

Specification

Ferrous Sulfate 7-Hydrate

Cryst., Ph.Eur.10.Ed., USP 43, FCC 12

Formula: $\text{FeSO}_4 \cdot 7\text{H}_2\text{O}$

Mol. weight: 278.02 g/mol

Parameters	Limits
Description	crystals
Colour	bluish-green
Identification Ferrous Iron	positive
Identification Sulfate (Ph.Eur.)	positive
pH (5 %)	3.0-4.0
Chloride (Cl)	max. 200 ppm
Ferric iron (FeIII)	max. 0.3 %
Arsenic (As)	max. 3 mg/kg
Lead (Pb)	max. 2 ppm
Chromium (Cr)	max. 50 ppm
Cobalt (Co, ICH-Q3D)	max. 15 ppm
Copper (Cu)	max. 50 ppm
Manganese (Mn)	max. 0.1 %
Nickel (Ni, ICH-Q3D)	max. 50 ppm
Nickel (Ni)	max. 50 ppm
Mercury (Hg)	max. 1.0 ppm

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V04-002/001

DPL-Code No.: 522004002

PPL: 7421

DB, 29.12.2021

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Parameters	Limits
Zinc (Zn)	max. 50 ppm
Assay $\text{FeSO}_4 \cdot 7\text{H}_2\text{O}$	99.5-104.5 %
Total aerobic count (TAMC)	max. 2000 CFU/g
Yeasts/moulds count (TYMC)	max. 200 CFU/g

Regarding the Residual Solvents we state herewith, that the controlled production, handling and storage of this material precludes the presence of the organic solvents as specified in Ph.Eur. (ICH 283/95) and USP <467>.

Heavy metal parameters of this spec. have been set in accordance to ICH Q3D guideline for elemental impurities on basis of a product related risk assessment. The risk assessment has been conducted considering option 1 (max. daily intake of 10g/d) for

an oral application. Unless otherwise indicated or specified, the elements of class 1-3 (classification acc. ICH Q3D) are not likely to be present above the ICH Q3D option 1 limit in accordance to our assessment.

Further elements are not intentionally added.

The specification comprises elemental impurities based on the corresponding monograph. These elements are furthermore considered in the specification to comply with the monograph.

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