



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: 14/09/2023 Version: 20.4

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
REACH registration exemptions	: Exempted from REACH registration Annex V
Product code	: K2900
Type of product	: Pharmaceutical
Formula	: NaCl
Product group	: End product

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 - 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

Nordic countries regulation

Denmark

MAL code : 00-3 (Executive Order No. 301 from 1993)

2.3. Other hazards

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

APISAL Sodium Chloride GMP grade

Safety Data Sheet

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

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

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
-----------------------------	---

The substance is not included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605

Component

Sodium chloride(7647-14-5)	The substance is not included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605
----------------------------	---

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	: Get medical advice/attention if you feel unwell.
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 observed effects.
Symptoms/effects after ingestion	: None under normal conditions.

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

Treat symptomatically.

APISAL Sodium Chloride GMP grade

Safety Data Sheet

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

SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media : If there is a fire close by, use suitable extinguishing agents.
Unsuitable extinguishing media : Strong water jet.

5.2. Special hazards arising from the substance or mixture

- Fire hazard : Non flammable.
Explosion hazard : No direct explosion hazard.
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.
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. 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. Clean contaminated surfaces with an excess of water.
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: metals. oxidizing agents. reducing agents. (strong) acids. (strong) bases. peroxides. water/moisture.

7.3. Specific end use(s)

No additional information available

APISAL Sodium Chloride GMP grade

Safety Data Sheet

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

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 ³
Regulatory reference	Ministru kabineta 2007. gada 15. maija noteikumiem Nr. 325 (Grozījumi Ministru kabineta 2011. gada 1. februārī noteikumiem Nr. 92)
Lithuania - Occupational Exposure Limits	
Local name	Natrio chloridas
IPRV (OEL TWA)	5 mg/m ³
Regulatory reference	LIETUVOS HIGIENOS NORMA HN 23:2011 (Nr. V-695/A1-272, 2018-06-12)
Sodium chloride (7647-14-5)	
Latvia - Occupational Exposure Limits	
Local name	Nātrija hlorīds
OEL TWA	5 mg/m ³
Regulatory reference	Ministru kabineta 2007. gada 15. maija noteikumiem Nr. 325 (Grozījumi Ministru kabineta 2011. gada 1. februārī noteikumiem Nr. 92)
Lithuania - Occupational Exposure Limits	
Local name	Natrio chloridas
IPRV (OEL TWA)	5 mg/m ³
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)	
DNEL/DMEL (Workers)	
Acute - systemic effects, dermal	295.52 mg/kg bw/day
Acute - systemic effects, inhalation	2068.62 mg/m ³
Long-term - systemic effects, dermal	295.52 mg/kg bw/day
Long-term - systemic effects, inhalation	2068.62 mg/m ³
DNEL/DMEL (General population)	
Acute - systemic effects, dermal	126.65 mg/kg bw/day
Acute - systemic effects, inhalation	443.28 mg/m ³
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 ³

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)	
Long-term - systemic effects, dermal	126.65 mg/kg bw/day
PNEC (Water)	
PNEC aqua (freshwater)	5 mg/l
PNEC (Soil)	
PNEC soil	4.86 mg/kg dwt
PNEC (STP)	
PNEC sewage treatment plant	500 mg/l

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. EN 143. Dust production: dust mask with filter type P2

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	: 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	: 1461 °C

APISAL Sodium Chloride GMP grade

Safety Data Sheet

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

Flammability	: Not available
Explosive properties	: Product is not explosive.
Oxidising properties	: Non oxidizing.
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: Not specifically applicable
Auto-ignition temperature	: Not specifically applicable
Decomposition temperature	: > 804 °C
SADT	: Not specifically applicable
pH	: 6 – 9 (50 g/l; 20°C; DIN 38404-5)
pH solution	: Not available
Viscosity, kinematic	: Not specifically applicable
Viscosity, dynamic	: Not specifically applicable
Solubility	: Soluble in water. Water: 35.9 g/100ml (20 °C)
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not specifically applicable
Vapour pressure at 50°C	: Not available
Density	: 2163 kg/m ³ (25 °C)
Relative density	: 2.16 (25 °C)
Relative vapour density at 20°C	: Not specifically applicable
Particle size	: 1.3 mm (D50, CIPAC MT 59.1)

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
Specific conductivity	: No data available
VOC content	: Not specifically applicable
Bulk density	: 1050 – 1300 kg/m ³
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.

APISAL Sodium Chloride GMP grade

Safety Data Sheet

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

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)
LD50 dermal rabbit	> 10000 mg/kg (Rabbit, Experimental value, Dermal)
LC50 Inhalation - Rat	> 42 mg/l air LC50 Inhalation - Rat

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 LC50 Inhalation - Rat

Skin corrosion/irritation : Not classified
pH: 6 – 9 (50 g/l; 20°C; DIN 38404-5)

Sodium chloride (7647-14-5)	
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)

Sodium chloride (7647-14-5)	
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 specifically applicable

Sodium chloride (7647-14-5)	
Viscosity, kinematic	Not specifically applicable

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), 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.

APISAL Sodium Chloride GMP grade

Safety Data Sheet

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

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)
-----------------	---

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

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

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.

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, EC 2000/532) : 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
14.1. UN number or ID number				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.2. UN proper shipping name				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards				
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

APISAL Sodium Chloride GMP grade

Safety Data Sheet

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

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

REACH Annex XVII (Restriction List)

Not listed on REACH Annex XVII

REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

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

POP Regulation (Persistent Organic Pollutants)

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

Ozone Regulation (1005/2009)

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

VOC Directive (2004/42)

VOC content : Not specifically applicable

Explosives Precursors Regulation (2019/1148)

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

Drug Precursors Regulation (273/2004)

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).

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

Joint storage table :

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.

APISAL Sodium Chloride GMP grade

Safety Data Sheet

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

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.
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.

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

Denmark

MAL code	: 00-3 (Executive Order No. 301 from 1993)
----------	--

Switzerland

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.