

83182-MALIC ACID

1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION

1.1. Identification of the substance or preparation

Name: Malic acid

Bulk code: 83182

Internal code: 401338

Valid from batch: 0118692

1.2. Synonyms

E296, succinomalic acid, oxysuccinic acid, pomic acid.

2. DESCRIPTION

Appearance: Crystalline powder

Colour: White or almost white

Odour: Characteristic

Origin: Synthetic

Geographical origin: Italy

3. COMPOSITION/INFORMATION ON COMPONENTS

Formula: $C_4H_6O_5$

CAS: 6915-15-7

EINECS: 230-022-8

Molecular weight: 134.1 g/mol

INCI: Malic acid

4. PHYSICO-CHEMICAL DATA

For more information see the analysis report.

Solubility: The product is highly soluble in water and alcohol, but not very soluble in acetone.**Incompatibility:** Oxidising agents.

5. PROPERTIES/USES

Excipient for pharmaceutical use.

Oral use.

Not suitable for the manufacture of dietary supplements or foods.

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6. DOSAGE

No information available.

7. REMARKS

The product has been handled in a NON-sterile room; for batches suitable for sterile use, check availability.

STORAGE:

Store at room temperature in a cool, dry place in a sealed airtight container away from sunlight, heat and moisture.

The documentation available related to the product's regulatory compliance is included below.

BSE/TSE:

The product poses no risk of BSE/TSE, as per Regulation (EC) 2001/999 and EMA 410/01.

GMOs:

The product does not contain nor does it derive from GMOs, as per Regulations (EC) 1829/2003 and 1830/2003.

NANOMATERIALS:

The product is not a nanomaterial according to Regulation (EC) 1169/2011.

RADIATION:

The product has not undergone irradiation, as per Directives (EC) 1999/2 and 1999/3.

PESTICIDES:

The product is compliant with Regulation (EC) 396/2005.

COLOURANTS/PRESERVATIVES:

The product does not contain preservatives or colourants.

RESIDUAL SOLVENTS:

The product is compliant with ICH Q3C Guidelines.

CONTAMINANTS/IMPURITIES:

The product does not contain:

- Gelatine
- Sweeteners
- Melamine (Regulation (EC) 1881/2006)
- Sugars (sucrose/dextrose)
- Latex
- Contaminants (as per Regulation (EC) 1881/2006)

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HEAVY METALS:Total heavy metals ≤ 20 ppmArsenic (As) ≤ 3 ppmLead (Pb) ≤ 2 ppmMercury (Hg) $\leq 0.0 - 1.0$ ppmIron (Fe) ≤ 5 ppm**ALLERGENS:**

- **Food allergens:** Absent, as per Annex II of Regulation 1169/2011.

VEGAN/VEGETARIAN:

The product is suitable for vegan/vegetarian use.

WADA:

The product does not contain any of the doping substances included in the WADA list of prohibited substances.

REACH:

01-2119906954-31-0000