

Certificate of Analysis

**APISAL sodium chloride GMP grade**
in pharmacopoeia quality**A.C.E.F. SPA**

Via Umbria 8-14

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Italie

For the attention of : documentazionetecnica@acef.it

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18/11/2024

K+S France SAS - Saline Dombasle
Laura MULLER
Responsable Assurance Qualité
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Manufacturer :	K+S France SAS	K+S Batch N° :	434101
K+S Order N° :	7100571711	Manufact. Start Date :	22/10/2024
Cust.Order N° :	00690 - 6761	Retest Date :	21/10/2027
Delivery/-Item N° :	7201279868	Batch size :	384 tons
Quantity :	24 Tons	K+S Article N°	53811
Shipping date :	15/11/2024		

General information :K+S France SAS - Saline Dombasle
ZA Solvay Porte Est, route des Diques
54110 - Dombasle Sur Meurthe - France**Appearance** : white or almost white, crystalline powder or colourless crystals**Solubility** : freely soluble in water, practically insoluble in anhydrous ethanol

This batch fulfils the current monographs of European, US, Japanese and British Pharmacopoeias .

APISAL is produced according to Good Manufacturing Practice (GMP) for active substances (EU GMP Part II)

Storage recommendation : this product does not require any special temperature storage conditions. Store in the original, closed package. The product is sensitive to moisture.

Parameter		Result	Specification
Assay NaCl (calc.on dried product)	validated method	99,8 %	99.0 .. 100.5 %
Bacterial endotoxins	Euro PH 2.6.14	<2 UI/g	≤ 5 UI/g
Loss on drying	Euro PH 2.2.32	0,07 %	≤ 0.50 %
Potassium	validated method	84 ppm	≤ 500 ppm
Heavy metals (J.P)	JP 1.07	corresponds	o.K.
Mg / alkaline-earth metals, calc.as Ca	validated method	8,4 ppm	≤ 100 ppm
Iron	validated method	< 0,2 ppm	≤ 2 ppm
Barium	validated method	< 0,3 ppm	≤ 5 ppm
Arsenic	validated method	< 0,5 ppm	≤ 1 ppm
Aluminium	validated method	< 0,1 ppm	≤ 0.20 ppm
Sulfates	validated method	98 ppm	≤ 200 ppm
Phosphates	validated method	< 2,5 ppm	≤ 25 ppm
Nitrites, absorbance ≤ 0.01	Euro PH 2.2.25	corresponds	o.K.
Iodides, no blue color	Euro PH	corresponds	o.K.
Ferrocyanides, no blue color	Euro PH	corresponds	o.K.
Bromides	Euro PH 2.2.25	corresponds	o.K.
Alkalinity, HCl 0.01 M	Euro PH	0,06 ml	≤ 0.5 ml
Appearance of solution, clear/colourless	Euro PH 2.2.1 / 2.2.2, II	corresponds	o.K.
Identification of sodium	Euro PH 2.3.1 B	corresponds	o.K.
Identification of chloride	Euro PH 2.3.1 A	corresponds	o.K.

On 2024-11-04 released by : Laura MULLER

Signature :

This certificate does not relieve the purchaser from examining the product upon delivery and gives no assurance of suitability of the product for any particular purpose

Analysed by Laboratory SOLVAY - Plant of Dombasle - Rue G. Péri - 54110 Dombasle Sur Meurthe - France