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21 Author

S Proisy.

22 Date of Revision

4 May 2017.

Citric Acid Monohydrate

1 Nonproprietary Names

BP: Citric Acid Monohydrate

JP: Citric Acid Hydrate

PhEur: Citric Acid Monohydrate

USP–NF: Citric Acid Monohydrate

2 Synonyms

Acidum citricum monohydricum; E330; 2-hydroxypropane-1,2,3-tricarboxylic acid monohydrate.

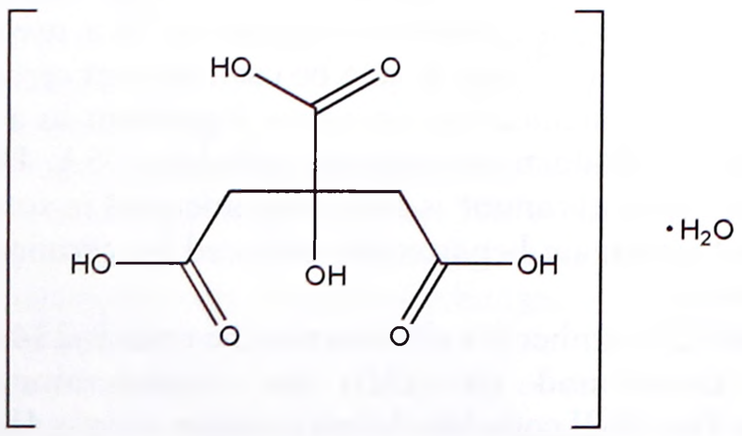
3 Chemical Name and CAS Registry Number

2-Hydroxy-1,2,3-propanetricarboxylic acid monohydrate [5949-29-1]

4 Empirical Formula and Molecular Weight

$C_6H_8O_7 \cdot H_2O$ 210.14

5 Structural Formula



6 Functional Category

Acidulant; antioxidant; buffering agent; complexing agent; flavor enhancer.

7 Applications in Pharmaceutical Formulation or Technology

Citric acid (as either the monohydrate or anhydrous material) is widely used in pharmaceutical formulations and food products, primarily to adjust the pH of solutions. Citric acid monohydrate is used in the preparation of effervescent granules, while anhydrous citric acid is widely used in the preparation of effervescent tablets.[1–3] Citric acid has also been shown to improve the stability of spray-dried insulin powder in inhalation formulations.[4]

In food products, citric acid is used as a flavor enhancer for its tart, acidic taste. Citric acid monohydrate is used as a sequestering agent and antioxidant synergist; *see* Table I. It is also a component of anticoagulant citrate solutions.

Table I: Uses of citric acid monohydrate.

Use	Concentration (%)
Buffer solutions	0.1–2.0
Complexing agent	0.3–2.0
Flavor enhancer for liquid formulations	0.3–2.0

8 Description

Citric acid monohydrate occurs as colorless or translucent crystals, or as a white crystalline, efflorescent powder. It is odorless and has a strong acidic taste. The crystal structure is orthorhombic.