

## Substance Information Document

### Citric acid monohydrate

#### 1. Substance identity

Name	Citric acid monohydrate
Synonyms	Citric acid hydrate 2-Hydroxypropane-1,2,3-tricarboxylic acid hydrate 1,2,3-Propanetricarboxylic acid, 2-hydroxy-, monohydrate 2-Hydroxypropane-1,2,3-tricarboxylic acid; hydrate Citric acid, hydrous
IUPAC Name	2-hydroxypropane-1,2,3-tricarboxylic acid; hydrate
CAS	5949-29-1

#### 2. Toxicological information

According to the ECHA registered dossier, citric acid has low toxicity via the oral and dermal routes as reflected by LD<sub>50</sub> of 5400 mg/kg bw in mice and >2000 mg/kg bw in rats, respectively. Based on the available in vivo eye irritation data for a 30% aqueous solution of citric acid, classification as eye irritant, Category 2, with the hazard phrase H319 (causes serious eye irritation), is proposed for citric acid according to Regulation (EC) No. 1272/2008. Based on the information from human volunteers, classification for specific target organ transient respiratory tract irritation STOT SE3 H335 is considered appropriate according to Regulation (EC) No. 1272/2008. In a skin sensitization study with limited details which was not conducted according to a guideline or in compliance with GLP, citric acid was concluded to not be a skin irritant or a sensitizer when tested in human volunteers. Citric acid has been tested in a bacterial reverse mutation assay conducted according to a protocol akin to OECD Test Guideline 471. No significant increase in the number of revertant colonies was detected in any Salmonella typhimurium strains TA1535, TA1537, TA98, TA100, TA92 and TA94 at the maximum dose, using the preincubation method with and without metabolic activation. It is concluded that citric acid is negative for mutagenicity to bacteria under the conditions of this test. Citric acid is negative in in vivo genotoxicity testing, although effects have been observed in some in vitro studies, e.g. micronuclei induction in cultured human lymphocytes. A study by the Food & Drug Research Laboratories researched the teratogenic effects of citric acid in mice (NOAEL >241 mg/kg/d), rats (NOAEL >295 mg/kg/d), rabbits (NOAEL >425 mg/kg/d) and hamsters (NOAEL >272 mg/kg/d), and there were no reported teratogenic effects in any of the species tested.

JECFA	<a href="https://apps.who.int/food-additives-contaminants-jecfa-database/Home/Chemical/3594">https://apps.who.int/food-additives-contaminants-jecfa-database/Home/Chemical/3594</a>
FEMA	-

EFSA	The use of citric acid in animal nutrition is safe for the consumer. It is prudent to regard it as potentially hazardous to workers by exposure of the skin, eyes or mucous membranes or by inhalation: <a href="https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2015.4010">https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2015.4010</a>
ECHA – REACH dossier	<a href="https://echa.europa.eu/registration-dossier/-/registered-dossier/15451">https://echa.europa.eu/registration-dossier/-/registered-dossier/15451</a>
PUBCHEM	<a href="https://pubchem.ncbi.nlm.nih.gov/compound/22230">https://pubchem.ncbi.nlm.nih.gov/compound/22230</a>
CIR	-
OSHA	-

### 3. Addictiveness and attractiveness

No substance-specific information was identified.

SCENIHR	-
EMA	-
PUBMED	-