanese (2010)”, considering the average intake of manganese in Japanese (3.7 mg/day) and neurotoxicity of manganese observed in animal studies.

Although there is no report on the excessive intake of dietary ingested manganese in Japanese, it is thought to be allowable to assess human health effects of intake of manganese from the compound, which is used as a feed additive, based on the above-mentioned TDI.

Manganese levels in the tissues were not much different between the dietary study of Mn-(HMTBa)₂ and that of inorganic manganese in animals.

Manganese and HMTBa were negative in *in vitro* genotoxicity studies, although *in vivo* studies were not conducted. Considering these data and other findings on genotoxicity of manganese and HMTBa, FSCJ concluded that Mn-(HMTBa)₂ has no genotoxic concern relevant to human health through food consumption as long as it is used appropriately as a feed additive.

No toxic effect was observed in the feeding trials with subjected animals, despite the subacute toxicity, chronic toxicity, carcinogenicity and reproductive-developmental toxicity were not studied.

Therefore, it was considered that the toxic effects of Mn-(HMTBa)₂ on human health through foods were not much different from those of the other Mn-containing feed additives that have been already designated in Japan.

From the above results and discussion, FSCJ concluded that risk to human health from Mn-(HMTBa)₂ through foods is negligible as long as it is used appropriately as a feed additive.