

Letter of confirmation

Heavy metals (Elemental impurities)

All table salts produced by Schweizer Salinen AG meet the requirements of Regulation EU 2023 / 915 on maximum levels for certain contaminants in foodstuffs and the FAO / WHO Codex Alimentarius CXS 150-1985.

For salts for pharmaceutical use, the specifications for elemental impurities have been defined taking into account ICH Q3D (Guideline for Elemental Impurities) and USP >232< and USP >233< respectively. The concentration limits in the following table have been determined on the basis of a daily intake of ≤ 10 g:

Elemental Impurities	Class	Potential impuritie		Oral conc. [mg/kg]	Parenteral conc. [mg/kg]	Inhalation conc. [mg/kg]	Epected conc. [mg/kg]
Arsenic	1	<input type="checkbox"/> yes	<input checked="" type="checkbox"/> no	1.5	1.5	0.2	< 0.1
Lead	1	<input type="checkbox"/> yes	<input checked="" type="checkbox"/> no	0.5	0.5	0.5	< 0.1
Cadmium	1	<input type="checkbox"/> yes	<input checked="" type="checkbox"/> no	0.5	0.2	0.3	< 0.1
Mercury	1	<input type="checkbox"/> yes	<input checked="" type="checkbox"/> no	3	0.3	0.1	< 0.1
Cobalt	2A	<input type="checkbox"/> yes	<input checked="" type="checkbox"/> no	5	0.5	0.3	< 0.1
Nickel	2A	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	20	2	0.6	< 0.25
Vanadium	2A	<input type="checkbox"/> yes	<input checked="" type="checkbox"/> no	10	1	0.1	< 0.1
Palladium	2B	<input type="checkbox"/> yes	<input checked="" type="checkbox"/> no	10	1	0.1	< 0.1
Iridium	2B	<input type="checkbox"/> yes	<input checked="" type="checkbox"/> no	10	1	0.1	< 0.1
Rhodium	2B	<input type="checkbox"/> yes	<input checked="" type="checkbox"/> no	10	1	0.1	< 0.1
Ruthenium	2B	<input type="checkbox"/> yes	<input checked="" type="checkbox"/> no	10	1	0.1	< 0.1
Selenium	2B	<input type="checkbox"/> yes	<input checked="" type="checkbox"/> no	15	8	13	< 1.0
Lithium	3	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	55	25	2.5	< 0.5
Antimony	3	<input type="checkbox"/> yes	<input checked="" type="checkbox"/> no	120	9	2	< 0.1
Barium	3	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	140	70	30	< 0.1
Molybdenum	3	<input type="checkbox"/> yes	<input checked="" type="checkbox"/> no	300	150	1	< 0.25
Copper	3	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	300	30	3	< 0.25
Tin	3	<input type="checkbox"/> yes	<input checked="" type="checkbox"/> no	600	60	6	< 1.0
Chromium	3	<input type="checkbox"/> yes	<input checked="" type="checkbox"/> no	1100	110	0.3	< 0.1
Boron	3	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	---	---	---	< 0.2
Calcium	3	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	---	---	---	< 10
Iron	3	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	---	---	---	< 0.25
Potassium	3	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	---	---	---	< 20
Magnesium	3	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	---	---	---	< 0.5

SCHWEIZER SALINEN AG

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