

Product Specification

APISAL Sodium Chloride GMP grade

in pharmacopoeia quality



Version 6.3

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CAS-No.: 7647-14-5 **EINECS-No.:** 231-598-3

Appearance crystalline, white product

Information

APISAL Sodium Chloride meets the requirements of the current European, British, USP, and Japanese Pharmacopoeias.

APISAL Sodium Chloride is produced in Borth (Germany) and Dombasle (France).

APISAL Sodium Chloride corresponds to the ICH Q7 GMP guidelines and is therefore well suited for pharmaceutical and medical applications.

CEP available for authorization

Analysis carried out according to the requirements of the above-mentioned Pharmacopoeias or with alternative validated methods.

Certificate of analysis listing the specifications of Pharmacopoeias and/or with alternative validated methods (see certificate of analysis according to plant of production).

Retest: After three years (on the final consumer's account).

Contact us for any other specific requirements.

Note

This non-treated salt naturally clumps. Preserve in well-closed containers.

Supply Data

- On request

Parameters	European Pharmacopoeia	British Pharmacopoeia	United States Pharmacopoeia	Japanese Pharmacopoeia
Assay, calculated with reference to the dried substance	99,0 – 100.5%	99,0 – 100.5%	99,0 – 100.5%	99,0 – 100,5%
Reactions of Chloride	Q	Q	Q	Q
Reactions of Sodium	Q	Q	Q	Q
Appearance of the solution S	clear and colourless	clear and colourless	clear and colourless	clear and colourless
Acidity of solution	≤ 0,5ml	≤ 0,5ml	≤ 0,5ml	≤ 0,5ml
Alkalinity of solution	≤ 0,5ml	≤ 0,5ml	≤ 0,5ml	≤ 0,5ml
Bromides	≤ 100ppm	≤ 100ppm	≤ 100ppm	≤ 100ppm
Ferrocyanides	Q	Q	Q	Q
Iodides	Q	Q	Q	Q
Nitrites	Q	Q	Q	-
Phosphates	≤ 25ppm	≤ 25ppm	≤ 25ppm	≤ 25ppm
Sulphates	≤ 200ppm	≤ 200ppm	≤ 200ppm	≤ 200ppm
Aluminium	≤ 0,2ppm	≤ 0,2ppm	≤ 0,2ppm	-
Arsenic	≤ 1ppm	≤ 1ppm	≤ 1ppm	≤ 2ppm
Barium	Q	Q	Q	Q
Iron	≤ 2ppm	≤ 2ppm	≤ 2ppm	≤ 2ppm
Magnesium and alkaline-earth metals as Ca	≤ 100ppm	≤ 100ppm	≤ 100ppm	≤ 100ppm
Heavy metals	-	-	-	≤ 3ppm
Potassium	≤ 500ppm	≤ 500ppm	≤ 500ppm	-
Loss on drying	≤ 0,5%	≤ 0,5%	≤ 0,5%	≤ 0,5%
Bacterial Endotoxins	≤ 5 UI/g	≤ 5 UI/g	-	-

Q: qualitative test -: not specified

The preceding data result from our quality control. They do not release the user from a control on entry. The qualification of the product for a certain application has to be checked by the customer.

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