

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

Risk Assessment Report Sodium Chlorite (The 3rd edition) (Food Additive)

Food Safety Commission of Japan (FSCJ)
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Executive summary

The Food Safety Commission of Japan (FSCJ) conducted a risk assessment of sodium chlorite (NaClO_2) [CAS No. 7758-19-2], a food additive that is used as a bleaching agent and bactericide, using various test results.

The test results used in the assessment are related to the repetitive dose toxicity, carcinogenicity, reproductive developmental toxicity, genotoxicity, etc. of sodium chlorite and other substances.

When administered orally, sodium chlorite is assumed to convert to chlorous acid (HClO_2) in gastric fluid. In addition to chlorous acid (HClO_2), substances such as chloride ion (Cl^-), chlorine dioxide (ClO_2), and chlorite ion (ClO_2^-) can also be produced by metabolism in the human body. Therefore, the toxicity of sodium chlorite was assessed mainly on the basis of safety data obtained for sodium chlorite, chlorite ion, and chlorine dioxide from various animal and human studies, with reference to findings related to hypochlorous acid solution and sodium hypochlorite (NaClO) as appropriate.

According to the results of the safety studies for sodium chlorite and the like, the most commonly observed major effect of sodium chlorite intake was thought to be the damage to the red blood cells by oxidative stress. No carcinogenicity was observed. With regard to genotoxicity, a weak positive result was observed in a reverse mutation test using bacteria. Although a positive result was obtained in a chromosomal abnormality test using mammalian cell cultures, the result was negative as to a micronucleus test performed using a high dose. Therefore, sodium chlorite is considered to have no genotoxicity relevant to human health.

Furthermore, for bromic acid—with which possible contamination had been pointed out—it was confirmed that bromic acid was not detected as far as judged from the analysis of actual measured data of the aqueous solution prepared using commercially available sodium chlorite products.

The minimum value of NOAEL for sodium chlorite was considered to be 2.9 mg/kg body weight/day in the form of chlorite ions based on decreased auditory startle reactions observed in a two-generation reproductive toxicity study in rats. Hence, FSCJ determined the acceptable daily intake (ADI) of sodium chlorite as 0.029 mg/kg body weight/day in the form of chlorite ion, which was obtained by dividing the above mentioned NOAEL value by a safety factor of 100.

It was thought that the study data of sodium chlorite administration in humans also supported the ADI above.