

PRODUCT DATA SHEET

USP Sodium Chloride

Description

- USP Sodium Chloride (Salt) is selected from chemically purified production of vacuum crystallized salt to meet the standards of the United States Pharmacopeia. It is acceptable for use in the manufacture of injectable dosage forms, peritoneal dialysis solutions, hemodialysis solutions, or hemofiltration solutions. The clear and colorless to white crystals are cubical or granular in form. The actual purity theoretically exceeds 99.95% sodium chloride, dry weight basis.
- This product meets the standards of the United States Pharmacopeia, Current Edition. It is annually certified as Kosher for Passover.
- Each lot of USP Sodium Chloride is open date coded and analyzed to determine compliance to USP standards. Lot codes, analyses, and samples are retained for three years. Copies of orders and lot codes shipped are also retained in files.
- Lot certificates of analysis are enclosed in a packing list pouch attached to one of the containers in the shipment, transmitted electronically or telefaxed to buyers.
- Please refer to Company Statement regarding Elemental Impurities for USP Sodium Chloride for customer's use in conducting the required risk analysis in accordance with the ICHQ3d-Guideline on elemental impurities.
- CAS# 7647-14-5

Chemical Properties

USP Limits

<u>Analyte</u>	<u>u/m</u>	<u>Limits</u>	<u>Typical</u>	<u>Note</u>
Identification - Sodium		Pass Test	Passes	
Identification - Chloride		Pass Test	Passes	
Acidity or alkalinity		Pass Test	Passes	
Appearance of solution		Pass Test	Passes	
Limit of bromides	PPM	<=100	Passes	
Limit of phosphates	PPM	<=25	Passes	
Limit of potassium	PPM	<=500	Passes	
Iodides		Pass Test	Passes	
Aluminum	PPM	<=0.2	Passes	
Mg and alkaline-earth metals as Ca	PPM	<=100	Passes	
Arsenic	PPM	<=1	Passes	
Iron	PPM	<=2	Passes	
Barium		Pass Test	Passes	
Ferrocyanides		Pass Test	Passes	

Sulfate	PPM	<=200	Passes	
Nitrites		Pass Test	Passes	
Heavy metals as Pb	PPM	<=5	Passes	
Loss on drying	%	<=0.5	0.03	
Assay	%	99.0 - 100.5	100	1
Bacterial Endotoxins (IU/g)		Pass Test (<=2.5)	Passes	

- Note 1. By chloride titration, dry weight basis

Physical Properties

- Typical loose (pour) bulk density (g/ml): 1.2
- Typical loose (pour) bulk density (lbs/cu.ft.): 75

Particle Size

<u>Screen</u>	<u>u/m</u>	<u>Typical</u>	<u>Retained/Passing</u>
U.S.S. 20 Mesh (850µm opening)	%	0	Retained
U.S.S. 30 Mesh (600µm opening)	%	2	Retained
U.S.S. 40 Mesh (425µm opening)	%	23	Retained
U.S.S. 50 Mesh (300µm opening)	%	47	Retained
U.S.S. 70 Mesh (212µm opening)	%	22	Retained
Pan	%	6	Retained

Codes

<u>Pack</u>	<u>Material Code</u>	<u>UPC</u>
50-Pound Paper Bag	F113820000	0 24600 01382 6
Totes	F1138600xx	N/A

Storage/Coding

- Salt is chemically stable and does not support microbial growth. To reduce the incidence of caking, store at ambient temperatures, where the humidity does not regularly cycle above 75% rh. The retest date is three years from the date of manufacture.
- A plant specific batch code is found on the package and/or on the drum label.

Plants

- Hutchinson, KS and Rittman, OH

These data are based on information we believe to be reliable. They are offered in good faith, but without guarantee, as conditions and methods of use of our products are beyond our control. We recommend that the prospective user determines the suitability of our material and suggestions before adopting them on a commercial scale.

Table 1 –Elemental Impurity Profile for USP Sodium Chloride Produced at Rittman, OH and Hutchinson, KS Facilities

Element	Morton Salt USP NaCl Typical Range (µg/g) ¹	
	Hutchinson, KS	Rittman, OH
Antimony (Sb)	<0.01	<0.01
Arsenic (As)	<0.1	<0.1
Barium (Ba)	<0.1	<0.1
Cadmium (Cd)	<0.01	<0.01
Chromium (Cr)	<0.05	<0.05
Cobalt (Co)	<0.01	<0.01
Copper (Cu)	<0.3	<0.3
Gold (Au)	<0.03	<0.03
Iridium (Ir)	<0.05	<0.05
Iron (Fe)	<0.25	<0.25
Lead (Pb)	<0.08	<0.08
Lithium (Li)	<0.1	<0.1
Manganese (Mn)	<0.1	<0.1
Mercury (Hg)	<0.02	<0.02
Molybdenum (Mo)	<0.1	<0.1
Nickel (Ni)	<0.1	<0.1
Osmium (Os)	<0.2	<0.2
Palladium (Pd)	<0.1	<0.1
Platinum (Pt)	<0.02	<0.02
Rhodium (Rh)	<0.01	<0.01
Ruthenium (Ru)	<0.03	<0.03
Selenium (Se)	<0.03	<0.03
Silver (Ag)	<0.01	<0.01
Thallium (Tl)	<0.01	<0.01
Tin (Sn)	<0.01	<0.01
Vanadium (V)	<0.05	<0.05
Zinc (Zn)	<0.05	<0.05

¹Typical is often detection limit and is based on the available data. The values listed are not meant to be a specification.