



# APISAL Sodium Chloride GMP grade

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878  
Issue date: 05/11/2021 Revision date: 29/11/2022 Version: 20.3

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

Product form	: Substance
Trade name	: APISAL Sodium Chloride GMP grade
EC-No.	: 231-598-3
CAS-No.	: 7647-14-5
Product code	: K2900
Type of product	: Pharmaceutical
Formula	: NaCl
Product group	: End product
REACH authorisation exemptions	: Exempted from REACH registration

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

##### 1.2.1. Relevant identified uses

Use of the substance/mixture	: Pharmaceuticals
Function or use category	: Pharmaceuticals

##### 1.2.2. Uses advised against

No additional information available

#### 1.3. Details of the supplier of the safety data sheet

K+S Minerals and Agriculture GmbH  
Bertha-von Suttner-Str., 7  
DE- 34131 Kassel  
Deutschland  
T +49 561 9301- 0  
[info@k-plus-s.com](mailto:info@k-plus-s.com) - [www.kpluss.com](http://www.kpluss.com)

#### 1.4. Emergency telephone number

Emergency number	: For Chemical Emergency Call : for incidents involving hazardous materials [or dangerous goods] spill, leak, fire, exposure or accident, call CHEMTREC 24hr/day 7days/week Within USA and Canada: +1 800 424 - 9300 Outside USA and Canada: +1 703 741 - 5970 (collect calls accepted)
------------------	--

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

##### Adverse physicochemical, human health and environmental effects

No additional information available

#### 2.2. Label elements

##### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

No labelling applicable

#### 2.3. Other hazards

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII  
This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII  
Contains no PBT/vPvB substances  $\geq 0.1\%$  assessed in accordance with REACH Annex XIII

# APISAL Sodium Chloride GMP grade

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

### Component

Sodium chloride (7647-14-5)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII
-----------------------------	---

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Substance type	: Mono-constituent
Name	: APISAL Sodium Chloride GMP grade
CAS-No.	: 7647-14-5
EC-No.	: 231-598-3

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Sodium chloride	CAS-No.: 7647-14-5 EC-No.: 231-598-3	> 98	Not classified

### 3.2. Mixtures

Not applicable

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

First-aid measures general	: If you feel unwell, consult a doctor/medical service.
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact	: Wash skin with plenty of water.
First-aid measures after eye contact	: Rinse eyes with water as a precaution.
First-aid measures after ingestion	: Rinse mouth out with water. If you feel unwell, seek medical advice.

### 4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects after skin contact	: No effects known.
Symptoms/effects after ingestion	: AFTER INGESTION OF HIGH QUANTITIES: Nausea. Vomiting.

### 4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable extinguishing media	: Adapt extinguishing media to the environment for surrounding fires.
Unsuitable extinguishing media	: Strong water jet.

### 5.2. Special hazards arising from the substance or mixture

Fire hazard	: DIRECT FIRE HAZARD: Non combustible.
Explosion hazard	: DIRECT EXPLOSION HAZARD: No direct explosion hazard. The product is not explosive. Is not classified according to Regulation (EU) 2019-1148.
Hazardous decomposition products in case of fire	: Toxic fumes may be released. hydrogenchloride.

### 5.3. Advice for firefighters

Protection during firefighting	: Do not attempt to take action without suitable protective equipment. Complete protective clothing. Self-contained breathing apparatus.
--------------------------------	--

# APISAL Sodium Chloride GMP grade

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Other information : Do not allow run-off from fire fighting to enter drains or water courses. Disposal must be done according to official regulations.

### SECTION 6: Accidental release measures

#### 6.1. Personal precautions, protective equipment and emergency procedures

##### 6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area.

##### 6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment.

#### 6.2. Environmental precautions

Prevent entry to sewers and public waters. Avoid sub-soil penetration. Do not allow product to spread into the environment. Do not allow to enter drains or water courses.

#### 6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Mechanically recover the product. Avoid dust formation. Wash down leftovers with plenty of water. This material and its container must be disposed of in a safe way, and as per local legislation. Take up mechanically (sweeping, shovelling) and collect in suitable container for disposal.

Other information : Disposal must be done according to official regulations. Ensure adequate air ventilation. Dispose of materials or solid residues at an authorized site.

#### 6.4. Reference to other sections

Wear personal protective clothing (see chapter 8). See Section 7. See Section 8. For further information refer to section 13.

### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment. Do not breathe dust. Avoid dust formation.

Hygiene measures : Observe normal hygiene standards.

#### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a dry place. Store at room temperature. Protect from moisture.

Information on mixed storage : KEEP SUBSTANCE AWAY FROM: oxidizing agents. metals. water/moisture.

#### 7.3. Specific end use(s)

No additional information available

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

##### 8.1.1 National occupational exposure and biological limit values

APISAL Sodium Chloride GMP grade (7647-14-5)	
Latvia - Occupational Exposure Limits	
Local name	Nātrija hlorīds
OEL TWA	5 mg/m <sup>3</sup>
Regulatory reference	Ministru kabineta 2007. gada 15. maija noteikumiem Nr. 325 (Grozījumi Ministru kabineta 2011. gada 1. februārī noteikumiem Nr. 92)

# APISAL Sodium Chloride GMP grade

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

APISAL Sodium Chloride GMP grade (7647-14-5)	
<b>Lithuania - Occupational Exposure Limits</b>	
Local name	Natrio chloridas
IPRV (OEL TWA)	5 mg/m <sup>3</sup>
Regulatory reference	LIETUVOS HIGIENOS NORMA HN 23:2011 (Nr. V-695/A1-272, 2018-06-12)
<b>Sodium chloride (7647-14-5)</b>	
<b>Latvia - Occupational Exposure Limits</b>	
Local name	Nātrija hlorīds
OEL TWA	5 mg/m <sup>3</sup>
Regulatory reference	Ministru kabineta 2007. gada 15. maija noteikumiem Nr. 325 (Grozījumi Ministru kabineta 2011. gada 1. februārī noteikumiem Nr. 92)
<b>Lithuania - Occupational Exposure Limits</b>	
Local name	Natrio chloridas
IPRV (OEL TWA)	5 mg/m <sup>3</sup>
Regulatory reference	LIETUVOS HIGIENOS NORMA HN 23:2011 (Nr. V-695/A1-272, 2018-06-12)

### 8.1.2. Recommended monitoring procedures

No additional information available

### 8.1.3. Air contaminants formed

No additional information available

### 8.1.4. DNEL and PNEC

APISAL Sodium Chloride GMP grade (7647-14-5)	
<b>DNEL/DMEL (Workers)</b>	
Acute - systemic effects, dermal	295.52 mg/kg bw/day
Acute - systemic effects, inhalation	2068.62 mg/m <sup>3</sup>
Long-term - systemic effects, dermal	295.52 mg/kg bw/day
Long-term - systemic effects, inhalation	2068.62 mg/m <sup>3</sup>
<b>DNEL/DMEL (General population)</b>	
Acute - systemic effects, dermal	126.65 mg/kg bw/day
Acute - systemic effects, inhalation	443.28 mg/m <sup>3</sup>
Acute - systemic effects, oral	126.65 mg/kg bw/day
Long-term - systemic effects, oral	126.65 mg/kg bw/day
Long-term - systemic effects, inhalation	443.28 mg/m <sup>3</sup>
Long-term - systemic effects, dermal	126.65 mg/kg bw/day
<b>PNEC (Water)</b>	
PNEC aqua (freshwater)	5 mg/l
<b>PNEC (Soil)</b>	
PNEC soil	4.86 mg/kg dwt
<b>PNEC (STP)</b>	
PNEC sewage treatment plant	500 mg/l

# APISAL Sodium Chloride GMP grade

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

### 8.1.5. Control banding

No additional information available

## 8.2. Exposure controls

### 8.2.1. Appropriate engineering controls

#### Appropriate engineering controls:

Ensure good ventilation of the work station.

### 8.2.2. Personal protection equipment

#### Personal protective equipment symbol(s):



#### 8.2.2.1. Eye and face protection

##### Eye protection:

Where excessive dust may result, wear goggles

#### 8.2.2.2. Skin protection

##### Skin and body protection:

Wear suitable protective clothing

#### 8.2.2.3. Respiratory protection

##### Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment. Dust formation: dust mask. EN 143

#### 8.2.2.4. Thermal hazards

No additional information available

### 8.2.3. Environmental exposure controls

#### Environmental exposure controls:

Avoid release to the environment.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: Colourless to white.
Appearance	: Crystals.
Molecular mass	: 58.44 g/mol
Odour	: Odourless.
Odour threshold	: Not available
Melting point	: 801 °C (1013 hPa)
Freezing point	: Not available
Boiling point	: No data available (test not performed)
Flammability	: Not available
Explosive properties	: Product is not explosive.
Oxidising properties	: Non oxidizing.
Explosive limits	: Not applicable
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable (solid)
Decomposition temperature	: > 804 °C
pH	: 6 – 9 (50 g/l; 20°C; DIN 38404-5)
pH solution	: Not available
Viscosity, kinematic	: Not applicable (solid)
Viscosity, dynamic	: Not applicable (solid)

# APISAL Sodium Chloride GMP grade

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Solubility	: Soluble in water. Water: 35.9 g/100ml (20 °C)
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: No data available (test not performed)
Vapour pressure at 50°C	: Not available
Density	: 2160 kg/m <sup>3</sup> (25 °C)
Relative density	: 2.16 (25 °C)
Relative vapour density at 20°C	: Not applicable
Particle size	: 1.293 mm (D50, CIPAC MT 59.1)
Particle size distribution	: Not available
Particle shape	: Not available
Particle aspect ratio	: Not available
Particle aggregation state	: Not available
Particle agglomeration state	: Not available
Particle specific surface area	: Not available
Particle dustiness	: Not available

### 9.2. Other information

#### 9.2.1. Information with regard to physical hazard classes

No additional information available

#### 9.2.2. Other safety characteristics

Minimum ignition energy	: Not applicable
VOC content	: Not applicable (inorganic)
Bulk density	: 1050 – 1300 kg/m <sup>3</sup>
Other properties	: Hygroscopic

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

### 10.2. Chemical stability

Hygroscopic.

### 10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

### 10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

### 10.5. Incompatible materials

Alkali metals. Acids. oxidising substances.

### 10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

## SECTION 11: Toxicological information

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Not classified
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified

#### APISAL Sodium Chloride GMP grade (7647-14-5)

LD50 oral rat	> 3980 mg/kg bodyweight (Rat, Experimental value, 20% aqueous solution, Oral)
---------------	---

# APISAL Sodium Chloride GMP grade

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

### APISAL Sodium Chloride GMP grade (7647-14-5)

LD50 dermal rabbit	> 10000 mg/kg (Rabbit, Experimental value, Dermal)
LC50 Inhalation - Rat	> 42 mg/l air (1 h, Rat, Male, Experimental value, 20% aqueous solution, Inhalation (aerosol))

### Sodium chloride (7647-14-5)

LD50 oral rat	> 3980 mg/kg bodyweight (Rat, Experimental value, 20% aqueous solution, Oral)
LD50 dermal rabbit	> 10000 mg/kg (Rabbit, Experimental value, Dermal)
LC50 Inhalation - Rat	> 42 mg/l air (1 h, Rat, Male, Experimental value, 20% aqueous solution, Inhalation (aerosol))

Skin corrosion/irritation	: Not classified pH: 6 – 9 (50 g/l; 20°C; DIN 38404-5)
Serious eye damage/irritation	: Not classified pH: 6 – 9 (50 g/l; 20°C; DIN 38404-5)
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified

### APISAL Sodium Chloride GMP grade (7647-14-5)

Viscosity, kinematic	Not applicable (solid)
----------------------	------------------------

## 11.2. Information on other hazards

### 11.2.1. Endocrine disrupting properties

No additional information available

### 11.2.2. Other information

Potential adverse human health effects and symptoms	: Practically non-toxic if swallowed (LD50 oral, rat > 2000 mg/kg), Not irritant to skin, Non-toxic in contact with skin (LD50 skin > 5000 mg/kg), Slightly harmful by inhalation, Not irritant to eyes
---	---

## SECTION 12: Ecological information

### 12.1. Toxicity

Ecology - general	: Not classified as dangerous for the environment according to the criteria of Regulation (EC) No 1272/2008.
Ecology - air	: Not included in the list of substances which may contribute to the greenhouse effect (IPCC). Not included in the list of fluorinated greenhouse gases (Regulation (EU) No 517/2014). Not classified as dangerous for the ozone layer (Regulation (EC) No 1005/2009).
Ecology - water	: Not harmful to crustacea (Daphnia). Not harmful to fishes. Not harmful to algae.
Hazardous to the aquatic environment, short-term (acute)	: Not classified
Hazardous to the aquatic environment, long-term (chronic)	: Not classified
Not rapidly degradable	

### APISAL Sodium Chloride GMP grade (7647-14-5)

LC50 - Fish [1]	5840 mg/l (ASTM, 96 h, Lepomis macrochirus, Flow-through system, Fresh water, Experimental value, Lethal)
-----------------	---

# APISAL Sodium Chloride GMP grade

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

### Sodium chloride (7647-14-5)

LC50 - Fish [1]	5840 mg/l (ASTM, 96 h, Lepomis macrochirus, Flow-through system, Fresh water, Experimental value, Lethal)
-----------------	---

### 12.2. Persistence and degradability

#### APISAL Sodium Chloride GMP grade (7647-14-5)

Persistence and degradability	Not applicable for inorganic substances.
Chemical oxygen demand (COD)	Not applicable (inorganic)
ThOD	Not applicable (inorganic)

#### Sodium chloride (7647-14-5)

Persistence and degradability	Not applicable for inorganic substances.
Chemical oxygen demand (COD)	Not applicable (inorganic)
ThOD	Not applicable (inorganic)

### 12.3. Bioaccumulative potential

#### APISAL Sodium Chloride GMP grade (7647-14-5)

Bioaccumulative potential	Not bioaccumulative.
---------------------------	----------------------

#### Sodium chloride (7647-14-5)

Bioaccumulative potential	Not bioaccumulative.
---------------------------	----------------------

### 12.4. Mobility in soil

#### APISAL Sodium Chloride GMP grade (7647-14-5)

Surface tension	73.03 mN/m (23 °C, 14.5 g/l)
Ecology - soil	No (test)data on mobility of the substance available.

#### Sodium chloride (7647-14-5)

Surface tension	73.03 mN/m (23 °C, 14.5 g/l)
Ecology - soil	No (test)data on mobility of the substance available.

### 12.5. Results of PBT and vPvB assessment

#### APISAL Sodium Chloride GMP grade (7647-14-5)

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

### 12.6. Endocrine disrupting properties

No additional information available

### 12.7. Other adverse effects

Additional information : No other effects known

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Product/Packaging disposal recommendations : Do not discharge into drains or the environment. Dispose of at authorized waste collection point. Remove waste in accordance with local and/or national regulations.



# APISAL Sodium Chloride GMP grade

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Additional information : Can be considered as non hazardous waste according to Directive 2008/98/EC, as amended by Regulation (EU) No 1357/2014 and Regulation (EU) No 2017/997.  
European List of Waste (LoW) code : 06 03 14 - solid salts and solutions other than those mentioned in 06 03 11 and 06 03 13

### SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
<b>14.1. UN number or ID number</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.2. UN proper shipping name</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.3. Transport hazard class(es)</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.4. Packing group</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.5. Environmental hazards</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
No supplementary information available				

### 14.6. Special precautions for user

#### Overland transport

Not applicable

#### Transport by sea

Not applicable

#### Air transport

Not applicable

#### Inland waterway transport

Not applicable

#### Rail transport

Not applicable

### 14.7. Maritime transport in bulk according to IMO instruments

Not applicable

### SECTION 15: Regulatory information

#### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

##### 15.1.1. EU-Regulations

Not listed on REACH Annex XVII

Not listed on the REACH Candidate List

Not listed on REACH Annex XIV (Authorisation List)

Not listed on the PIC list (Regulation EU 649/2012)

Not listed on the POP list (Regulation EU 2019/1021)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

VOC content : Not applicable (inorganic)

# APISAL Sodium Chloride GMP grade

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

### 15.1.2. National regulations

France	
Occupational diseases	
Code	Description
RG 78	Diseases caused by sodium chloride in salt mines and their dependencies

### Germany

Employment restrictions : Observe restrictions according Act on the Protection of Working Mothers (MuSchG)  
Observe restrictions according Act on the Protection of Young People in Employment (JArbSchG)

Water hazard class (WGK) : WGK 1, Slightly hazardous to water (Classification according to AwSV; ID No. 270)

Hazardous Incident Ordinance (12. BImSchV) : Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

Technical Instructions on Air Quality Control (TA Luft) : 5.2.1 Total Dust, including Micro Dust

Storage class (LGK, TRGS 510) : LGK 13 - Non-combustible solids

LGK 1	LGK 2A	LGK 2B	LGK 3	LGK 4.1A
LGK 4.1B	LGK 4.2	LGK 4.3	LGK 5.1A	LGK 5.1B
LGK 5.1C	LGK 5.2	LGK 6.1A	LGK 6.1B	LGK 6.1C
LGK 6.1D	LGK 6.2	LGK 7	LGK 8A	LGK 8B
LGK 10	LGK 11	LGK 12	LGK 13	LGK 10-13

Joint storage not permitted for : LGK 1, LGK 6.2, LGK 7

Joint storage with restrictions permitted for : LGK 4.1A, LGK 5.1C

Joint storage permitted for : LGK 2A, LGK 2B, LGK 3, LGK 4.1B, LGK 4.2, LGK 4.3, LGK 5.1A, LGK 5.1B, LGK 5.2, LGK 6.1A, LGK 6.1B, LGK 6.1C, LGK 6.1D, LGK 8A, LGK 8B, LGK 10, LGK 11, LGK 12, LGK 13, LGK 10-13

### Netherlands

ABM category : C(2) - low hazard for aquatic organisms occurs naturally in surface water

SZW-lijst van kankerverwekkende stoffen : The substance is not listed

SZW-lijst van mutagene stoffen : The substance is not listed

SZW-lijst van reprotoxische stoffen – Borstvoeding : The substance is not listed

SZW-lijst van reprotoxische stoffen – Vruchtbaarheid : The substance is not listed

SZW-lijst van reprotoxische stoffen – Ontwikkeling : The substance is not listed

Storage class (LK) : NG - Non-hazardous

### 15.2. Chemical safety assessment

No additional information available

### SECTION 16: Other information

No additional information available

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.