



APISAL Sodium Chloride GMP grade

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)

Issue date: 08/05/2020 Revision date: 08/05/2020 Supersedes: 01/11/2019 Version: 11.0

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 HD-NaCl Sodium Chloride
Chemical name	: sodium chloride
EC-No.	: 231-598-3
CAS-No.	: 7647-14-5
REACH registration exemptions	: Exempted from REACH Pharmaceuticals

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

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

K+S Minerals and Agriculture GmbH
Bertha-von-Suttner-Str. 7
34131 Kassel - Germany
T (+49) 561 9301-0 - F (+49) 561 9301-1753

Email competent person

sds@kft.de

1.4. Emergency telephone number

Emergency number : For Hazardous Materials [or Dangerous Goods] Incidents
Spill, Leak, Fire, Exposure, or Accident
Call CHEMTREC Day or Night
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

To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

2.2. Label elements

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

Extra phrases : Pharmaceuticals : Excluded from the classification and labeling requirements of Regulation (EC) 1272/2008.

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

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SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%
sodium chloride	(CAS-No.) 7647-14-5 (EC-No.) 231-598-3	≤ 99.8

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: In all cases of doubt, or when symptoms persist, seek medical attention.
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	: Call a poison center or a doctor if you feel unwell.

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

No additional information available

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	: Use extinguishing media appropriate for surrounding fire. Water spray. Dry powder. Foam.
Unsuitable extinguishing media	: Strong water jet.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire	: Toxic fumes may be released. Corrosive vapours. Hydrogen chloride.
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5.3. Advice for firefighters

Protection during firefighting	: Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.
Other information	: Do not allow run-off from fire fighting to enter drains or water courses.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures	: Avoid dust formation. Ensure adequate air ventilation. Wear personal protective equipment.
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6.1.1. For non-emergency personnel

Emergency procedures	: Ventilate spillage area.
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6.1.2. For emergency responders

Protective equipment	: Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".
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6.2. Environmental precautions

Avoid sub-soil penetration. Prevent entry to sewers and public waters.

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6.3. Methods and material for containment and cleaning up

- Methods for cleaning up : Take up mechanically (sweeping, shovelling) and collect in suitable container for disposal. Avoid dust formation. Wash away remainder with plenty of water.
- Other information : Ensure adequate air ventilation. Disposal must be done according to official regulations.

6.4. Reference to other sections

Information for safe handling. See section 7. Concerning personal protective equipment to use, 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 : Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

- Storage conditions : Store in a well-ventilated place. Store at room temperature. Protect from moisture.

7.3. Specific end use(s)

No additional information available.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

sodium chloride (7647-14-5)	
DNEL/DMEL (Workers)	
Acute - systemic effects, dermal	295.52 mg/kg bodyweight/day
Acute - systemic effects, inhalation	2068.62 mg/m ³
Long-term - systemic effects, dermal	295.52 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	2068.62 mg/m ³
DNEL/DMEL (General population)	
Acute - systemic effects, dermal	126.65 mg/kg bodyweight
Acute - systemic effects, inhalation	443.28 mg/m ³
Acute - systemic effects, oral	126.65 mg/kg bodyweight
Long-term - systemic effects, oral	126.65 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	443.28 mg/m ³
Long-term - systemic effects, dermal	126.65 mg/kg bodyweight/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

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8.2. Exposure controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

Hand protection:

In case of repeated or prolonged contact wear gloves. Butyl rubber. Chloroprene rubber. Fluoroelastomer (FKM). Nitrile rubber. EN 374. Choosing the proper glove is a decision that depends not only on the type of material, but also on other quality features, which differ for each manufacturer. Please follow the instructions related to the permeability and the penetration time provided by the manufacturer. Gloves must be replaced after each use and whenever signs of wear or perforation appear

Eye protection:

In case of dust production: protective goggles. EN 166

Skin and body protection:

Wear suitable protective clothing. EN 340. EN ISO 13982

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment. EN 143. Particle filter. P2. Breathing equipment is only to be used in order to handle the residual risk of short term jobs if all other risk minimizing measures have been carried out e.g. retention and/or local exhaust

Environmental exposure controls:

Avoid release to the environment.

Other information:

Wash contaminated clothes. Avoid contact with skin.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: Crystalline powder.
Colour	: colourless.
Odour	: odourless.
Odour threshold	: Not applicable
pH	: 6 – 9 (20 °C; 50 g/L; DIN 38404-5)
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: 801 °C
Freezing point	: Not applicable
Boiling point	: 1641 °C
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: No data available
Flammability (solid, gas)	: Not flammable Not flammable
Vapour pressure	: 0 mbar (20 °C)
Relative vapour density at 20 °C	: No data available
Relative density	: Not applicable
Density	: 2.1615 g/cm ³ (25 °C)
Solubility	: Water: 359 g/l (20 °C)
Partition coefficient n-octanol/water (Log Pow)	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: Not applicable
Explosive properties	: Product is not explosive.
Oxidising properties	: Non oxidizing.
Explosive limits	: Not applicable

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9.2. Other information

Bulk density : $\approx 1200 \text{ kg/m}^3$

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

Stable under normal conditions.

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

Acids. Oxidizing agent. alkali metals.

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 toxicological effects

Acute toxicity (oral) : Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal) : Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation) : Not classified (Based on available data, the classification criteria are not met)

sodium chloride (7647-14-5)

LD50 oral rat	3550 mg/kg bodyweight (male)
LD50 dermal rat	> 10000 mg/kg bodyweight

Skin corrosion/irritation : Not classified (Based on available data, the classification criteria are not met)
pH: 6 – 9 (20 °C; 50 g/L; DIN 38404-5)
Additional information : May be slightly irritating to skin and eyes
Serious eye damage/irritation : Not classified (Based on available data, the classification criteria are not met)
pH: 6 – 9 (20 °C; 50 g/L; DIN 38404-5)
Additional information : May be slightly irritating to skin and eyes
Respiratory or skin sensitisation : Not classified (Based on available data, the classification criteria are not met)
Germ cell mutagenicity : Not classified (Based on available data, the classification criteria are not met)
Additional information : Mutagenicity : Ames test : negative
Mutagenicity (mammalian cell test): micronucleus negative
Carcinogenicity : Not classified (Based on available data, the classification criteria are not met)
Reproductive toxicity : Not classified (Based on available data, the classification criteria are not met)
STOT-single exposure : Not classified (Based on available data, the classification criteria are not met)
STOT-repeated exposure : Not classified (Based on available data, the classification criteria are not met)
Aspiration hazard : Not classified (Not relevant)

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SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	: The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment.
Hazardous to the aquatic environment, short-term (acute)	: Not classified (Based on available data, the classification criteria are not met)
Hazardous to the aquatic environment, long-term (chronic)	: Not classified (Based on available data, the classification criteria are not met)

sodium chloride (7647-14-5)

LC50 fish 1	5840 mg/l (96 h; Lepomis macrochirus)
EC50 Daphnia 1	4136 mg/l (static; 48 h; Daphnia magna; (OECD 202 method))

12.2. Persistence and degradability

sodium chloride (7647-14-5)

Persistence and degradability	Not applicable for inorganic substances.
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12.3. Bioaccumulative potential

sodium chloride (7647-14-5)

Bioaccumulative potential	Not applicable.
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12.4. Mobility in soil

sodium chloride (7647-14-5)

Ecology - soil	Not applicable.
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12.5. Results of PBT and vPvB assessment

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. Other adverse effects

Additional information	: No other effects known
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SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods	: Disposal must be done according to official regulations. European waste catalogue. Do not discharge into drains or the environment. Do not dispose of with domestic waste.
Product/Packaging disposal recommendations	: Dispose in a safe manner in accordance with local/national regulations.
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 / RID / IMDG / IATA / ADN

ADR	IMDG	IATA	ADN	RID
14.1. UN number				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

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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

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

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

No REACH Annex XVII restrictions

sodium chloride is not on the REACH Candidate List

sodium chloride is not on the REACH Annex XIV List

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HD-NaCl Sodium Chloride is not subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

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HD-NaCl Sodium Chloride is not subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

Other information, restriction and prohibition regulations

: A safety data sheet is not required for this product under Article 31 of REACH. This Product Safety Information Sheet has been created on a voluntary basis.

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

Information provided by the manufacturer.

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Section	Changed item	Change	Comments
1.1	Trade name	Modified	
2.2	Extra phrases	Added	

Abbreviations and acronyms:	
IMDG	International Maritime Dangerous Goods
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
IATA	International Air Transport Association
EC50	Median effective concentration
GHS	Globally Harmonised System of Classification and Labelling of Chemicals
LD50	Median lethal dose
LC50	Median lethal concentration
PBT	Persistent Bioaccumulative Toxic
vPvB	Very Persistent and Very Bioaccumulative

Data sources : ECHA (European Chemicals Agency). Information provided by the manufacturer.

Department issuing data : KFT Chemieservice GmbH
specification sheet: Im Leuschnerpark. 3 64347 Griesheim
Germany

Phone: +49 6155-8981-400 Fax: +49 6155 8981-500

Safety Data Sheet Service: +49 6155 8981-522

Contact person : Dr. Lisa Schmitt

Other information : The versioning of the safety data sheet for this product begins with the version number 10.0 due to a change of the company's name on November 1, 2019.

KFT SDS EU 07

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.