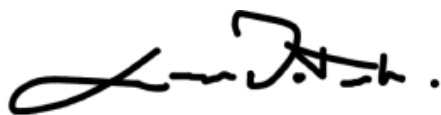


Specialty Food & Pharma Ingredients you can trust

Quality Information Pack **Nutrinova® Sorbates**

Version March 2020

Released by:



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Disclaimer

The information presented in this Nutrinova® Sorbates Quality Information Pack is based on our present state of knowledge and is intended to provide general notes on our products and their uses. It must not be construed as guaranteeing specific properties of the products described herein or their suitability for a particular application. The user of Nutrinova® Sorbates is solely responsible for investigating whether existing patents are infringed by the use of Nutrinova® Sorbates. Additionally, the user is solely responsible for investigating and checking the regulatory approval status with respect to any intended use of Nutrinova® Sorbates. Any sales and/or the deliveries of Nutrinova® Sorbates are always subject to our General Terms and Conditions, unless otherwise agreed between the parties in writing. Any reference to laws, regulations, standards, guidelines etc. refers to such laws, regulations, standards, guidelines etc. as in force and effect as at March 2020.

Technical Note

The user is responsible for the microbiological stability of its products. The water used in the production of aqueous sorbate solutions should not contain any reactive substances, such as free chlorine. We recommend following the hygienic requirements according to "Good Manufacturing Practice" (GMP).



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1. Contacts

Address:	Celanese Sales Germany GmbH Am Unisys-Park 1 65843 Sulzbach (Taunus) Germany
Manufacture by:	Celanese Production Germany GmbH & Co. KG Am Unisys-Park 1 65843 Sulzbach (Taunus) Germany
Production Facility:	Nutrinova® Sorbates Plant, Building D 420 Industriepark Höchst 65926 Frankfurt / Main Germany
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Americas:	Phone: +1-800-786-3883 E-mail: foodingredients-AM@celanese.com
Web:	www.celanese.com/food-ingredients/about-us.aspx

Emergency Contact: 24 h Emergency No: +49 (0)69 305 6418
(Please contact only in emergency situations)

2. GENERAL INFORMATION

Nutrinova® Sorbic Acid and Nutrinova® Potassium Sorbate are manufactured in a closed production system which meets all current legal requirements for environmental protection and plant safety.

A modern computer-supported process routing system controls the production process. The continuous in-process control shall provide a constant high quality of the operation of the manufacturing process, as well as a constant product quality.

Safety and quality-relevant control points are registered in a database and are frequently monitored. The results of this monitoring are documented in writing and are available if needed. At Celanese Food Ingredients, an HACCP (Hazard Analysis and Critical Control Points) program has been implemented to prevent mistakes and hazards and to achieve a predictable product quality. Employees are checking the critical control points according to schedule.

All raw materials are obtained from authorized suppliers and are checked according to a testing plan.

The operations of the manufacturing process as well as the application of state-of-the-art technology require qualified personnel. A training plan is drawn up every year for each employee. The implementation of the plan is continuously checked.

Whereas the production itself is a closed system, the finished product encounters the environment in the filling area for the first time. Nutrinova® Sorbic Acid and Nutrinova® Potassium Sorbate are filled in silo trucks and transported to our contractor. There the products are filled into the final packages. The contractor is integrated into the Celanese Food Ingredients requirements for food safety and security. Consequently, the hygienic demands on employees, plant and packaging are very high.

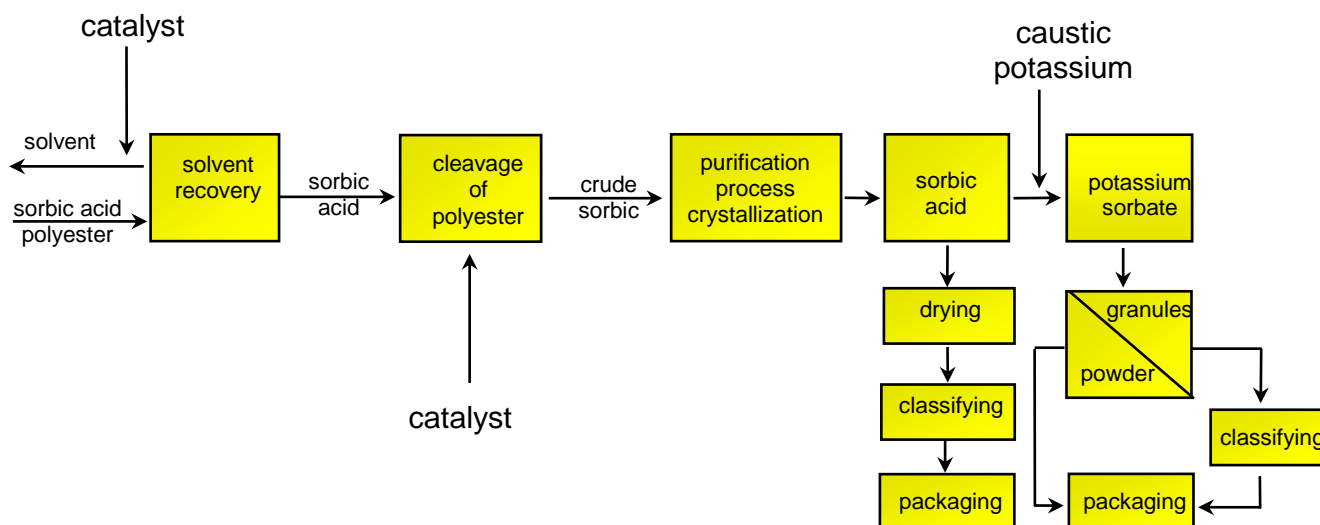
3. PRODUCTION

3.1. Production Process of Nutrinova® Sorbic Acid and Potassium Sorbate

Nutrinova® Sorbic Acid (E 200) is manufactured synthetically according to a process developed by former Hoechst AG / Celanese Food Ingredients, Germany, using ketene and crotonaldehyde.

Nutrinova® Potassium Sorbate (E 202) is manufactured synthetically through neutralization of Nutrinova® Sorbic Acid with potassium hydroxide.

3.2. Production Flow Chart



Questions & Answers: PRODUCTION

Celanese Food Ingredients has developed SOPs for plan hygiene. Below there are the most frequent questions:

Premises and Facilities	
Are floor drains equipped with Back Flow Prevention Devices?	Yes
Are there separate areas for receipt, identification, sampling and quarantine of incoming materials, pending release or rejection?	Yes
Are there separate areas for holding rejected materials before further disposition (e.g. return, reprocessing or destruction)?	Yes
Are there separate areas for Storage of released materials?	Yes

3.3. Source of Product

Source	YES	NO
Animal		X
Vegetable		X
Mineral		X
Natural		X
Nature Identical		X
Synthetic	X	

3.4. Manufacture of Nutrinova® Sorbates (in Germany only)

Nutrinova® Sorbic Acid and Nutrinova® Potassium Sorbate are manufactured in Germany by:

Celanese Production Germany GmbH & Co. KG
 Am Unisys-Park 1
 65843 Sulzbach (Taunus), Germany

Production Facility:

Nutrinova® Sorbates Plant, Building D 420, Industriepark Höchst
 65926 Frankfurt / Main, Germany

3.5. Ingredient Declaration

<i>Ingredient / Component</i> List of all ingredients contained in Nutrinova® Potassium Sorbate, including ingredients within compound ingredients	<i>% in Product</i>	<i>Supplier</i>	<i>Country Of Origin</i>	<i>Technical Function</i> (e.g. emulsifier, color, processing aid, etc.)
Potassium Sorbate	100	Celanese Sales Germany GmbH	Germany	Preservative

<i>Ingredient / Component</i> List of all ingredients contained in Nutrinova® Sorbic Acid, including ingredients within compound ingredients	<i>% in Product</i>	<i>Supplier</i>	<i>Country Of Origin</i>	<i>Technical Function</i> (e.g. emulsifier, color, processing aid, etc.)
Sorbic Acid	100	Celanese Sales Germany GmbH	Germany	Preservative

3.6. Change Control System

Changes with respect to our products Nutrinova® Sorbic Acid and Nutrinova® Potassium Sorbate and their production are subject to a Change Control Policy which is part of Celanese Food Ingredients Food Safety & Security Management System. According to such a change control system all changes that affect or may affect the quality / purity of our products are subject to the prior approval by the Celanese Food Ingredients Hazards Analysis Critical Control Point Team (HACCP) led by Celanese Food Ingredients Quality Management.

3.7. Lot Size

The lot size of Nutrinova® Potassium Sorbate is defined as per filling of a silotruck.

The lot size of Nutrinova® Sorbic Acid is defined as per filling of two silotrucks. The assignment of lot numbers (a ten-digit number) is controlled by SAP. Each lot is linked to specific material numbers. The combination of lot and material numbers guarantee a definite classification and consistent traceability.

3.8. Irradiation

Neither the starting materials, the end products nor our packaging materials are irradiated during production. This is in compliance with the irradiation legislation of the EU Directive 1999/2/EC as amended, the US FDA regulation 21 CFR 179 and the Japanese Food Sanitation Act.

3.9. Pest Control

Celanese Food Ingredients has an active pest control program in place, carried out by an external pest control contractor. The company conducts all control procedures and is completing all relevant documentation.

Methods

Insect control:	UV lights are used to attract insects which then are caught on sticky film. Any insect will be identified and counted.
Internal rodent control:	Non-poisoned baited traps are positioned according to available plan.
External rodent control:	Secure metal traps with toxic baits are externally placed according to available plan.

Checking procedure

All control methods are checked daily by the plant staff and once per month by the pest control company. In case of action required this task is conducted and documented by the pest control company. If no action is required, the premises will be certified by the pest control company.

Documentation

The documentation is archived for ten years.

3.10. Cleaning Agents

Only cleaning agents which have been approved for use in the food sector are applied. They are diluted according to the manufacturer's specifications and applied according to the regulations of our cleaning plans.

3.11. Personal and Plant Hygiene Program

The personal and plant hygiene program conforms to the requirements of the GFSI-recognized FSSC 22000 standard and other food safety standards like BRC etc.

3.12. Foreign Object Recognition in the Production of Nutrinova® Sorbates

The production process takes place within a closed system. A modern, computer-based process control system directs the course of the production process. The filling process of the end product is conducted in special filling rooms according to the food GMP standards. Thus, the hygienic requirements for people, equipment and packaging materials are high. To exclude the contamination of our product with foreign objects, we have integrated the following measures for the recognition and avoidance of foreign objects into our production and filling processes:

1. Filtration of the liquid potassium sorbate solution
2. Sieving of the dried products
3. Permanent magnets (9000 GAUSS) before filling of the silotrucks and final packages
4. Metal detectors located during / after filling process

The functional check of the metal detector is done daily, before and after filling the manufactured batch.

Sensitivity (25kg PE-bag):	3.0 mm stainless steel, 2.5 mm steel, 3.0 mm brass.
Sensitivity (Big Bag):	1.6 mm stainless steel, 1.0 mm steel, 1.2 mm brass.

3.13. Traceability / Retained sample

The European General Food Law Regulation 178 / 2002 requires a system for traceability for food ingredients and primary packaging. Celanese Food Ingredients meets these requirements. Traceability is warranted through all stages of purchase of raw materials, packaging materials, production, processing and distribution and allows a complete traceability within only few hours' time.

Celanese Food Ingredients has implemented an identification tool based on SAP in combination with an EAN 128 bar coding system to identify shipment units and trace them back through all stages of the supply chain to the manufacturing and packaging process. Additionally, an installed an internationally readable Serial Shipping Container Code (SSCC) is implemented.

For each manufactured batch we take a retained sample from final product and keep it for 4 years from the date of manufacture.

4. PACKAGING AND LABELING

4.1. Packaging and Coding

Nutrinova® Sorbic Acid and Potassium Sorbate are filled into 25kg low density polyethylene (LDPE) bags or in Big Bags. The PE liner conforms to food legislation governing products in contact with food, including Regulation (EU) 10/2011 as amended and FDA regulations 21 CFR 177.

The packaging materials are lot numbered and traceable. The used packaging materials comply with the Directive 1935/2004/EC.

The bags are marked on one bag side with the material / batch number and underneath with the date of manufacture and best before date. The PE-bags are closed by heat sealing and printed with the statutory labeling text.

Polyethylene (PE) Bag

In order to protect them from humidity and for transport reasons, the pallet stacks are covered with a polyethylene stretch film and are secured. To maintain the product quality we recommend storing the products in a cool and dry place which is protected from direct sunlight.

Packaging	Material	Weight (kg) approx.	Size (mm)
LDPE bag (25kg)	3 layer co-extruded film	0.1	full approx. 600 x 400 x 150
Pallet CP1*	Chamber dried wood	19	1200 x 1000 x 138

*Stamped with IPPC (International Plant Protection Convention)

Notes: Bags are not re-sealable. Pallets should not be double stacked.

Packing Pattern

1000 kg per pallet, containing 40 bags, 8 layers, 5 bags per layer

Packed pallet	Dimensions
Height	Approx. 130 cm
Length	Approx. 130 cm
Width	Approx. 100 cm
Net weight	1000 kg
Gross weight	Approx. 1027 kg

Big Bag

The Big Bag is sealed with a numbered seal. The packaging unit is wrapped with a PE stretch film.

Packaging	Material	Weight (kg) Approx.	Size (mm)
Big bag 500 kg	PE/PP	1.9	990 x 990 x 920
Big bag 1000 kg	PE/PP	2.6	990 x 990 x 1500

Nutrinova® Potassium Sorbate Powder

Nutrinova® Potassium Sorbate Powder is filled into cardboard boxes with polyester/aluminium/polyethylene inner liners.

The box is bonded with a water-resistant adhesive and protected from water splashes by a water-resistant coating. The polyethylene for the liner is conforming to food legislation governing products in contact with food, including Regulation (EU) 10/2011 and FDA regulations 21 CFR 177. The inner liner is closed by heat-sealing.

The boxes are marked on one side with the material/batch number and underneath that with the product name Potassium Sorbate and best before date. They are sealed with polypropylene adhesive tape which is printed with our company name.

MOSH/MOHA

Regarding MOSH (Mineral Oil Saturated Hydrocarbons) and MOAH (Mineral Oil Aromatic Hydrocarbons) the packaging materials comply with the current limits set by the Federal Institute for Risk Assessment (BfR).

The inks used for the printing of the packaging material are free of mineral oil compounds.

If the packaging material contains a functional barrier layer of plastic, its effectiveness is proved per Art. 13, para. 2, 3 and 4 or Art. 14, para. 2 and 3 of the European regulation no. 10/2011.

4.2. Labeling, Storage and Distribution, Storage Conditions

The units which are ready for dispatch can be identified and retraced at any time by the following details:

- Material number
- Lot number
- Product name
- CAS No.
- EC No.
- E No.
- Company name and address
- Date of manufacturing
- Best before date
- Country of origin

The finished products are stored at temperature and humidity monitored warehouse under GMP conditions (FSSC-certified). Removal from storage takes place according to the principle of first in first out (FIFO).

Transport and dispatch are carried out exclusively by authorized haulage contractors and distribution companies. The regulations governing the dispatch of food are observed.

During the storage of our products the following requirements must be fulfilled:

- Ambient temperature: max 30°C
- Dry conditions (max 65 % relative humidity)
- Protection from direct sunlight.

If Nutrinova® Sorbates are stored under these conditions in the unopened, originally sealed packaging unit, the shelf life is 3 years from date of manufacturing.

4.3. Product Label – examples

Labeling according to Globally Harmonized System of Classification and Labelling of Chemicals (GHS) by the United Nations which was adopted by the EU under Regulation (EC) No 1272/2008 on classification, labeling and packaging of substances and mixtures and the USA under the Hazard Communication Standards.

Example for Nutrinova® Sorbic Acid

Celanese Production Germany GmbH & Co. KG
Am Unisys-Park 1
65843 Sulzbach (Taunus)
Germany

Emergency telephone number: CHEMTREC: +1 703 527 3887 (Collect calls accepted)

Country of Origin: Germany

Nutrinova® Sorbic acid

Sorbic Acid, 100% (E 200)

1180

PE-LD

For Food
Store cool and dry
Preservative
not for retail sale
für Lebensmittel
Kühl und trocken lagern
Konservierungsmittel
Nicht für den Verkauf im Einzelhandel

Warning	Achtung	Attention	Atención	Waarschuwing
<p>H315 - Causes skin irritation H319 - Causes serious eye irritation H335 - May cause respiratory irritation</p> <p>P280 - Do not breathe dust/fume/gas/mist/vapors/spray P273 - Do not get in eyes, on skin, or on clothing P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing P337 + P313 - If eye irritation persists: Get medical advice/attention</p>	<p>H315 - Verursacht Hautreizungen H319 - Verursacht schwere Augenreizung H335 - Kann die Atemwege reizen</p> <p>P280 - Staub oder Nebel nicht einatmen P273 - Nicht in die Augen, auf die Haut oder auf die Kleidung gelangen lassen P305 + P351 + P338 - BEI KONTAKT MIT DEN AUGEN: Einige Minuten lang behutsam mit Wasser spülen. Vorhandene Kontaktlinsen nach Möglichkeit entfernen. Weiter spülen P337 + P313 - Bei anhaltender Augenreizung: Ärztlichen Rat einholen/ ärztliche Hilfe hinzuziehen</p>	<p>H315 - Provoque une irritation cutanée H319 - Provoque une sévère irritation des yeux H335 - Peut irriter les voies respiratoires</p> <p>P280 - Ne pas respirer les poussières ou brouillards P273 - Éviter le contact avec les yeux, la peau ou les vêtements P305 + P351 + P338 - EN CAS DE CONTACT AVEC LES YEUX: rincer avec précaution à l'eau pendant plusieurs minutes. Enlever les lentilles de contact si la victime en a portées et si elles peuvent être facilement enlevées. Continuer à rincer P337 + P313 - Si l'irritation oculaire persiste: consulter un médecin</p>	<p>H315 - Provoxa irritación cutánea H319 - Provoxa irritación ocular grave H335 - Puede irritar las vías respiratorias</p> <p>P280 - No respirar los vapores o neblinas P273 - Evitar el contacto con los ojos, la piel o la ropa P305 + P351 + P338 - EN CASO DE CONTACTO CON LOS OJOS: Aclarar cuidadosamente con agua durante varios minutos. Quitar las lentes de contacto, si lleva y resulta fácil. Seguir aclarando P337 + P313 - Si persiste la irritación ocular: Consultar a un médico</p>	<p>H315 - Veroorzaakt huidirritatie H319 - Veroorzaakt ernstige oogirritatie H335 - Kan irritatie van de luchtwegen veroorzaken</p> <p>P280 - Voorkom inademen van stof of nevel P273 - Contact met de ogen, de huid of de kleding vermijden P305 + P351 + P338 - BIJ CONTACT MET DE OGEN: voorzichtig afspülen met water gedurende een aantal minuten; contactlenzen verwijderen, indien mogelijk; blijven spoeien P337 + P313 - Bij aanhoudende oogirritatie: een arts raadplegen</p>
<p>Avvertenza</p> <p>H315 - Provoca irritazione cutanea H319 - Provoca grave irritazione oculare H335 - Può irritare le vie respiratorie</p> <p>P280 - Non respirare la polvere o la nebbia P273 - Evitare il contatto con gli occhi, la pelle o gli indumenti P305 + P351 + P338 - IN CASO DI CONTATTO CON GLI OCCHI: sciacquare accuratamente per parecchi minuti. Togliere le eventuali lenti a contatto se è agevole farlo. Continuare a sciacquare P337 + P313 - Se l'irritazione degli occhi persiste, consultare un medico</p>	<p>Aviso</p> <p>H315 - Provoca irritação cutânea H319 - Provoca irritação ocular grave H335 - Pode provocar irritação das vias respiratórias</p> <p>P280 - Não respirar a poeira ou a névoa P273 - Não pode entrar em contacto com os olhos, a pele ou a roupa P305 + P351 + P338 - SE ENTHALTE EM CONTACTO COM OS OLHOS: enxaguar cuidadosamente com água durante vários minutos. Se usar lentes de contacto, retire-as, se for tão possível. Continuar a enxaguar P337 + P313 - Caso a irritação ocular persista: consulte um médico</p>	<p>Varning</p> <p>H315 - Irriterar huden H319 - Orsakar allvarlig ögonirritation H335 - Kan orsaka irritation i luftvägarna</p> <p>P280 - Andas ej in damm eller dimma P273 - För undgå kontakt med ögonen, huden eller kläderna P305 + P351 + P338 - VID KONTAKT MED ÖGONEN: Skölj försiktigt med vatten i flera minuter. Ta ur eventuella kontaktlinser om det går lätt. Fortsätt att skölja P337 + P313 - Vid bestående ögonirritation: Sök läkare hjälp</p>	<p>Advarsel</p> <p>H315 - Irriterer huden H319 - Gir alvorlig øynerirritasjon H335 - Kan forårsake irritasjon av luftveiene</p> <p>P280 - Ikke innånd støv eller tåke P273 - Unngå kontakt med øyne, huden eller klær P305 + P351 + P338 - VID KONTAKT MED ØYENNE: Skyll forsiktig med vann i flere minutter. Fjern eventuelle kontaktlinser dersom dette enkelt lar seg gjøre. Fortsett skyllingen P337 + P313 - Ved vedvarende øynerirritasjon: Søk legehjelp</p>	<p>Varoitus</p> <p>H315 - Ärsyttää ihoa H319 - Ärsyttää voimakkaasti silmiä H335 - Saattaa aiheuttaa hengitysteiden ärsytystä</p> <p>P280 - Välttää pölyä tai sumua hengittämästä P273 - Välttää kontaktia silmien, ihon tai vaatteiden kanssa P305 + P351 + P338 - JOS KEMIKAALIA JOUTUU SILMIIN: Huuhdo huolellisesti vedellä usean minuutin ajan. Poista silmälasit, jos sen voi tehdä helposti. Jatka huuhottamista P337 + P313 - Jos silmiä ärsyy jatkuvasti: Hakeudu lääkärin</p>
<p>Advarsel</p> <p>H315 - Får/skader hudirritation H319 - Får/skader alvorlig øynerirritasjon H335 - Kan forårsake irritasjon av luftveiene</p> <p>P280 - Ikke innde støv eller tåke P273 - Unngå kontakt med øyne, hud eller klær P305 + P351 + P338 - VID KONTAKT MED ØYENNE: Skyll forsiktig med vann i flere minutter. Fjern eventuelle kontaktlinser, hvis dette kan gjøres let. Fortsett skylling P337 + P313 - Ved vedvarende øynerirritasjon: Søk legehjelp</p>	<p>Uyarı</p> <p>H315 - Deri tahrişine neden olur H319 - Ciddi derecede göz tahrişine neden olur H335 - Solunum tahrişine neden olabilir</p> <p>P280 - Toz veya dumanı solunmamalıdır P273 - Göz, deri veya giysilere bulaştırmamalıdır P305 + P351 + P338 - GÖZE KACMIŞSA: Birkaç dakika için suyla durulayınız. Eğer mevcut ve kolayca kontakt lensleri çıkartırsanız, durulamaya devam ediniz P337 + P313 - Göz tahrişi devam ederse: Tıbbi yardım alınız</p>	<p>Προσοχή</p> <p>H315 - Προκαλεί ερεθισμό του δέρματος H319 - Προκαλεί σοβαρό οφθαλμικό ερεθισμό H335 - Μπορεί να προκαλέσει ερεθισμό της αναπνευστικής οδού</p> <p>P280 - Μην εισπνέετε σκόνη ή τσίχλα P273 - Να αποφευχθεί ο έπoς με τα όπλα, το δέρμα ή τα ρούχα P305 + P351 + P338 - ΣΕ ΠΕΡΙΠΤΩΣΗ ΕΠΕΛΘΕΙ ΜΕΤΑ ΜΑΤΙΑ: Σπλύνετε προσεκτικά με νερό για αρκετά λεπτά. Εάν υπάρχει επαρκής πρόσβαση στο νερό, αφαιρέστε τα φακούς, εάν είναι εύκολο. Συνεχίστε να ξεπλύνετε P337 + P313 - Εάν ο ερεθισμός του οφθαλμικού ερεθισμού διαρκεί, ζητήστε ιατρική βοήθεια</p>	<p>Осторожно</p> <p>H315 - Вызывает раздражение кожи H319 - Вызывает серьезное раздражение глаз H335 - Может вызвать раздражение дыхательных путей</p> <p>P280 - Избегать выделения пыли или тумана P273 - Избегать попадания в глаза, на кожу или на одежду P305 + P351 + P338 - ПРИ ПОПАДАНИИ В ГЛАЗА: Осторожно промывать глаза водой в течение нескольких минут. Снять контактные линзы, если вы пользуетесь ими и если это легко сделать. Продолжить промывание глаз P337 + P313 - Если раздражение глаз продолжается: обратиться к врачу</p>	<p>Предупреждение</p> <p>H315 - Предвизвава дразнене на кожата H319 - Предвизвава сериозно дразнене на очите H335 - Може да предвизвава дразнене на дихателните пътища</p> <p>P280 - Не дихайте праха или мъгла P273 - Да се избягва контакт с очите, кожата или облеклото P305 + P351 + P338 - ПРИ КОНТАКТ С ОЧЕТЕ: Промывайте внимателно с вода в продължение на няколко минути. Свалете контактните лещи, ако имате такива и ако е лесно това е възможно. Продължавайте да промивате P337 + P313 - При продължително дразнене на очите: Потърсете медицински съвет/помощ</p>

Example for Nutrinova® Potassium Sorbate

Celanese Production Germany GmbH & Co. KG
Am Unisys-Park 1
65843 Sulzbach (Taunus)
Germany

Emergency telephone number: CHEMTREC: +1 703 527 3887 (Collect calls accepted)

Country of Origin: Germany

Nutrinova® Potassium Sorbate Granules

Potassium Sorbate, 100% (E 202)

1180



PE-LD

For Food
Store cool and dry
Preservative
not for retail sale
für Lebensmittel
Kühl und trocken lagern
Konservierungsmittel
Nicht für den Verkauf im Einzelhandel

Warning	Achtung	Attention	Atención	Waarschuwing
<p>H319 - Causes serious eye irritation</p> <p>P204 - Wash face, hands and any exposed skin thoroughly after handling P280 - Wear protective gloves/protective clothing/eye protection/face protection P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing P337 + P313 - If eye irritation persists: Get medical advice/attention</p>	<p>H319 - Verursacht schwere Augenreizung</p> <p>P204 - Nach Gebrauch Gesicht, Hände und alle exponierten Hautstellen gründlich waschen P280 - Schutzhandschuhe/ Schutzbekleidung/ Augenschutz/ Gesichtsschutz tragen P305 + P351 + P338 - BEI KONTAKT MIT DEN AUGEN: Einige Minuten lang behutsam mit Wasser spülen. Vorhandene Kontaktlinsen nach Möglichkeit entfernen. Weiter spülen P337 + P313 - Bei anhaltender Augenreizung: Ärztlichen Rat einholen/ ärztliche Hilfe hinzuziehen</p>	<p>H319 - Provoque une sévère irritation des yeux</p> <p>P204 - Se laver soigneusement le visage, les mains et toute partie de la peau exposée, après manipulation P280 - Porter des gants de protection des vêtements de protection un équipement de protection des yeux et du visage P305 + P351 + P338 - EN CAS DE CONTACT AVEC LES YEUX: rincer avec précaution à l'eau pendant plusieurs minutes. Enlever les lentilles de contact si la victime en a portées et si elles peuvent être facilement enlevées. Continuer à rincer P337 + P313 - Si l'irritation oculaire persiste: consulter un médecin</p>	<p>H319 - Provoxa irritación ocular grave</p> <p>P204 - Lavarse la cara, manos y toda la piel expuesta, cuidadosamente tras la manipulación P280 - Llevar guantes/ prendas/ gafas/ máscara de protección P305 + P351 + P338 - EN CASO DE CONTACTO CON LOS OJOS: Aclarar cuidadosamente con agua durante varios minutos. Quitar las lentes de contacto, si lleva y resulta fácil. Seguir aclarando P337 + P313 - Si persiste la irritación ocular: Consultar a un médico</p>	<p>H319 - Veroorzaakt ernstige oogirritatie</p> <p>P204 - Na het werken met dit product gezicht, handen en blootgestelde huid grondig wassen P280 - Beschermdere handschoenen/ beschermende kleding/ oogbescherming/ gezichtsbescherming dragen P305 + P351 + P338 - BIJ CONTACT MET DE OGEN: voorzichtig afspülen met water gedurende een aantal minuten; contactlenzen verwijderen, indien mogelijk; blijven spoeien P337 + P313 - Bij aanhoudende oogirritatie: een arts raadplegen</p>
<p>Avvertenza</p> <p>H319 - Provoca grave irritazione oculare</p> <p>P204 - Lavare accuratamente il viso, le mani e ogni parte esposta della pelle dopo l'uso P280 - Indossare guanti/ indumenti protettivi/ Proteggere gli occhi/ il viso P305 + P351 + P338 - IN CASO DI CONTATTO CON GLI OCCHI: sciacquare accuratamente per parecchi minuti. Togliere le eventuali lenti a contatto se è agevole farlo. Continuare a sciacquare P337 + P313 - Se l'irritazione degli occhi persiste, consultare un medico</p>	<p>Aviso</p> <p>H319 - Provoca irritação ocular grave</p> <p>P204 - Lavar a cara, as mãos e toda a pele exposta cuidadosamente após manuseamento P280 - Usar luvas de proteção/ vestuário de proteção/ proteção ocular/ proteção facial P305 + P351 + P338 - SE ENTHALTE EM CONTACTO COM OS OLHOS: enxaguar cuidadosamente com água durante vários minutos. Se usar lentes de contacto, retire-as, se for tão possível. Continuar a enxaguar P337 + P313 - Caso a irritação ocular persista: consulte um médico</p>	<p>Varning</p> <p>H319 - Orsakar allvarlig ögonirritation</p> <p>P204 - Tvätta ansiktet, händerna och alla utsatta hudpartier grundligt efter användning P280 - Använd skyddshandskar/ skyddskläder/ ögonskydd/ ansiktsskydd P305 + P351 + P338 - VID KONTAKT MED ÖGONEN: Skölj försiktigt med vatten i flera minuter. Ta ur eventuella kontaktlinser om det går lätt. Fortsätt att skölja P337 + P313 - Vid bestående ögonirritation: Sök läkare hjälp</p>	<p>Advarsel</p> <p>H319 - Gir alvorlig øynerirritasjon</p> <p>P204 - Vask ansikt, hender og annen utsatt hud grundig etter bruk P280 - Bær beskytteshansker/ verneklær/ vernebriller/ ansiktsskjerm P305 + P351 + P338 - VID KONTAKT MED ØYENNE: Skyll forsiktig med vann i flere minutter. Fjern eventuelle kontaktlinser dersom dette enkelt lar seg gjøre. Fortsett skyllingen P337 + P313 - Ved vedvarende øynerirritasjon: Søk legehjelp</p>	<p>Varoitus</p> <p>H319 - Ärsyttää voimakkaasti silmiä</p> <p>P204 - Kasvot, kädet ja muu mahdollisesti altistunut ihoalue on pestävä huolellisesti käsiteltyä vettä P280 - Käytä suojakäsineitä/ suojavästeitä/ silmänsuojainta/ kasvonsuojainta P305 + P351 + P338 - JOS KEMIKAALIA JOUTUU SILMIIN: Huuhdo huolellisesti vedellä usean minuutin ajan. Poista silmälasit, jos sen voi tehdä helposti. Jatka huuhottamista P337 + P313 - Jos silmiä ärsyy jatkuvasti: Hakeudu lääkärin</p>
<p>Advarsel</p> <p>H319 - Får/skader alvorlig øynerirritasjon</p> <p>P204 - Vask ansikt, hender og alt utsatt hud grundig etter bruk P280 - Bær beskytteshandsker/ beskyttelse/ vernebriller/ ansiktsskjerm P305 + P351 + P338 - VID KONTAKT MED ØYENNE: Skyll forsiktig med vann i flere minutter. Fjern eventuelle kontaktlinser, hvis dette kan gjøres let. Fortsett skylling P337 + P313 - Ved vedvarende øynerirritasjon: Søk legehjelp</p>	<p>Uyarı</p> <p>H319 - Ciddi derecede göz tahrişine neden olur</p> <p>P204 - Kullandiktan sonra yüz, el ve muar kalımlı deriyi iyice yıkayınız P280 - El ve muar koruyucu eldivenler/ koruyucu giysi/ göz koruyucu/ yüz koruyucu kullanınız P305 + P351 + P338 - GÖZE KACMIŞSA: Birkaç dakika için suyla durulayınız. Eğer mevcut ve kolayca kontakt lensleri çıkartırsanız, durulamaya devam ediniz P337 + P313 - Göz tahrişi devam ederse: Tıbbi yardım alınız</p>	<p>Προσοχή</p> <p>H319 - Προκαλεί σοβαρό οφθαλμικό ερεθισμό</p> <p>P204 - Πλύνετε το πρόσωπο, χέρια κα αποκαλύπτει δάκτυλα καθαρίζοντας προσεκτικά τα χέρια με νερό P280 - Να φοράτε προστατευτικά γάντια/ προστατευτική οργάνωση/ προστατευτική οργάνωση για το πρόσωπο P305 + P351 + P338 - ΣΕ ΠΕΡΙΠΤΩΣΗ ΕΠΕΛΘΕΙ ΜΕΤΑ ΜΑΤΙΑ: Σπλύνετε προσεκτικά με νερό για αρκετά λεπτά. Εάν υπάρχει επαρκής πρόσβαση στο νερό, αφαιρέστε τα φακούς, εάν είναι εύκολο. Συνεχίστε να ξεπλύνετε P337 + P313 - Εάν ο ερεθισμός του οφθαλμικού ερεθισμού διαρκεί, ζητήστε ιατρική βοήθεια</p>	<p>Осторожно</p> <p>H319 - Вызывает серьезное раздражение глаз</p> <p>P204 - После работы тщательно вымыть лицо, руки и все участки кожи, подвергавшиеся воздействию P280 - Пользоваться защитными перчатками/ защитной одеждой/ средствами защиты лица P305 + P351 + P338 - ПРИ ПОПАДАНИИ В ГЛАЗА: Осторожно промывать глаза водой в течение нескольких минут. Снять контактные линзы, если вы пользуетесь ими и если это легко сделать. Продолжить промывание глаз P337 + P313 - Если раздражение глаз продолжается: обратиться к врачу</p>	<p>Предупреждение</p> <p>H319 - Предвизвава сериозно дразнене на очите</p> <p>P204 - След работи лицето и ръцете и другите части на кожата, които са били изложени, старателно се измиват с вода P280 - Използвайте защитни перчатки/ защитна облекло/ средства за защита на лицето P305 + P351 + P338 - ПРИ КОНТАКТ С ОЧЕТЕ: Промывайте внимателно с вода в продължение на няколко минути. Свалете контактните лещи, ако имате такива и ако е лесно това е възможно. Продължавайте да промивате P337 + P313 - При продължително дразнене на очите: Потърсете медицински съвет/помощ</p>

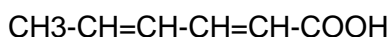
For USA only:

Celanese Production Germany GmbH & Co. KG Am Unisys - Park 1 65843 Sulzbach (Taunus) Germany Emergency telephone number: CHEMTREC: +1 703 527 3887 (Collect calls accepted) Country of Origin: Germany	
Nutrinova® Sorbic Acid Sorbic acid, 100%	
   <div> <p>For Food Store cool and dry Preservative not for retail sale für Lebensmittel Kühl und trocken lagern Konservierungsmittel nicht für den Einzelverkauf</p> <p>Net.: 25,0 KG / 55,1 LBS Gross: 25,1 KG / 55,3 LBS CAS-No.: 110-44-1 EC-No.: 203-768-7</p> </div>	
<p>WARNING</p> <p>Causes skin irritation Causes eye irritation May cause respiratory irritation</p> <p>Avoid breathing dust/fume/gas/mist/vapors/spray. Use only outdoors or in a well-ventilated area. Wash face, hands and any exposed skin thoroughly after handling. Wear protective gloves. IF ON SKIN: Wash with plenty of water. Take off contaminated clothing and wash before reuse. If skin irritation occurs: Get medical advice/attention. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER or doctor if you feel unwell. Store locked up. Store in a well-ventilated place. Keep container tightly closed. Dispose of contents/container to an approved waste disposal plant.</p> <p>Advertencia</p> <p>Provoca irritaciones de la piel Provoca una irritación en los ojos Puede irritar las vías respiratorias</p> <p>Evitar respirar polvos/ humos/ gases/ nieblas/ vapores/ aerosoles. Utilizar sólo al aire libre o en un lugar bien ventilado. Lávese la cara, manos y toda la piel expuesta, minuciosamente después del manejo. Usar guantes de protección. EN CASO DE CONTACTO CON LA PIEL: Lavar con abundante agua. Quitar la ropa contaminada y lavarla antes de volverla a usar. En caso de irritación cutánea: consultar a un médico. EN CASO DE CONTACTO CON LOS OJOS: Enjuagar con agua cuidadosamente durante varios minutos. Quitar las lentes de contacto cuando estén presentes y pueda hacerse con facilidad. Proseguir con el lavado. Si persiste la irritación ocular: consultar a un médico. EN CASO DE INHALACIÓN: Transportar a la persona al aire libre y mantenerla en una posición que le facilite la respiración. Llamar a un CENTRO DE TOXICOLOGÍA o a un médico si la persona se encuentra mal. Guardar bajo llave. Almacenar en un lugar bien ventilado. Guardar el recipiente herméticamente cerrado. Eliminación de contenidos/ contenedor a una planta de eliminación de residuos aprobada.</p>	
<p>Avertissement</p> <p>Provoque une irritation de la peau Provoque une irritation des yeux Peut irriter les voies respiratoires</p> <p>Éviter de respirer les poussières/ fumées/ gaz/ brouillards/ vapeurs/ aérosols. Utiliser seulement en plein air ou dans un endroit bien ventilé. Se laver à fond la figure, les mains et la peau exposée après avoir manipulé. Porter des gants de protection. EN CAS DE CONTACT AVEC LA PEAU : Laver abondamment à l'eau. Enlever les vêtements contaminés et les laver avant réutilisation. En cas d'irritation cutanée : consulter un médecin. EN CAS DE CONTACT AVEC LES YEUX: Rincer avec précaution à l'eau pendant plusieurs minutes. Enlever les lentilles de contact si la victime en porte et si elles peuvent être facilement enlevées. Continuer à rincer. Si l'irritation oculaire persiste : consulter un médecin. EN CAS D'INHALATION : Transporter la personne à l'extérieur et la maintenir dans une position où elle peut confortablement respirer. Appeler un CENTRE ANTIPOISON ou un médecin en cas de malaise. Garder sous clef. Stocker dans un endroit bien ventilé. Maintenir le récipient fermé de manière étanche. Éliminer le contenu/ le conteneur dans une installation d'élimination des déchets agréée.</p> <p>Aviso</p> <p>Causa irritação da pele Causa irritação nos olhos Pode causar irritação respiratória</p> <p>Evitar a respiração de poeira/ fumaça/ gás/ névoa/ vapor/ borrfio. Usar apenas ao ar livre ou em áreas bem ventiladas. Lavar o rosto, as mãos e a pele exposta cuidadosamente após o manuseio. Usar luvas de proteção. EM CASO DE CONTATO COM A PELE: Lavar com água abundante. Retirar a roupa contaminada e lavar antes de usar de novo. Em caso de irritação cutânea: Consulte um médico. SE NOS OLHOS: Lavar cuidadosamente com água durante vários minutos. Remover as lentes de contato, se presentes e de fácil remoção. Continue enxaguando. Caso a irritação ocular persista: consulte um médico. SE INALADO: Remova a vítima para um local arejado e mantenha-a em repouso, em uma posição confortável para respirar. Ligue para um CENTRO DE INFORMAÇÕES TOXICOLÓGICAS ou um médico se sentir mal-estar. Armazenar fechado à chave. Armazenar em local bem ventilado. Conservar o recipiente bem fechado. Descartar o conteúdo/ recipiente em uma estação aprovada de tratamento de resíduos.</p>	

Celanese Production Germany GmbH & Co. KG Am Unisys-Park 1 65843 Sulzbach (Taunus) Germany Emergency telephone number: CHEMTREC: +1 703 527 3887 (Collect calls accepted) Country of Origin: Germany			
Nutrinova® Potassium Sorbate Granules Potassium sorbate, 100%			
<div> <p>WARNING</p>   <div> <p>For Food Store cool and dry Preservative not for retail sale für Lebensmittel Kühl und trocken lagern Konservierungsmittel nicht für den Einzelverkauf</p> <p>Net.: 25,0 KG / 55,1 LBS Gross: 25,1 KG / 55,3 LBS CAS-No.: 24634-61-5 EC-No.: 246-376-1</p> </div> </div>			
Causes eye irritation Wash face, hands, and any exposed skin thoroughly after handling. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.	<p>Avertissement</p> <p>Provoque une irritation des yeux</p> <p>Se laver à fond la figure, les mains et la peau exposée après avoir manipulé.</p> <p>EN CAS DE CONTACT AVEC LES YEUX: Rincer avec précaution à l'eau pendant plusieurs minutes. Enlever les lentilles de contact si la victime en porte et si elles peuvent être facilement enlevées. Continuer à rincer.</p> <p>Si l'irritation oculaire persiste : consulter un médecin.</p>	<p>Advertencia</p> <p>Provoca una irritación en los ojos</p> <p>Lávese la cara, manos y toda la piel expuesta, minuciosamente después del manejo.</p> <p>EN CASO DE CONTACTO CON LOS OJOS: Enjuagar con agua cuidadosamente durante varios minutos. Quitar las lentes de contacto cuando estén presentes y pueda hacerse con facilidad. Proseguir con el lavado.</p> <p>Si persiste la irritación ocular: consultar a un médico.</p>	<p>Aviso</p> <p>Causa irritação nos olhos</p> <p>Lavar o rosto, as mãos e a pele exposta cuidadosamente após o manuseio.</p> <p>SE NOS OLHOS: Lavar cuidadosamente com água durante vários minutos. Remover as lentes de contato, se presentes e de fácil remoção. Continue enxaguando.</p> <p>Caso a irritação ocular persista: consulte um médico.</p>

5. PROPERTIES

5.1. Structural Formula of Nutrinova® Sorbates



Sorbic Acid



Potassium Sorbate

5.2. Analytical Laboratory

Our laboratory is situated at the Industriepark Höchst, Frankfurt, Germany and belongs to the Celanese Group. Quality Management (QM) department is independent from production and responsible for the whole quality control process. The laboratory conducts analytical tasks for incoming raw material, in-process testing and for the final release of the products.

Release of product is controlled by SAP.

Analytical Testing & Subcontracting (Question & Answers)	
Are all analytical testing performed in house? Yes, excluding microbiological and heavy metal testing conducted by an external laboratory. Does your company utilize Third Parties to complete a portion of or all of the GMP related activities? Yes, these are according to the requirements of food GMP.	
Calibration	In-house
Testing of incoming materials	In-house
Testing of In-process materials	In-house
Final release testing	In-house (and/or external laboratory)
Microbiological Testing	External accredited laboratory
Heavy Metal Testing	External ISO certified laboratory

Retain sample policy:

We store retain samples of Nutrinova® Sorbic Acid and Nutrinova® Potassium Sorbate for 4 years from date of manufacture.

5.3. Microbiological Properties

Nutrinova® Sorbic Acid and Nutrinova® Potassium Sorbate are produced synthetically and are virtually free from microorganisms. Any viable microorganisms are killed at temperatures occurring during production and subsequent drying. The products are virtually free from water; therefore, it is very unlikely that microorganisms can grow in sorbates. In addition, Sorbic Acid / Potassium Sorbate inhibit growth of several bacteria, moulds and yeasts.

Nutrinova® Sorbic Acid and Nutrinova® Potassium Sorbate are packed under hygienic conditions and all people involved in packing have been properly trained and wear required protective clothing.

Microbiological testing is conducted by Institute Fresenius, an external accredited laboratory according to the requirements of Ph. Eur. and USP-NF.

Microbiological Specification of Nutrinova® Sorbic Acid (E 200) and Nutrinova® Potassium Sorbate (E 202)

Property	CFU	
Total mesophilic counts	< 10 in	1 g
Yeasts	< 10 in	1 g
Moulds	< 10 in	1 g
Enterobacteriaceae	< 10 in	1 g
Staphylococcus aureus	negative in	1 g
Pseudomonas aeruginosa	negative in	1 g
Escherichia coli	negative in	1 g
Salmonellae	negative in	10 g

5.4. Food Grade Compliance

The food quality of Nutrinova® Sorbic Acid and Nutrinova® Potassium Sorbate fulfills the purity requirements of the FAO/WHO/CODEX/JECFA, those of the US Food Chemicals Codex (FCC) 12th edition, the JSFA 9th edition and the EU Commission Regulation 231/2012.

Nutrinova® Sorbic Acid and Nutrinova® Potassium Sorbate have been adopted by the FAO/WHO Codex Alimentarius Commission as food additive, is approved as preservative in the US according to 21CFR, in Japan according to the Japanese Food Sanitation Act and in the EU according to the Regulation (EC) No 1333/2008.

5.4.1 Product Specifications Food Grade

Please contact Celanese Sales Germany GmbH for the official product specification documents.

Nutrinova® Sorbic Acid – Food Grade – Chemical and physical properties

Definition

Chemical name	2,4-hexadienoic acid
CAS number	110-44-1
E number	E 200
EINECS number	203-768-7
Chemical formula	C ₆ H ₈ O ₂
Relative molecular mass	112.12

Description

White to yellowish-white crystalline powder
 Freely soluble in methanol and ethyl alcohol (approx. 129 g/L at 20 °C);
 Less soluble in water (approx. 1.2 g/L at 20 °C)

Identification

Ultra-violet absorption UV-Maximum 264 ± 2 nm (solution of 0.002 g/L in water at pH <3)

Purity

Assay	99,0 % to 101,0 % of C ₆ H ₈ O ₂ , on dry weight basis
Water Content	Not more than 0.5 % (Karl Fischer method)
Heat resistance	No discoloration after 90 minutes at 105 °C
Melting range	132 - 135 °C (FCC)
Sulfated ash	Not more than 0.1 %
Aldehydes	Not more than 0.1 % (as formaldehyde)
Heavy metals	Not more than 10 ppm (expressed as lead)
Lead	Not more than 0.1 ppm
Arsenic	Not more than 0.1 ppm
Mercury	Not more than 0.01 ppm
Cadmium	Not more than 0.02 ppm
Zinc	Not more than 0.1 ppm
Chloride	Not more than 100 ppm
Sulphate	Not more than 150 ppm

Shelf life

3 years from date of manufacture
 provided that the product is stored in the originally closed packaging,
 protected from sunlight, at ambient temperature (max. 30 °C) and dry
 conditions (max. 65 % relative humidity)

Nutrinova® Sorbic Acid conforms to the specifications published by FAO/WHO/CODEX/JECFA, those of the US Food Chemicals Codex, of the JSFA and/or the EC as well as to national specifications published in food regulations for Sorbic Acid. Any existing legal restrictions for the use in foods, drugs and cosmetics must be observed by users of Nutrinova® Sorbic Acid.

The information presented herein is based on our present state of knowledge and is intended to provide general notes on our products and their uses. It must not be construed as guaranteeing specific properties of the products described herein or their suitability for a particular application. The user of Nutrinova® Sorbic Acid is solely responsible for investigating whether existing patents are infringed by the use of Nutrinova® Sorbic Acid. Additionally, the user is solely responsible for investigating and checking the regulatory approval status with respect to any intended use of Nutrinova® Sorbic Acid. Any sales and/or the deliveries of Nutrinova® Sorbic Acid are always subject to our General Terms and Conditions, unless otherwise agreed between the parties in writing. Any reference to laws, regulations, standards, guidelines etc. refers to such laws, regulations, standards, guidelines etc. as in force and effect as the date of this document.

Technical Note

The product may contain traces of potassium sorbate. The user is responsible for the microbiological stability of its products. The water used in the production of aqueous Sorbic acid solutions should not contain any reactive substances, such as free chlorine. We recommend following the hygienic requirements according to "Good Manufacturing Practice" (GMP).

Nutrinova® Potassium Sorbate – Food Grade – Chemical and physical properties

Definition

Chemical name	Potassium salt of 2,4-hexadienoic acid
CAS number	24634-61-5
EINECS number	246-376-1
E number	E 202
Chemical formula	C ₆ H ₇ KO ₂
Relative molecular mass	150.22

Description

White to yellowish-white crystalline powder or spherical granules
 Freely soluble in water (approx. 1400 g/L at 20 °C);
 less soluble in ethyl alcohol (approx. 1 g/L at 20 °C)

Identification

Ultra-violet absorption	UV-Maximum 264 ± 2 nm (solution of 0.002 g/L in water at pH <3)
Test for potassium	Positive

Purity

Assay	99,0 % to 101,0 % of C ₆ H ₇ KO ₂ , on dry weight basis
Loss on drying	Not more than 0.5 % (Karl Fischer method)
pH-value	8.5 – 10.5 (10 % water solution)
Heat resistance	No discoloration after 90 minutes at 105 °C
Melting range	132 - 135 °C (FCC) - based on the range of sorbic acid
Alkalinity (calc. as K ₂ CO ₃)	Not more than 0.1 %
Aldehydes	Not more than 0.1 % (as formaldehyde)
Heavy metals	Not more than 10 ppm (expressed as lead)
Lead	Not more than 0.1 ppm
Arsenic	Not more than 0.1 ppm
Mercury	Not more than 0.01 ppm
Cadmium	Not more than 0.02 ppm
Zinc	Not more than 0.1 ppm
Chloride	Not more than 100 ppm
Sulphate	Not more than 150 ppm

Shelf life

3 years from date of manufacture
 provided that the product is stored in the originally closed packaging,
 protected from sunlight and at ambient temperature (max. 30 °C)
 and under dry conditions (max. 65 % relative humidity)

Nutrinova® Potassium Sorbate conforms also to the specifications published by FAO/WHO/CODEX/JECFA, those of the US Food Chemicals Codex, of the JSFA and/or the EC as well as to national specifications published in food regulations for Potassium Sorbate. Any existing legal restrictions for the use in foods, drugs and cosmetics must be observed by users of Nutrinova® Potassium Sorbate.

The information presented herein is based on our present state of knowledge and is intended to provide general notes on our products and their uses. It must not be construed as guaranteeing specific properties of the products described herein or their suitability for a particular application. The user of Nutrinova® Potassium Sorbate is solely responsible for investigating whether existing patents are infringed by the use of Nutrinova® Potassium Sorbate. Additionally, the user is solely responsible for investigating and checking the regulatory approval status with respect to any intended use of Nutrinova® Potassium Sorbate. Any sales and/or the deliveries of Nutrinova® Potassium Sorbate are always subject to our General Terms and Conditions, unless otherwise agreed between the parties in writing. Any reference to laws, regulations, standards, guidelines etc. refers to such laws, regulations, standards, guidelines etc. as in force and effect as the date of this document.

Technical Note

The product may contain traces of sorbic acid. The user is responsible for the microbiological stability of its products. The water used in the production of aqueous Sorbate solutions should not contain any reactive substances, such as free chlorine. We recommend following the hygienic requirements according to "Good Manufacturing Practice" (GMP).

5.4.2 Certificate of Analysis Food Grade (examples)

Certificate of Analysis

Nutrinova® Sorbic Acid; 40 x 25 kg sack on pallet

Cert Issue Date: 13 Nov 2019

Material No.: 20008714

Produced at: Frankfurt am Main

Produced on: 17 Sep 2019

Best before date: 16 Sep 2022

Country of origin: Germany

Batch 0001260092

Characteristic	(Method)	UoM	Value	
Abs. max. (in Water)	(UV)	nm	263,0	262,0 - 266,0
Appearance	VISUAL		white, crystalline powder	
Assay	(FCC, Titrimetric)	%	100,4	99,0 - 101,0
Heat Test (90 min/105°C)	(EC)		no discoloration	
Identity Sorbic acid	(UV)		Pass	
Water content	(Karl Fischer)	%	0,21	max. 0,50

The following values are based upon statistical evaluation and are adhered to with each batch.

Aldehydes (as Formaldehyde)	(FCC, Limit-Test)	%	< 0,10	max. 0,10
Heavy metals (calc. as lead)	(Limit-Test)	ppm	< 10	max. 10
Lead	(ICP MS)	ppm	< limit of detection	0,02 - 0,10
Arsenic	(ICP MS)	ppm	< limit of detection	0,02 - 0,10
Mercury	(AAS)	ppm	< limit of detection	0,01 - 0,01
Cadmium	(ICP MS)	ppm	< limit of detection	0,02 - 0,02
Zinc	(ICP MS)	ppm	< limit of detection	0,04 - 0,10
Chloride	(IC)	ppm	25,8	0,0 - 100,0
Sulfate	(IC)	ppm	26,9	0,0 - 150,0
Melting Range	(FCC)	°C	Pass	132 - 135
Residue on Ignition	(FCC)	%	< 0,10	max. 0,10

Manufacturer (registered office address):
Celanese Production Germany GmbH & Co. KG, Am Unisys-Park 1, 65843 Sulzbach (Taunus), Germany

Certificate of Analysis

Nutrinova® Potassium Sorbate Granular; 40 x 25 kg sack on pallet

Cert Issue Date: 13 Nov 2019

Material No.: 20008709
 Produced at: Frankfurt am Main
 Produced on: 24 Sep 2019
 Best before date: 23 Sep 2022
 Country of origin: Germany

Batch 0001260968

Characteristic	(Method)	UoM	Value	
Abs. max. (In Water)	(UV)	nm	264,8	262,0 - 266,0
Alkalinity (calc. as K ₂ CO ₃)	(FCC, Titrimetric)	%	0,05	max. 0,10
Appearance	VISUAL			white to yellowish-white granular
Assay	(FCC, Titrimetric)	%	100,3	99,0 - 101,0
Heat Test (90 min/105°C)	(EC)			no discoloration
Identity Potassium	(FAO / WHO)			Pass
Identity Sorbate	(UV)			Pass
pH-value (10% solution)	(potentiometric)		9,9	8,5 - 10,5
Water content	(Karl Fischer)	%	0,10	max. 0,50

The following values are based upon statistical evaluation and are adhered to with each batch.

Aldehydes (as Formaldehyde)	(FCC, Limit-Test)	%	< 0,10	max. 0,10
Heavy metals (calc. as lead)	(Limit-Test)	ppm	< 10	max. 10
Lead	(ICP MS)	ppm	< limit of detection	0,02 - 0,10
Arsenic	(ICP MS)	ppm	< limit of detection	0,02 - 0,10
Mercury	(AAS)	ppm	< limit of detection	0,01 - 0,01
Cadmium	(ICP MS)	ppm	< limit of detection	0,02 - 0,02
Zinc	(ICP MS)	ppm	< limit of detection	0,04 - 0,10
Chloride	(IC)	ppm	25,8	0,0 - 100,0
Sulfate	(IC)	ppm	< 150,0	0,0 - 150,0

Manufacturer (registered office address):

5.5. Pharma Grade Compliance

Nutrinova® Sorbates are conforming to the monographs published by the European Pharmacopoeia, US Pharmacopoeia and other national Pharmacopoeias. for Sorbates. Following please find our Celanese Specification and examples of the Certificate of Analysis:

5.5.1 Product Specifications Pharma Grade

Please contact Celanese Sales Germany GmbH for the official product specification documents.

Nutrinova® Sorbic Acid – Pharma Grade – Chemical and physical properties according to European Pharmacopoeia 10.0* and US Pharmacopoeia 43-NF 38*

Definition

Chemical name	(2E,4E)-Hexa-2, 4-dienoic acid; (E, E)-Sorbic Acid
CAS number	110-44-1
Chemical formula	C ₆ H ₈ O ₂
Relative molecular mass	112.13 (USP-NF)

Description

White to yellowish-white crystalline powder
 Freely soluble in methanol and ethyl alcohol (approx. 129 g/L at 20 °C);
 less soluble in water (approx. 1.2 g/L at 20 °C)

Identification

Ultra-violet absorption	UV-Maximum 264 ± 2 nm (solution of 0.002 g/L in water at pH <3)
IR-spectrum	Complies with reference spectrum

Pharma specific tests

Appearance of solution:	Clear and colourless
Aldehydes	Not more than 0.15 % (as acetaldehyde) (C ₂ H ₄ O)
Identification (double bonds)	Positive (USP)
Residual solvents:	According to the requirements of the USP

Purity

Assay	99,0 % to 101,0 % of C ₆ H ₈ O ₂ , on the anhydrous basis (Ph Eur) 98,0 % to 102,0 % of C ₆ H ₈ O ₂ , on the anhydrous basis (USP-NF)
Water content	Not more than 0.5 % (Karl Fischer method)
Heat resistance	No discoloration after 90 minutes at 105 °C
Melting range	132 - 135 °C (USP-NF)
Sulfated ash	Not more than 0.1 %
Heavy metals	Not more than 10 ppm (expressed as lead)
Lead	Not more than 0.1 ppm
Arsenic	Not more than 0.1 ppm
Mercury	Not more than 0.01 ppm
Cadmium	Not more than 0.02 ppm
Zinc	Not more than 0.1 ppm
Chloride	Not more than 100 ppm
Sulphate	Not more than 150 ppm

Microbiology

Total mesophilic counts	< 10 KBE in 1 g
Yeasts	< 10 KBE in 1 g
Moulds	< 10 KBE in 1 g
Enterobacteriaceae	< 10 KBE in 1 g
Staphylococcus aureus	negative in 1 g
Pseudomonas aeruginosa	negative in 1 g
Escherichia coli	negative in 1 g
Salmonellae	negative in 10 g

Shelf life

3 years from date of manufacture
 provided that the product is stored in the originally closed packaging,
 protected from sunlight and at ambient temperature (max. 30 °C)
 and under dry conditions (max. 65 % relative humidity)

Nutrinova® Potassium Sorbate - Pharma Grade – Chemical and physical properties according to European Pharmacopoeia 10.0* and US Pharmacopoeia 43-NF 38*

Definition

Chemical name	2,4-Hexadienoic acid, (E,E)-, potassium salt; Potassium (2E,4E)-hexa-2,4-dienoate; Potassium (E,E)-sorbate
CAS number	24634-61-5; 590-00-1
Chemical formula	C ₆ H ₇ KO ₂
Relative molecular mass	150.22

Description

White to yellowish-white crystalline powder or spherical granules
 Freely soluble in water (approx. 1400 g/L at 20 °C);
 less soluble in ethyl alcohol (approx. 1 g/L at 20 °C)

Identification

Ultra-violet absorption	UV-Maximum 264 ± 2 nm (solution of 0.002 g/L in water at pH <3)
IR-spectrum	Complies with reference spectrum
Test for potassium	Positive

Pharma specific tests

Appearance of solution	Clear and colourless
Acidity (calc. as Sorbic Acid)	Not more than 0.1 %
Alkalinity (calc. as K ₂ CO ₃)	Not more than 0.1 %
Aldehyde	Not more than 0.15 %, as acetaldehyde (C ₂ H ₄ O)
Identification (double bonds)	Positive (USP)
Residual solvents	According to the requirements of the USP

Purity

Assay	99,0 % to 101,0 % of C ₆ H ₇ KO ₂ , on dry weight basis (Ph Eur) 98,0 % to 102,0 % of C ₆ H ₇ KO ₂ , on dry weight basis (USP-NF)
Loss on drying	Not more than 0.5 % (Karl Fischer method)
pH-value	8.5 – 10.5 (10 % water solution)
Heat resistance	No discoloration after 90 minutes at 105 °C
Melting range	132 - 135 °C (USP-NF) - based on the range of sorbic acid
Heavy metals	Not more than 10 ppm (expressed as lead)
Lead	Not more than 0.1 ppm
Arsenic	Not more than 0.1 ppm
Mercury	Not more than 0.01 ppm
Cadmium	Not more than 0.02 ppm
Zinc	Not more than 0.1 ppm
Potassium	24,5 % - 27,6 %
Chloride	Not more than 100 ppm
Sulphate	Not more than 150 ppm

Microbiology

Total mesophilic counts	< 10 KBE in 1 g
Yeasts	< 10 KBE in 1 g
Moulds	< 10 KBE in 1 g
Enterobacteriaceae	< 10 KBE in 1 g
Staphylococcus aureus	negative in 1 g
Pseudomonas aeruginosa	negative in 1 g
Escherichia coli	negative in 1 g
Salmonellae	negative in 10 g

The chemistry inside innova

Shelf life

3 years from date of manufacture
 provided that the product is stored in the originally closed packaging,
 protected from sunlight and at ambient temperature (max. 30 °C)
 and under dry conditions (max. 65 % relative humidity)

5.5.2 Certificate of Analysis Pharma Grade (examples)

Deliveries are accompanied by the product-related Certificate of Analysis, following please find examples:

Certificate of Analysis

Nutrinova® Sorbic Acid Pharma Grade; 40 x 25 kg sack on pallet

Cert Issue Date: 13 Nov 2019

Material No.: 20008717

Produced at: Frankfurt am Main

Produced on: 16 Feb 2018

Best before date: 15 Feb 2021

Country of origin: Germany

Batch 0001036214

Characteristic	(Method)	UoM	Value	
Abs. max. (In Isopropanol)	(UV)	nm	254,5	252,0 - 256,0
Abs. max. (In Water)	(UV)	nm	263,2	262,0 - 266,0
Aldehydes (as Acetaldehyde)	(EP, Limit-Test)	%	< 0,15	max. 0,15
Appearance	VISUAL		white, crystalline powder	
Appearance of Solution	(EP)		clear and colourless	
Ash content (Sulfatash)	(EP / USP)	%	0,05	max. 0,10
Assay	(FCC, Titrimetric)	%	99,8	99,0 - 101,0
Colour	VISUAL		Pass	
Heat Test (90 min/105°C)	(EC)		no discoloration	
Heavy metals (calc. as lead)	(Limit-Test)	ppm	< 10	max. 10
Identification Double Bonds	(USP)		Pass	
Identity Sorbic acid	(UV)		Pass	
IR spectrum	(EP, IR)		Pass	
Melting point	(FAO / WHO)	°C	133,4	132,0 - 135,0
Residual solvents	(USP,GC)		Pass	
Water content	(Karl Fischer)	%	0,24	max. 0,50

The following values are based upon statistical evaluation and are adhered to with each batch.

Total mesophilic counts	(PH.EUR)	< 10 CFU / 1g
Moulds	(PH.EUR)	< 10 CFU / 1g
Yeasts	(PH.EUR)	< 10 CFU / 1g
Staphylococcus aureus	(PH.EUR)	neg. / 1g

Enterobacteriaceae	(PHEUR)		< 10 CFU / 1g	
Pseudomonas aeruginosa	(PHEUR)		neg. / 1g	
Escherichia coli	(PHEUR)		neg. / 1g	
Salmonella bacilli	(PHEUR)		neg. / 10g	
Lead	(ICP MS)	ppm	< limit of detection	0,02 - 0,10
Arsenic	(ICP MS)	ppm	< limit of detection	0,02 - 0,10
Mercury	(AAS)	ppm	< limit of detection	0,01 - 0,01
Cadmium	(ICP MS)	ppm	< limit of detection	0,02 - 0,02
Zinc	(ICP MS)	ppm	< limit of detection	0,04 - 0,10
Chloride	(IC)	ppm	25,8	0,0 - 100,0
Sulfate	(IC)	ppm	26,9	0,0 - 150,0

Manufacturer (registered office address):

Celanese Production Germany GmbH & Co. KG, Am Unisys-Park 1, 65843 Sulzbach (Taunus), Germany

Production Facility: Sorbates Plant, Building D 420, Industriepark Höchst, 65926 Frankfurt / Main, Germany.

Nutrinova® Potassium Sorbate Granular Pharma Grade; 40 x 25 kg sack on pallet

Cert issue Date: 16 Mar 2018

Material No.: 20008711
 Produced at: Frankfurt am Main
 Produced on: 19 Oct 2017
 Best before date: 18 Oct 2020
 Country of origin: Germany

Batch 0000996436

Characteristic	(Method)	UoM	Value	
Abs. max. (in Water)	(UV)	nm	263,0	262,0 - 266,0
Acidity (calc. as Sorbic Acid)	(FCC, Titrimetric)	%	0,00	max. 0,10
Aldehydes (as Acetaldehyde)	(EP, Limit-Test)	%	< 0,15	max. 0,15
Alkalinity (calc. as K ₂ CO ₃)	(FCC, Titrimetric)	%	0,04	max. 0,10
Appearance	VISUAL		white to yellowish-white granular	
Appearance of Solution	(EP)		clear and colourless	
Assay	(FCC, Titrimetric)	%	100,0	99,0 - 101,0
Colour	VISUAL		Pass	
Heat Test (90 min/105°C)	(EC)		no discoloration	
Heavy metals (calc. as lead)	(Limit-Test)	ppm	< 10	max. 10
Identification Double Bonds	(USP)		Pass	
Identity Potassium	(FAO / WHO)		Pass	
Identity Sorbate	(UV)		Pass	
IR spectrum	(EP, IR)		Pass	
Loss on drying (3h/105°C)	(EP)	%	0,06	max. 0,50
Melting point	(FAO / WHO)	°C	132,2	132,0 - 135,0
Residual solvents	(USP, GC)		Pass	
pH-value (10% solution)	(potentiometric)		9,8	8,5 - 10,5

The following values are based upon statistical evaluation and are adhered to with each batch.

Total mesophilic counts	(PHEUR)		< 10 CFU / 1g	
Moulds	(PHEUR)		< 10 CFU / 1g	
Yeasts	(PHEUR)		< 10 CFU / 1g	
Staphylococcus aureus	(PHEUR)		neg. / 1g	
Enterobacteriaceae	(PHEUR)		< 10 CFU / 1g	
Pseudomonas aeruginosa	(PHEUR)		neg. / 1g	
Escherichia coli	(PHEUR)		neg. / 1g	
Salmonella bacilli	(PHEUR)		neg. / 10g	
Lead	(ICP MS)	ppm	< limit of detection	0,02 - 0,10
Arsenic	(ICP MS)	ppm	< limit of detection	0,02 - 0,10
Mercury	(AAS)	ppm	< limit of detection	0,01 - 0,01
Cadmium	(ICP MS)	ppm	< limit of detection	0,02 - 0,02
Zinc	(ICP MS)	ppm	< limit of detection	0,04 - 0,10
Chloride	(IC, JSFA)	ppm	25,8	0,0 - 100,0
Sulfate	(IC)	ppm	26,9	0,0 - 150,0

Manufacturer (registered office address):

Celanese Production Germany GmbH & Co. KG, Am Unisys-Park 1, 65843 Sulzbach (Taunus), Germany

Production Facility: Sorbates Plant, Building D 420, Industriepark Höchst, 65926 Frankfurt / Main, Germany.

Methods are validated against official PHEUR. and USP methods.

Nutrinova® Potassium Sorbate Pharma Grade meets the requirements of the European Pharmacopoeia 9.0, the US Pharmacopoeia 40-NF 35 and the Monograph of the Japanese Pharmaceutical Excipients (JPE) in the updated version.

5.5.3 Compliance to ICH Q3C Guideline for Residual Solvents

According to the ICH Guideline for residual solvents (Q3C), EMA/CHMP/ICH/82260/2006, hereby we confirm, that no Class 1, no Class 2 or other Residual Solvents listed in Table 4 are likely to be present in our product.

Acetone as a Class 3 solvent is used in the manufacturing process. The limit for Acetone according to CPMP/ICH/283/95 is max. 5000 ppm. The level found in Nutrinova® Sorbates is less than 200 ppm.

5.5.4 Compliance to ICH Q3D Guideline for Elemental Impurities

Nutrinova® Potassium Sorbate and Nutrinova® Sorbic Acid are fully in compliance with the ICH Q3D Guideline EMA/CHMP/ICH/353369/2013 ("Guideline on elemental impurities") and its implementation in USP-NF and Ph Eur.

5.5.5 Specification Limits for Residues of Metal Catalysts or Metal Reagents

In accordance to the Guideline EMEA/CHMP/SWP/4446/2000 (The European Agency for the Evaluation of Medicinal Products Evaluation of Medicines for Human Use), zinc (Zn)-compounds are used as metal catalysts (Class 3-Classification) in the Nutrinova® Sorbates production process.

5.6. Allergens in Foods

Allergens (Question & Answers)	
Do these products contain animal or plant-derived ingredients?	No, Nutrinova® Sorbic Acid and Potassium Sorbate are manufactured synthetically without using animal or plant-derived ingredients.
Do these products contain any ingredients identified as allergens?	No, Nutrinova® Sorbic Acid and Potassium Sorbate are manufactured synthetically without using ingredients identified as allergens.
Is a cross-contamination possible?	No, Nutrinova® Sorbic Acid and Potassium Sorbate are manufactured synthetically in a dedicated plant. A potential cross-contamination during mixing, filling, packaging and storage can be ruled out because none of the allergens listed below nor products containing allergens as listed below are handled during manufacture and storage in the production side.

Nutrinova® Sorbic Acid and Nutrinova® Potassium Sorbate comply with the EU-Regulation 1169/2011, the US Food Allergen Labeling and Consumer Protection Act and the Japanese Food Labeling Act as part of the Food Sanitation Act, and does not contain any ingredients listed as following:

- Cereals containing gluten namely wheat, rye, barley, oats, spelt, kamut or their hybridized strains, and products thereof
- Crustaceans and products thereof
- Eggs and products thereof
- Fish and products thereof
- Peanuts and products thereof
- Soybeans and products thereof
- Milk and products thereof (including lactose)
- Nuts, namely: almonds (*Amygdalus communis* L.), hazelnuts (*Corylus avellana*), walnuts (*Juglans regia*), cashews (*Anacardium occidentale*), pecan nuts (*Carya illinoensis* (Wangenh) K. Koch), Brazil nuts (*Bertholletia excelsa*), pistachio nuts (*Pistacia vera*), macadamia or Queensland nuts (*Macadamia ternifolia*), and products thereof

- Celery and products thereof
- Mustard and products thereof
- Sesame seeds and products thereof
- Sulphur dioxide and sulphites
- Lupin and products thereof
- Molluscs and products thereof
- Fabaceae or Leguminosae including chick peas
- Other materials with high allergenic potential

Furthermore, Nutrinova® Sorbic Acid and Nutrinova® Potassium Sorbate do not contain any of the following substances or products thereof:

garlic	buckwheat	coconut	seasonings
millet	stone fruits	pine nut	rice
vanillin	glutamate	benzoic acid	maize

5.7. Genetically Modified Organisms (GMO)

Nutrinova® Sorbates contain no genetically modified organisms (GMO) or components and are not obtained from genetically modified crops.

The starting materials employed in the production of our food ingredients have not been manufactured by the use of genetically modified micro-organisms. Thus our products are not obliged to be labeled according to EU Regulations 1829/2003 and 1830/2003 respectively nor according to the Japanese Food Sanitation Act.

5.8. Nutritional Information

Nutrinova® Sorbic Acid has the following nutritional values:

Based on 100 g	Sorbic Acid
Energy value (kcal)/Energy value (KJ)	330*/1380*
Total Carbohydrates (g)	0
• Dietary fiber	0
• Sugars/Added Sugars	0
Fat (g)	0
Cholesterol (mg)	0
Protein (g)	0
Sodium (g)	0
Potassium (g)	0
Calcium (g)	0
Iron (g)	0
Vitamin D	0

* based on literature data: Sorbic acid is a polyunsaturated fatty acid which is metabolized like other fatty acids with 27,6 kJ/g but in biological examination only 50 % are digestible (reference: E. Lück: Chemische Lebensmittelkonservierung, Heidelberg, Springer Verlag)

Nutrinova® Potassium Sorbate has the following nutritional values:

Based on 100 g	Potassium Sorbate
Energy value (kcal)/Energy value (KJ)	246*/1030*
Total Carbohydrates (g)	0
• Dietary fiber	0
• Sugars/Added Sugars	0
Fat (g)	0
Cholesterol (mg)	0
Protein (g)	0
Sodium (g)	0
Potassium (g)	26
Calcium (g)	0
Iron (g)	0
Vitamin D (g)	0

* based on literature data: Potassium Sorbate/Sorbic acid is a polyunsaturated fatty acid which is metabolized like other fatty acids with 27,6 kJ/g but in biological examination only 50 % are digestible (reference: E. Lück: Chemische Lebensmittelkonservierung, Heidelberg, Springer Verlag)

5.9. Vegan Statement

Nutrinova® Sorbates are manufactured without the use of animal matter or products derived from animal origin. At no stage of production and processing, use has been made of products of animal origin including:

- ingredients (including additives, carriers, aromas, fragrances, flavorings and enzymes) or
- processing aids or
- substances which are not additives but are used in the same way and with the same purpose as processing aids

This comprises especially:

- No meat or any other slaughter products, e.g. offal
- No fish or any other marine animals
- No eggs
- No honey
- No milk
- No wax of animals such as wool fat/lanoline, beeswax or shellac
- No fur, no leather, no silk
- No royal jelly
- No colouring agents of animal origin
- No substances, which were bleached with animal charcoal
- No substances, which were clarified with animal substances such as gelatin or fish bladder
- No substances manufactured, obtained or produced from the above-mentioned substances.

In addition, the raw materials used for the manufacture of Nutrinova® Sorbates are ketene, crotonaldehyde and potassium hydroxide. The production process can be divided into the following steps:

- Chemical synthesis
- Purification
- Drying
- Packaging
- Storage
- Shipment

5.10. Absence of specific substances

Nutrinova® Sorbates are manufactured without the use of the following substances nor do contain them:

5.10.1 Non-containing Dioxins, PCBs or PAHs

Our products comply to Commission Regulation (EC) No. 1881/2006 and do not contain Dioxins (PCDD / FCDF) or PCBs nor polycyclic aromatic hydrocarbons.

5.10.2 Mycotoxin Data

Nutrinova® Sorbic Acid and Nutrinova® Potassium Sorbate are produced synthetically without use of agricultural raw materials, which excludes the contamination by mycotoxins.

Mycotoxin	Does the product conform to legislative maximum levels?		
	YES	NO	N/A
Total Aflatoxins			X
Aflatoxin B1			X
Ochratoxin A			X
Patulin (Apples only)			X

5.10.3 Nitrofen

Nutrinova® Sorbic Acid and Nutrinova® Potassium Sorbate do not contain any Nitrofen.

5.10.4 Latex

Latex is not used during the manufacturing process. Nutrinova® Sorbic Acid and Nutrinova® Potassium Sorbate do not contain any Latex.

5.10.5 Compliance with the California Proposition 65

Proposition 65 includes chemicals known to the state of California to cause cancer or reproductive toxicity. Nutrinova® Sorbic Acid and Nutrinova® Potassium Sorbate are not carcinogenic or reproductive toxicant, therefore, they are not listed in the Proposition 65 list, therefore, do not require a warning label.

5.10.6 Compliance with Toxic Substance Control Act (TSCA)

Nutrinova® Sorbic Acid and Nutrinova® Potassium Sorbate comply with all applicable rules or orders under TSCA. Celanese Food Ingredients is not offering a chemical substance for entry in violation of TSCA or any applicable rule or order under TSCA.

5.10.7 Non-containing Substances mentioned in the Prohibited List of WADA

None of the substances mentioned in the World Anti-Doping Agency (WADA) code of prohibited substances are present in Nutrinova® Sorbates. As Nutrinova® Sorbates are manufactured synthetically in a dedicated plant, a cross-contamination with any substances mentioned in the WADA code of prohibited substances can also be ruled out.

5.10.8 Palm Oil

Palm oil, palm kernel oil and/or palm oil derivatives are not used in the manufacturing process, furthermore these are not stored in our manufacturing plant nor in our warehouse, so a cross-contamination can be ruled out.

5.10.9 Transmitting Animal Spongiform Encephalopathy / Certificate of Suitability

Nutrinova® Sorbates are manufactured synthetically in a dedicated plant, not used for any other purpose. All raw materials used are of petrochemicals and inorganic chemicals and no animal/ruminant material is used.

Therefore, guideline EMA/410/01 (as revised) on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products and a Certificate of Suitability are not applicable for our products.

5.11. Animal Non-Testing Declaration

Nutrinova® Sorbic Acid and Nutrinova® Potassium Sorbate have not been subjected to animal testing for cosmetic or toiletry applications by our company or tested on its behalf after January 1st, 1998, nor do they contain any material from animal origin.

6. QUALITY AND FOOD SAFETY MANAGEMENT SYSTEM

6.1. DIN EN ISO Certification

Celanese Food Ingredients, including the Sorbic Acid Plant, has been certified according to the requirements of DIN EN ISO 9001:2015, DIN EN ISO 14001:2015 both since 1997, FSSC 22000, version 4.1 (DIN EN ISO 22000:2005, ISO/TS 22002-1:2009 and additional FSSC 22000 requirements) and Food Defense of IFS Food Standard, version 6 of chapter 6. The current certificates are available at

<http://www.celanese.com/food-ingredients/products/Nutrinova-Sorbic-Acid/media-literature.aspx>.

6.2. Good Manufacturing Practice (GMP) of Nutrinova® Sorbates

The manufacture, filling, packaging and storage of our products are conducted according to the regulations of Current Good Manufacturing Practice (GMP) in Manufacturing, Packing, or Holding Human Food (21 CFR Part 110 and 21 CFR Part 117). Thus, Celanese Food Ingredients provides a very high standard of food safety and hygiene during all processing, filling and storage steps. Our safety and hygiene system were inspected according to the requirements of FSSC 22000 standard.

6.3. HACCP

The Celanese Food Ingredients Hazards Analysis Critical Control Point (HACCP) system is based upon the principles of the HACCP system of Codex Alimentarius (ALI-Norm 97/13, Annex 2, created by FAO/WHO), an internationally accepted standard for food and food safety. It also fulfills the HACCP requirements of British Retail Consortium Standard (BRC) and ISO 22.000. Additionally, HACCP is part of the external GFSI recognized FSSC 22000 certification and the Celanese Food Ingredients HACCP system and plan is external audited yearly.

- PRINCIPLE 1: Conduct a hazard analysis
- PRINCIPLE 2: Determine the Critical Control Points (CCP's)
- PRINCIPLE 3: Establish critical limit(s)
- PRINCIPLE 4: Establish a system to monitor control of the CCP
- PRINCIPLE 5: Establish the corrective action to be taken when monitoring indicates it that a particular CCP is not under control
- PRINCIPLE 6: Establish procedures for verification to confirm that the HACCP system is working effectively
- PRINCIPLE 7: Establish documentation concerning all procedures and records appropriate to these principles and their application

A HACCP team is responsible for implementing and maintaining the Celanese Food Ingredients HACCP system. They will have to check if the HACCP system is working correctly and effectively. In relation to this, audits of the HACCP system are conducted by internal auditors at least once a year. The Board of Management and HACCP teams are kept informed about the results by an audit report as well as during the yearly management review.

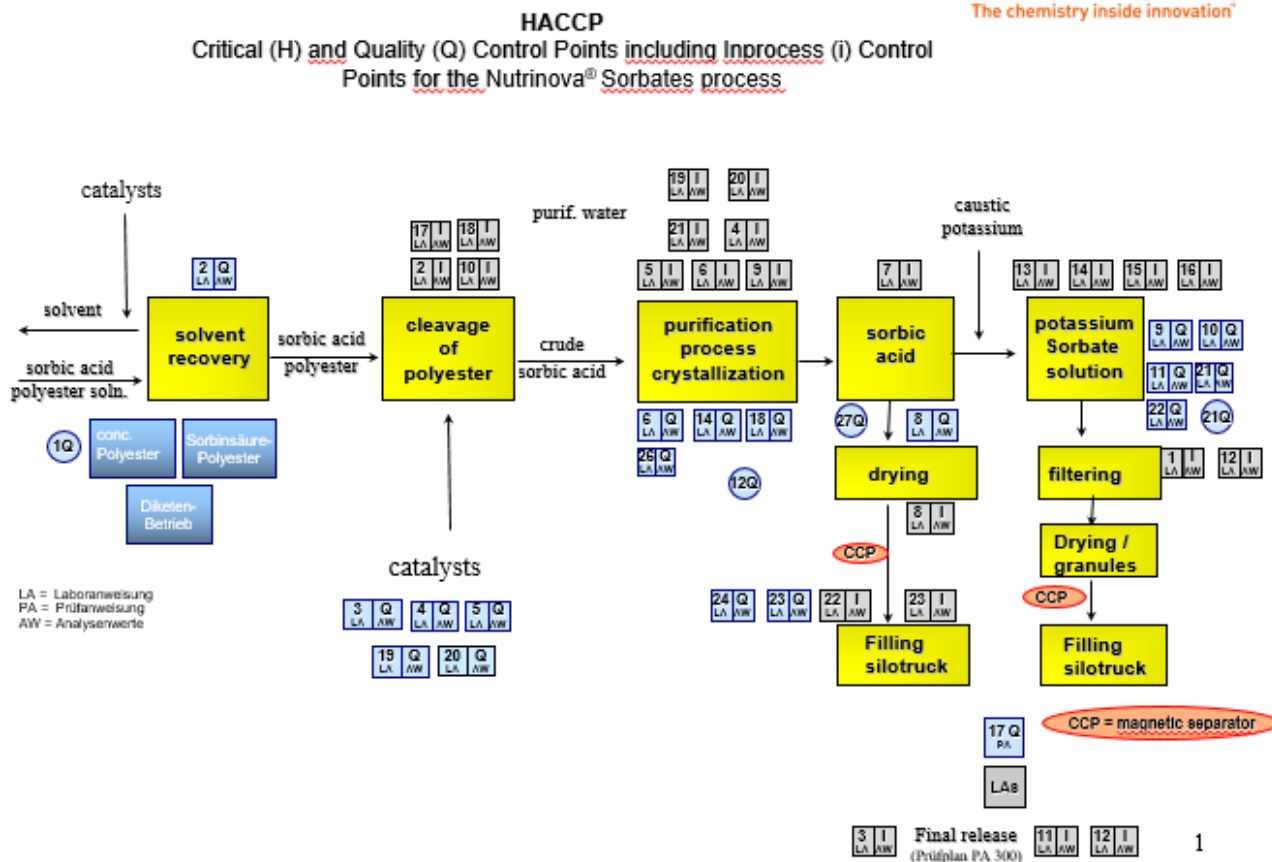
The Celanese Food Ingredients HACCP system is validated routinely by the multi-disciplinary team. Within this scope comprehensive reviews of particular hazard analysis and HACCP plan are conducted. The defined critical limit of particular Critical Control Points (CCP's) and Quality Control Points (QCP's) are validated and fitted accordingly, if appropriate. The CCP's and QCP's are checked on accuracy. In the case of changes and/or new information, it will be necessary to check whether the HACCP system and/or hazard analysis will also need to be changed. If so, an adoption of the HACCP plan and system will be conducted and documented.

According to the HACCP concept, testing plans and regulations are established to detect and prevent errors. This procedure maintains a high standard of hygiene and safety:

- Spatial separation of the production and the filling areas
- Regular cleaning according to approved cleaning SOPs
- Personal hygiene
- Protective filtering
- Metal detectors / metal separators / sieves
- Glass and plastic policy
- Hygiene controls of the filling area
- Microbiological control

The determined particular Critical Control Point (CCP's) of Nutrinova® Sorbates in the production is:

- metal detection and magnetic separation at the end of the filling process



6.4. Shelf life Certificate Nutrinova® Sorbates and Stability Testing Program (IPEC)

The shelf life of Nutrinova® Sorbic Acid and Potassium Sorbate is

3 years from date of manufacture

provided that the product is stored in the originally closed packaging, protected from sunlight, at ambient temperature (max. 30 °C) and dry conditions (max. 65 % relative humidity).

Stability Testing Program is done according to the “Good Manufacturing Practise Guide for Bulk Pharmaceutical Excipients” of the International Pharmaceutical Excipients Councils (IPEC, version 2017, Chapter 8.2.4.7).

It is a documented testing and evaluation program in place to assess the stability characteristics of the excipients Nutrinova® Sorbic Acid and Potassium Sorbate. The results of the stability testing are used in determining appropriate storage conditions and re-evaluation or expiration dates. The testing program is on-going and includes the following:

- The number of lots, sample sizes and test intervals
- Storage conditions and test methods sufficient to indicate stability
- Storage of the excipients Nutrinova® Sorbic Acid and Potassium Sorbate in original closed packaging.

6.5. Supplier Approval

Only approved suppliers are allowed to deliver packaging and raw materials. Suppliers will be approved according to the Standard Operation Procedure (SOP) for supplier approval which includes questionnaires, audits, samples/ analytical control, product specification, etc. In addition, the incoming packaging and raw materials are controlled according to the SOP for packaging and raw material testing SOP's. All approved suppliers are listed and communicated to the proper departments.

6.6. Sustainability

Celanese is a registered supplier on EcoVadis for Corporate Social Responsibility (CSR). Our manufacturing site in Frankfurt is certified according to SEDEX standard (also CSR), ISO 50001 (Energy Management System) and ISO 14001 (Environmental Management System). Official certificates are available on <http://www.celanese.com/food-ingredients/products/Nutrinova-Sorbic-Acid/media-literature.aspx>.

6.7. Kosher Certification

The processing, filling and packaging are regularly inspected by an authorized and globally recognized Rabbinat. The current Kosher Lamahdrin (Parve) and Passover certificate is available on <http://www.celanese.com/food-ingredients/products/Nutrinova-Sorbic-Acid/media-literature.aspx>.

6.8. Halal Certification

The processing, filling and packaging are regularly inspected by an authorized and globally recognized Halal organization. The current Halal certificate is available on <http://www.celanese.com/food-ingredients/products/Nutrinova-Sorbic-Acid/media-literature.aspx>.

6.9. Food Safety and Security Management System

Celanese Food Ingredients is committed to produce high quality and safe food additives. Official certificates are available on <http://www.celanese.com/food-ingredients/products/Nutrinova-Sorbic-Acid/media-literature.aspx>.

FSSC 22000*, version 4.1 (DIN EN ISO 22000:2005, ISO/TS 22002-1:2009 and additional FSSC 22000 requirements)

ISO 9001:2008 (Quality Management System)

ISO 14001:2015 (Environmental Management System)

ISO 22000:2005 (Food Safety Management System)

Food Defense of IFS Food (version 6 at chapter 6)

GMP (Good Manufacturing Practices)

GDP (Good Distribution Practices)

HACCP (Hazard Analysis and Critical Control Point)

EC Directive 178/2002 (Traceability)

USA Food Safety Modernization Act (2011)

FAMI QS Code of Practice (Version 5.1, 2014)

Risk Management

Control program for food safety and hygiene

Traceability of the product and its used raw materials, auxiliary materials and packaging materials up to 4 years

Purchase of raw, auxiliary and packaging materials only from approved suppliers

Customer audits upon request

Complete control of the manufacturing process

Crisis Management

Emergency Availability 24 hours 7 days a week

*FSSC 22000 is one of the most important GFSI-recognized certification programs for the Food industry. GFSI (Global Food Safety Initiative) is a global, industry wide set of standards and requirements that a certification program must meet (<https://mygfsi.com>).

7. FREQUENTLY ASKED QUESTIONS

Quality Assurance (QA)

Do you have a document that describes your quality systems, e.g. Quality Manual?	Yes
To whom does QA report within your organization?	To the Vice President Quality Celanese
Is QA independent of production?	Yes
Do you have an internal auditing system (i.e. self-inspection program)?	Yes
If so, please describe.	Internal audit schedule in place
Do you have a Supplier Evaluation Program?	Yes
Describe the method of evaluation (i.e. audit by mail etc.).	Questionnaire, audit, specification, analytical raw material release, etc.
Do you have an approved list of suppliers and which department is responsible for approving and disapproving suppliers?	Yes, Quality Management, Product Stewardship, Production & Purchasing
In case you supplied a customer with a defective product, would you or your distributor notify the customers and is there a recall procedure in place?	Yes, system for recall in place, a responsible person is available 24h / 7days Emergency number: + 49 (0) 69 305 6418
If so, please describe how products are recalled.	Crisis Management System in place
Describe your procedure to handle customer complaints?	SAP Complaint Management System
Are complaints investigated and records maintained on file?	Yes, two-weekly report to the management
Are deviations and non-conformances investigated, documented and filed?	Yes
Do you have a formalized documentation control system in place?	Yes

If yes, please describe this system.	Documentation Control System in place with approval documents
How long do you keep the analytical and the production records?	4 years
Who is responsible for the release of your product into the market?	Quality Manager
Does QA perform a batch record review? If so, is it part of your release decision?	Yes Yes
Does the product comply with the TSE Note for Guidance EMEA/410/01?	N/A*, synthetically manufactured product without using animals as source of material
Does the product comply with the ICH Q3C Guideline (Residual Solvents)?	Yes, Acetone (Class 3) is used during production, results for "Residual solvent" mentioned in CoA for Nutrinova® Sorbates Pharma Grade
Does the product comply with German Guideline "Aflatoxin VerbotsV dated 19.07.00"?	N/A*, synthetically manufactured product without use of agricultural raw materials, which excludes possible contamination by mycotoxins.

Analytical Control (QC, Quality Control)

Is QC independent of production?	Yes
What kind of laboratory facilities do you have?	Analytical Laboratory
Do you use any contract laboratory? If so, for which tests?	Yes 1) Institute SGS Fresenius, Taunusstein, Germany: <ul style="list-style-type: none"> • Microbiological testing 2) CLAS laboratory Industriepark Höchst, Germany: <ul style="list-style-type: none"> • Heavy metals testing • Residual Solvents testing
Have you qualified/ evaluated these contract laboratories?	YES

*N/A = Not applicable

Do you release incoming raw materials based on Supplier Certificates of Analysis (CoA)?	Yes
If so, do you perform any testing on your own?	Yes
Do you have procedures that define the control of raw materials?	Yes
Are there formal written procedures in place for all analyses performed?	Yes
Are the analytical methods used validated?	Yes
Please provide product specifications and test methods of the product in question.	Test methods are mentioned on CoA
Do you analyze according to the current Pharmacopoeia Testing Methods?	Yes, our methods are validated against the official Ph. Eur. and USP-NF methods.
If yes, according to which one, e.g. Ph. Eur., USP-NF?	Both Ph. Eur. and USP-NF
Will you provide a Certificate of Analysis (CoA) with each shipment, including actual analytical data to customer?	Yes
How long is the product stable and how do you assess the shelf life (i.e. are stability-testing data for the product in question available)?	3 years from date of manufacture, stability data according to IPEC guidelines
Which storage or handling conditions do you recommend for the product (temperature, humidity)?	Store in originally packaging, at ambient temperature (max. 30°C) and dry conditions (max. 65%) protected from direct sunlight.
Who performs the sampling and the testing of <ul style="list-style-type: none"> ▪ raw materials ▪ in-process checks and ▪ finished products 	Trained personal

Do you keep records of all samples entering the laboratories?	Yes
Do these records include <ul style="list-style-type: none"> ▪ date sample received ▪ identity of samples ▪ testing results ▪ date sample taken and ▪ name of person who took sample? 	Yes
Do you have procedures defining the handling of quality documents regarding <ul style="list-style-type: none"> ▪ update ▪ approval and ▪ use and archiving? 	Yes
How are Out-Of-Specification (OOS) results investigated and documented in the laboratories?	Via SAP system, process in place
Describe your procedure for analytical reagent standardization.	SOP in place
How do you assure that testing equipment is calibrated at appropriate intervals?	SOP in place
Describe any electronic data processing systems, which are used in the laboratory (i. e. LIMS).	SAP QM module
Are these systems validated?	Yes
What kind of water do you use in the laboratory?	Demineralized water
Please state the physical/ chemical and the micro-biological quality of this type of water.	Pharma filter in place, micro checks routinely done
How often do you control this type of water?	Once per month

**Production and Process
General Questions**

To whom does the production report within your organization?	To the Site Director Industrial Park Hoechst, Celanese
Do you manufacture/handle products of high activity or toxicity such as β -lactams, other antibiotics, cytotoxins or pesticides on the site?	No
Do you manufacture other products than the one being questioned in your manufacturing facility (Monoplant)?	No, this plant is dedicated for Nutrinova® Sorbates
Are <u>all</u> the manufacturing steps for the stated material performed at this site (including purification and packaging, etc.)?	Yes
Did you work out risk analysis of production processes using tools like HACCP?	Yes
If so, please give document reference number.	DQS certificate FSSC 22000 Registration No. 003122 FSSCV4
Do you issue a batch record for each batch/lot manufactured?	Yes
Is non-conforming final product ever mixed with conforming product to bring it into specification?	No
Is there a formal procedure for production deviations in place?	Yes
Who does approve such deviations?	SOP in place
Are room and equipment log books available?	Yes
Do all product containers bear identification labels, e.g. stating batch/lot number, product name, etc.?	Yes
How do you mark the status of your manufacturing equipment (e.g. <cleaned>, <calibrated>, <in use>)?	SOP in place
Describe the segregation and control of approved, quarantined and rejected material.	SAP positive release, red and green labels, separated storage areas

Do you have segregated dispensing areas for different raw materials?	Yes
Is there a maintenance and preventive maintenance program for all relevant pieces of equipment in place?	Yes
Describe your procedure for instrument calibration.	SOP in place
Are there written procedures and schedules covering these calibrations?	Yes
Are rest and eating areas separate from other areas?	Yes
Do you have a pest control program against rodents, vermin and other animals?	Yes, monitored monthly according to pest control program.

Product related Questions

Is your production process continuous or per batch?	Continuous production, batch size is defined as per filling of a silotruck (Potassium Sorbate) and as per filling of two silotrucks (Sorbic acid).
Do you use dedicated equipment for the production of the product in question?	Yes
Describe the convention used for batch or lot numbering.	SAP code
Does the lot number represent one homogenous production run?	Yes
Are there validated yield ranges for the manufacturing process?	Yes
Are deviations investigated and documented?	Yes
Are there cleaning procedures in place for each area and piece of equipment?	Yes
Are your manufacturing and cleaning processes validated?	Yes

Are manufacturing and cleaning procedures approved by QA?	Yes
Are there separate dust extraction facilities in areas where dust is generated?	N/A
Is compressed air filtered and dried? Please indicate type of filters.	Yes, Pharma filter
Do you clean the ventilation and dust extraction systems according to a defined plan and with which frequency?	Yes, according to SOP / cleaning schedule
Please state the different types of water used in production.	Only water according to German "Trinkwasserverordnung" (tap water regulation) purified and filtered
Please state the physical/ chemical and the micro-biological quality of this type of water.	According to German "Trinkwasserverordnung" (tap water regulation)
How often do you control this type of water?	Monthly
Describe any electronic data processing systems which are used in production.	SAP system Production control system
Is the product directly filled into the shipping pack after production and then stored until shipment or is the product first stored in containers and only filled into the shipping pack just before shipment?	Directly filled into final packaging. We have a contracted warehouse in Worms, Germany where the final products are stored until distribution.
What kind of containers do you use (fiber drums, inner linings etc.)?	25 kg PE-bags or 500/1000kg Big Bags Packaging materials are delivered with protective cover.
Are there special pre-cautions (e.g. nitrogen, desiccant for packing)?	No
What measures have you implemented to make sure that the product is not contaminated by foreign matters? Do you sieve the material before final packing? Do you use magnetic bars to remove metal particles?	Sieve, metal detection, permanent magnets
Under what conditions do you store the final product (temperature, humidity)?	Ambient temperature (max 30° C), dry conditions (rel. humid max 65%), protected from sunlight

How do you make sure that customer purchase orders, packaging and shipping requirements are followed?	Input into SAP
Can you pack to order (Yes/No) or do you have standard pack sizes?	Standard pack size
Is each bag/container labeled with the name of the product and lot no.?	Yes
Will each bag/container/roll on a pallet bear the lot no. and/or description clearly visible?	Yes
Do you put different batches of one product on one pallet?	No, only one batch per pallet
Do you keep records of all shipments to customers, including batch number and quantity?	Yes

8. ATTACHMENT

8.1. ICH Q3C - Residual Solvents

Nutrinova® Potassium Sorbate and Nutrinova® Sorbic Acid are fully in compliance with the ICH Q3C Guideline for Residual Solvents, adopted by CHMP, 15 December 2016 and issued as EMA/CHMP/ICH/82260/2006.

Supplier Trade Names	Nutrinova® Sorbic Acid Nutrinova® Potassium Sorbate
Manufacture by	Celanese Production Germany GmbH & Co. KG Am Unisys-Park 1 65843 Sulzbach (Taunus) Germany

Class 1 Solvents

The product in question was manufactured (including all manufacturing steps) with the use of Class 1 Solvents?

☐ Yes

☒ No

Class 2 Solvents

The product in question was manufactured (including all manufacturing steps) with the use of Class 2 Solvents?

☐ Yes

☒ No

Class 3 Solvents

The product in question was manufactured (including all manufacturing steps) with the use of Class 3 Solvents?

☒ Yes

☐ No

If YES, please fill out the table below!

Name of Class 3 Solvent	Maximum Concentration [ppm]	Complies with ICH Guideline Q3C for Residual Solvents
Acetone	200	Yes

8.2. Table according to ICH – Q3D-Guideline for Elemental Impurities

Nutrinova® Potassium Sorbate and Nutrinova® Sorbic Acid are fully in compliance with the ICH Q3D Guideline. None of the elements mentioned in this guideline is added intentionally during production. Nevertheless Nutrinova® Potassium Sorbate and Nutrinova® Sorbic Acid are analyzed regularly per AAS (Mercury) and ICP-MS (others) on different elements by an external laboratory, the reports can be received on request. Following an overview regarding the analyzed elements:

<u>Element</u>	<u>Class</u>	<u>Oral concentration acc ICH Q3D (R1), Table A2.2. [µg/g]</u>	<u>Intentionally added</u>	<u>If not intentionally added but likely to be present</u>	<u>LOD (of used Method) [µg/g]</u>	<u>CFI Specification [µg/g]</u>
Cd	1	0,5	No	No	0,01	0,10
Pb	1	0,5	No	No	0,02	0,10
As	1	1,5	No	No	0,02	0,10
Hg	1	3	No	No	0,01	0,01
Co	2A	5	No	No	0,02	0,10
V	2A	10	No	No	0,02	0,02
Ni	2A	20	No	No	0,02	0,02
Tl	2B	0,8	No	No	0,02	0,02
Au	2B	10	No	No	0,02	0,02
Pd	2B	10	No	No	0,10	0,10
Ir	2B	10	No	No	0,10	0,10
Os	2B	10	No	No	0,10	0,10
Rh	2B	10	No	No	0,10	0,10
Ru	2B	10	No	No	0,10	0,10
Se	2B	15	No	No	0,20	0,20
Ag	2B	15	No	No	0,02	0,02
Pt	2B	10	No	No	0,10	0,10
Li	3	55	No	No	0,10	0,10
Sb	3	120	No	No	0,02	0,10
Ba	3	140	No	No	0,02	0,10
Mo	3	300	No	No	0,02	0,10
Cu	3	300	No	No	0,02	0,10
Sn	3	600	No	No	0,20	0,20
Cr	3	1100	No	No	0,02	0,10

8.3. GMO Questionnaire

Does the product conform to the current EU food regulations?

☒ Yes ☐ No

Does the product contain genetically modified material?

☐ Yes ☒ No

Has the product been tested to be free of genetically modified material (i.e. < 1%)?

☐ Yes ☒ No

Has the product been sourced from non-genetically modified raw materials by means of segregation measures (i.e. only non-GM materials in the entire supply chain)?

☒ Yes, only non-GM materials in the entire supply chain ☐ No
