

TECHNICAL DATA SHEET

151266-TDS-ENG-2025

ALUMINIO SULFATO POLVO 18 HIDRATO (EUR. PH.)		
DESCRIPTION DCI: ALUMINIUM SULFATE OCTADECALYDRATE		DESCRIPTION DOE: ALUMINIO SULFATO OCTAHIDRATO
CAS Nº: 7784-31-8	EC Nº: 616-524-3	AEMPS CODE: ---
MOL. WEIGHT: 666.15	MOL. FORMULA: $\text{Al}_2\text{O}_3 \cdot 18\text{H}_2\text{O}$	ARTICLE CODE: 151266

ATTRIBUTES	SHOULD BE
Appearance	Colourless, lustrous crystals or crystalline masses
Solubility	Soluble in cold water, freely soluble in hot water, practically insoluble in ethanol (96 %)
Identification A	Complies
Identification B	Complies
Appearance of solution	Not more opalescent than ref. sus. III and colourless
pH	2.5 - 4.0
Alkali and alkaline-earth metals	$\leq 0.4 \%$
Ammonium	$\leq 500 \text{ ppm}$
Iron	$\leq 100 \text{ ppm}$
Assay	51.0 - 59.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Store in a well-ventilated place. Keep container tightly closed.

REMARKS

Aluminium Sulfate is subjected to the requirements of the ICH Q3D "Elemental Impurities" and the requirements of the EMA/CHMP/ICH/82260/2006 guideline.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

The product is not of animal origin and animal product is used in its production, so it is risk-free BSTE/TSE.

The product is not derived from GMO. No genetically modified organism is used in its production and no GMO product comes in contact with the product during any stage of production.