

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

## Risk Assessment Report

### Sodium chlorite (Food Additives)

Food Safety Commission of Japan (FSCJ)  
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#### ABSTRACT

Sodium chlorite ( $\text{NaClO}_2$ , CAS No. 7758-19-2) is an additive used for fungicide and bleaching. FSCJ conducted a risk assessment of this additive using results from various studies<sup>1</sup>.

The data used in the assessment include genotoxicity, repeated dose toxicity, carcinogenicity, reproductive and developmental toxicity, and human data of sodium chlorite and sodium chlorate as the test substances. An additive, sodium chlorite, in an aqueous solution, may dissociate into chloride ion ( $\text{Cl}^-$ ), chlorate ion ( $\text{ClO}_3^-$ ), chlorine dioxide ( $\text{ClO}_2$ ) and chlorite ion ( $\text{ClO}_2^-$ ), and exist as the mixture depend on the pH. In the sodium chlorite acidified with citric acid or phosphoric acid etc. (ASC) sodium chlorite ( $\text{HClO}_2$ ) is generated, and then chlorite ion ( $\text{ClO}_2^-$ ), chlorate ion ( $\text{ClO}_3^-$ ), chlorine dioxide ( $\text{ClO}_2$ ) and chloride ion ( $\text{Cl}^-$ ) are formed.

According to JACFA(2008), chlorine dioxide ( $\text{ClO}_2$ ) is volatile, and the amount of chloride ion derived from sodium chloride used as an additive is negligible as compared to the amounts already contained in foods.

Usage of sodium chlorite in a form of ASC is requested as a relevant amendment.

FSCJ considered it appropriate, from the properties described above, to conduct a risk assessment of sodium chlorite ion using the data of chlorite ion and chlorate ion.

With regard to the possible contamination of bromic acid in sodium chlorite preparation, FSCJ assessed the possibility with analytical data on the commercially available aqueous preparation and confirmed the absence.

#### 1. Chlorite ion

Sodium chlorite is reasonably considered to undergo the conversion to chlorous acid, chloride ion, chlorine dioxide, chlorite ion and others in *in vivo*. Chlorite ion is absorbed rapidly and distributed throughout the whole body, and then excreted in urine mainly as chloride ion.

Therefore, FSCJ conducted an assessment of toxicity of chlorite ion based on the various data from studies in animals and humans on sodium chlorite, chlorite ion and chlorine dioxide, also referring to data on hypochlorous acid water and sodium hypochlorite appropriately. Data on sodium chlorite and others

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<sup>1</sup> The assessment was conducted in relation to a request of amendment of the standards for use of it to the Ministry of Health, Labour and Welfare (MHLW) based on item (i) of paragraph (1) of article 24 of the Food Safety Basic Act.

suggested that the most obvious and major adverse effect of ingested chlorite ion is oxidative stress-induced damage of erythrocytes. No genotoxicity relevant to human health was suggested for chlorite ion. From acute toxicity, repeated dose toxicity and reproductive developmental toxicity of sodium chlorite, FSCJ specified the NOAEL of 2.9 mg/kg bw per day for chlorite ion based on the data of two generation reproductive toxicity in rats. Carcinogenicity of chlorite ion was not observed.

FSCJ considered it necessary to specify an ADI for chlorite ion, taking into account the intake of chlorite ion (0.025 mg/kg bw per day) which is estimated in relation to the use of additives, sodium chlorite or chlorous acid water, in Japan. Consequently, FSCJ specified an ADI of 0.029 mg/kg bw per day for chlorite ion applying a safety factor of 100 to the NOAEL of 2.9 mg/kg bw per day (as chlorite ion) obtained in the two generation reproductive toxicity in rats. Data from all the human studies with sodium chlorite were consistent with the ADI mentioned above.

## 2. Chlorate ion

Chlorate ion is absorbed rapidly and distributed throughout the whole body, and then excreted in urine mainly as chloride ion.

No genotoxicity relevant to human health was suggested for chlorate ion.

From acute toxicity, subacute toxicity, chronic toxicity and reproductive developmental toxicity of sodium chlorate, FSCJ specified the LOAEL of 4 mg/kg bw per day (as chlorate ion) for chlorate ion based on the data from 2-year studies on chronic toxicity and carcinogenicity in rats.

Carcinogenicity of chlorate ion could not be determined from the data.

From data of human studies, NOAEL of 36 µg/kg bw per day (as chlorate ion) was obtained in interventional studies. However, the above mentioned LOAEL was considered to be supported also from the human data, because 36 µg/kg bw per day (as chlorate ion) was the maximum dose in the relevant study.

As for chlorate ion related with the use of sodium chlorite or chlorous acid water as an additive, there is enough margin between its estimated daily intake of 0.0008 mg/kg bw per day and the LOAEL of 4 mg/kg bw per day. Therefore, FSCJ concluded that there is no safety concern with chlorate ion as long as sodium chlorite is used appropriately as an additive.