



K+S Minerals and Agriculture GmbH, P.O. Box 10 20 29,
34111 Kassel, Germany

TobiasTrieschmann
Specialist Total Quality Management

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To whom it may concern

February 14th, 2024

Product General Information

Product Name: **Potassium Chloride 99.9% KCl Ph. Eur., USP**

(where requested the product is treated with silicon dioxide on pharmaceutical grade as anti-caking agent)

Chemical Name: Potassium chloride

CAS-No. : 7447-40-7, EINECS-No.: 231-211-8

Customs Tariff Number: 31.042.090

FDA Facility Establishment Identifier: 3004269288

Information on pure product:

KCl content: min. 99.0%

K₂O content: min. 62.6%

K content : min. 51.9%

Manufacturing address

K+S Minerals and Agriculture GmbH

Werk Werra, Standort Wintershall

In der Aue 1

36266 Heringen/Werra

Germany

Origin – TSE/BSE and Materials of animal or plant origin

The above mentioned product is produced from raw materials, deriving from underground salt deposits of geological origin. The product is therefore of mineral origin. During manufacturing and storage no material of animal or plant origin is used so that contamination with these products/substances can be omitted.

Geographic origin

The above mentioned product is produced in Germany from crude salt that stems from German potash mines. The anti-caking agent on synthetic origin is also produced in Germany.

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A K+S Company

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Aufsichtsratsvorsitzender: Dr. Andreas Kreimeyer
Geschäftsführung: Dr. Burkhard Lohr (Vors.),
Christina Daske, Dr. Christian H. Meyer,
Dr. Carin-Martina Tröltzsch
Sitz der Gesellschaft: Kassel
Registergericht: Kassel (HRB 7452)

**GMO**

In the production process of the above mentioned product we do not use any Genetically Modified Organisms (GMO). The above mentioned product is no GMO, it does not contain any GMO and has not been in contact with any GMO. Therefore the Regulations (EC) No 1829/2003 (as amended) and No 1830/2003 (as amended) are not applicable.

Continuing guarantee

We confirm that each shipment or other delivery hereafter made by K+S Minerals and Agriculture GmbH of above mentioned the product is hereby guaranteed, as of the date of such shipment or delivery to be in compliance with the current Ph. Eur. and USP specifications.

Allergens

During the manufacturing of above mentioned product we do not use or add intentionally any additives, preservatives, flavours etc. The product itself does not contain, is not derived from and/or could it be cross-contaminated by any of the following:

Legal allergens

- Cereals containing gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridised strains) and products thereof
- Crustaceans and products thereof
- Fish and products thereof
- Eggs and products thereof
- Peanuts and products thereof
- Soybeans and products thereof
- Milk and products thereof
- Nuts, i.e. almonds, hazelnuts, walnuts, cashews, pecan nuts, Brazil nuts, pistachio nuts, macadamia nuts and Queensland nuts and products thereof
- Celery and products thereof
- Mustard and products thereof
- Sesame seeds and products thereof
- Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre expressed as SO₂
- Lupin and products thereof
- Molluscs and product thereof

Additional allergens

- Lactose and products thereof
- Glucose and products thereof
- Cocoa and products thereof
- Glutamate and products thereof
- Chicken meat and products thereof
- Coriander and products thereof
- Corn/ maize and products thereof
- Legumes and products thereof
- Beef and products thereof
- Pork and products thereof
- Carrot and products thereof

The analysis on above mentioned substances is not part of our quality monitoring.



Product suitability

The above mentioned product is a natural inorganic substance. It is suitable for Vegetarians, Ovo-lacto Vegetarians, Vegans, Coeliacs and people with lactose intolerance.

Kosher and Halal-Certificates

The above mentioned product is in line with Kosher and Halal requirements. The certificates are available on <https://www.kpluss.com/de-de/geschaeftsfelder-produkte/produktverantwortung/zertifikate/>

Irradiation/Ionisation

The above mentioned product is not subject to an irradiation and/or an ionisation.

Microbiological contamination

The above mentioned product is an inorganic substance that is produced from raw materials, deriving from underground salt deposits of geological origin. Due to the closed beneficiation process, the heat treatment during drying and the origin of the raw material, bacteria, moulds, yeast, mycotoxins, aflatoxins and dioxins are unlikely to be present in the product.

Acceptance criteria for microbiological quality of non-sterile pharmaceutical preparations and substances for pharmaceutical use as listed in USP <1111> and Ph. Eur. 5.1.4 are periodically checked.

Thus, we can guarantee that our above mentioned product fulfills the following criteria:

Total Aerobic Microbial Count (TAMC): 10^3 cfu/g or cfu/ml

Total Combined Yeasts/Molds Count (TYMC): 10^2 cfu/g or cfu/ml

Further analyses on microbiological contamination are not part of our standard quality monitoring. Please note that it is the responsibility of the customer/purchaser to check, within the incoming controls of the product after reception, further parameters, which should be relevant for the particular use.

Impurities

As no chemical processing is performed during the manufacturing of our above mentioned product, the potential impurities in our potassium chloride are those present in the crude salt. Furthermore we herewith confirm, that according to the "Guideline on Summary of Requirements for Active Substances in the Quality Part of the Dossier" (CHMP / QWP / 297 / 97)" no process is used which may leave impurities not adequately controlled by the monograph of the European Pharmacopoeia.

Nutritional value

The above mentioned product is a completely inorganic substance and constitutionally does not include any carbohydrates, fats or proteins. Above mentioned product has therefore no nutritional value.

Parameter	Unit	Typical Value (KCl)
Energy	kJ/100 g	0
Fat	g/100 g	0
Saturated fat	g/100 g	0
Proteins	g/100 g	0
Carbohydrates	g/100 g	0



Sugar	g/100 g	0
Fibre	g/100 g	0
Sodium	mg/100 g	4
Calcium	mg/100 g	0.5
Potassium	g/100 g	52.3
Magnesium	g/100 g	0.001
Chloride	g/100 g	47.4
Vitamins		No vitamins added
Water	g/100 g	0.2

California List of Chemicals, Proposition 65

During beneficiation no materials are used from which a contamination with compounds mentioned on the Proposition 65 list could arise.

C.M.R. classified substances

Please refer to our REACH Statement on the last page of this document..

Residual solvents

During the manufacturing process of above mentioned product only water is used as solvent. Organic solvents are not applied. Due to the geological origin of the raw material and the lack of organic solvents in the manufacturing processes, residual solvents are unlikely to be present. Therefore testing on the specified substances is not necessary and is not done.

This procedure is in conformance with ICH guidelines EMA/CHMP/ICH/82260/2006 and test <467> of the United States Pharmacopoeia.

Residues of metal catalysts or metal reagents

During the manufacturing process no material are used from which a contamination with residual metal catalysts or metal reagents could arise.

Furthermore it is demonstrated that the packaging material does not pose a risk of metal contamination to the product.

Consequently the product is in compliance with the ICH guideline Q3D on elemental impurities EMA/CHMP/ICH/353369/2013.

Change control

A formal change control system according to ICH Q7, section 13 has been implemented. In case of major changes, modifications that could affect the specification of the relevant product, a notification is sent to our direct customers prior implementation.

Furthermore a notification will be sent to all customers having received a Letter of Access for our current CEP certificate in case that updates or changes of the CEP dossier have been done and communicated to the European Directorate for the Quality of Medicines & HealthCare (EDQM).

Animal testing

We herewith confirm that the product never underwent experiments on animals. Furthermore such experiments are not planned.

Sewage sludge



For the manufacturing of the above mentioned product, potable water, checked regularly according to the requirements of the German Drinking Water Ordinance, is used. Furthermore sludge from the sewer system is neither used as raw material nor is there any risk of contamination with such compounds.

During the production process of the above mentioned product we do not use or intentionally add any of the following substances:

- Melamine
- Gluten
- Glutamates
- Nitrosamine
- Palm oil
- Maleic acid
- Latex
- Cyanuric acid
- BAC and DDAC
- Quaternary ammonium compounds
- Bisphenol A, Bisphenol F
- Polyethylene sulfide (PPS)
- Dimethylfumarat (DMF)
- Asbestos
- DEHP (diethylhexyl phthalate) and DINP (diisononyl phthalate) or any other phthalates
- Acrylamide
- Ethyl alcohol and Alcohol
- Dioxins and PCBs
- Ethylene Oxide
- Acrylamide
- Pesticides and herbicides
- Hormones or hormone residues
- Biosolids or sludge
- Antibiotics, narcotic products, steroidal anabolic
- Compounds mentioned on the WADA Prohibited List (effective 01.01.2024)
- Enzymes
- Partially hydrogenated oils (PHOs)
- Cumin
- Paprika
- Artificial color
- Propyl para-hydroxybenzoate (INS 216) and its sodium salt, sodium propyl para-hydroxybenzoate (INS 217)
- Polycyclic Aromatic Hydrocarbons (PAHs)
- Flavouring substances

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January 10, 2024

REACH, SVHC and CLP information Herewith

Herewith we would like to inform you that our products which are based on

**Sodium chloride (NaCl CAS 7647-14-5; EINECS number 231-598-3) or
Potassium chloride (KCl CAS 7447-40-7; EINECS number 231-211-8) or
Magnesium sulphate (MgSO₄ all hydrate levels
CAS 7487-88-9, 14168-73-1, 10034-99-8; EINECS number 231-298-2)**

are exempted from registration as natural mineral (EC Regulation 1907/2006, Article 2(7), Annex 5). Also exempted from registration are products for food, feed and pharmaceutical applications.

Our suppliers have also confirmed to us that all purchased substances are REACH-compliant.

The safety data sheets for our products are already REACH-compliant. We always keep these documents up to date. However, registration numbers cannot be communicated as there is no obligation to register. The EINECS and CAS numbers of the components of our products can be found in our respective safety data sheets or product data sheets.

For our products it will not be necessary to indicate identified uses, as they are not hazardous substances in the sense of the European Regulation (EC) No. 1272/2008.

For these products we do not expect any future limitation by authorisation or by REACH restriction.

The product and its packaging materials contain no substances included on the candidate list according to Article 59 or in Annex XIV REACH in a concentration above 0.1 % weight by weight (is current as of 10.06.2022).

For more detailed product information please refer to our homepage <https://www.kpluss.com>.

Kind regards,



Tobias Trieschmann

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