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The chemistry inside innovation™

Specialty Food Ingredients you can trust

Quality Information Pack

Nutrinova® Sorbates

Version April 2014

Released by:

Christoph Katz
Managing Director

Frank Goergen
Head of Global Quality Management

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 01 April 2014.

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).

COMMITTED TO QUALITY
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1. Contacts

Address:	Celanese Nutrinova Nutrition Specialties & Food Ingredients GmbH Am Unisys-Park 1 65843 Sulzbach (Taunus) Germany E-mail: foodingredients-emea@celanese.com Web: www.celanese.com/food-ingredients/about-us.aspx
Manufacturing Site:	Nutrinova Nutrition Specialties & Food Ingredients GmbH Nutrinova® Sorbic acid plant, building D 420 Industriepark Höchst 65926 Frankfurt / Main Germany
Quality Contact:	Mr. Frank Goergen Head of Global Quality Management Phone: +49 (0)69 45009 1378 Fax: +49 (0)69 45009 58294 E-mail: frank.goergen@celanese.com
Product Stewardship/ Regulatory Contact:	Dr. Mari Stavanja Global Product Stewardship Leader Phone: +1 972 443 4983 E-mail: mari.stavanja@celanese.com
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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 Nutrinova, 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 Potassium Sorbate are filled in silotrucks and transported to our contractor. There the products are filled into the final packages. The contractor is integrated into the Nutrinova requirements for food safety and security. Consequently, the hygienic demands on employees, plant and packaging are very high.

3. Lot Size

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

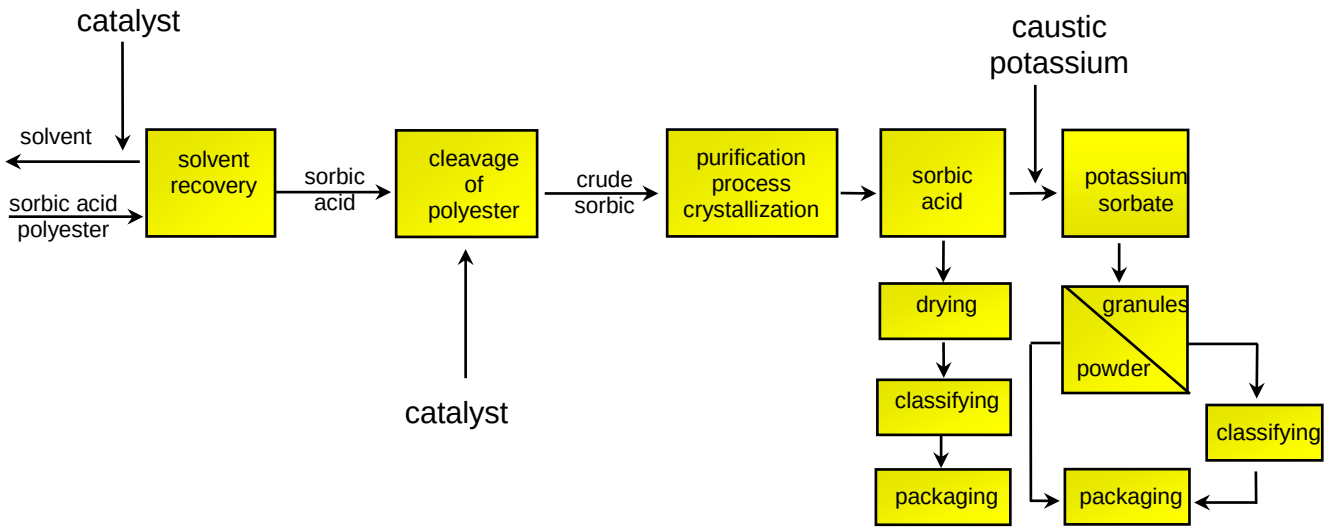
The lot size of Nutrinova® Sorbic Acid is defined as per filling of two silotrucks. The assignment of lot numbers (a ten digit number) is controlled by SAP. Each lot is linked to specific material numbers. The combination of lot and material numbers guarantee a definite classification and consistent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

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

Nutrinova® Sorbic Acid (E 200) is manufactured synthetically according to a process developed by Hoechst AG / Nutrinova, Nutrition Specialties & Food Ingredients GmbH, Frankfurt/Main, Germany, using ketene and crotonaldehyde.

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

5. Production Flow Chart



Questions & Answers: PRODUCTION
Nutrinova 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**

6. Structural Formula of Nutrinova® Sorbic Acid and Nutrinova® Potassium Sorbate

CH3-CH=CH-CH=CH-COOH **CH3-CH=CH-CH=CH-COOK**

Sorbic Acid **Potassium Sorbate**

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

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

Nutrinova Nutrition Specialties & Food Ingredients GmbH
Industriepark Höchst
65926 Frankfurt am Main
Germany

8. Source of Product

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

9. Ingredient Declaration

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

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

10. DIN EN ISO Certification

Nutrinova, including the Sorbic Acid Plant, has been certified according to the requirements of **DIN EN ISO 9001:2008, and DIN EN ISO 14001:2004** both since 1997 and **FSSC 22000:2010** (DIN EN ISO 22.000:2005 & PAS 220) since 2011. The current certificates are available on http://www.celanese.com/food-ingredients/products/Nutrinova-Sorbic-Acid/media-literature.aspx.

11. 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. Thus, Nutrinova 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 **American Institute of Baking (AIB), British Retail Consortium Standard (BRC)** and **Grocery Manufacturing Association GMA-SAFE (formerly FPA)**. Because of the regional acceptance of these standards by our customers Nutrinova switched to the globally accepted **FSSC 22000:2010** standard.

12. HACCP

The Nutrinova **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 the GMA-SAFE program and those of British Retail Consortium Standard (BRC) and ISO 22.000.

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 Nutrinova 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 Nutrinova 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

13. 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 (i) in the originally closed packaging protected from sunlight and (ii) 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 2001, Chapter 7.5.1.19).

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.

14. Product Specifications / Purity Requirements: Nutrinova® Sorbates Food Grade and Nutrinova® Sorbates Pharma Grade

Food Grade

Please contact Nutrinova for the official product specification documents.

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) 9th edition, the JSFA 8th edition and the EU Commission Regulation 231/2012.

Furthermore, Nutrinova® Sorbic Acid and Nutrinova® Potassium Sorbate, which are available in pharmaceutical quality, also comply with the legal requirements of the European Pharmacopoeia & US Pharmacopoeia.

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	$C_6H_8O_2$
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 $\pm$ 2 nm (solution of 0.002 g/L in water at pH <3)

Purity

Assay	99 % to 101 % of $C_6H_8O_2$, on dry weight basis	
Loss on drying	Not more than 0.5 % (Karl Fischer method)	
Heat resistance	No discoloration after 90 minutes at 105 °C	
Melting range	133 - 135 °C (EU/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

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

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	$C_6H_7KO_2$
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 % to 101 % of $C_6H_7KO_2$, 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	133 - 135 °C (EU/FCC)	
Alkalinity (calc. as K2CO3)	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

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 the EC/EFSA as well as to national specifications published in food regulations for sorbates. Any existing legal restrictions for the use in foods, drugs, feeding stuff and cosmetics must be observed by users of Nutrinova® Potassium Sorbate.

Pharma Grade

Nutrinova® Sorbic Acid – Pharma 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	$C_6H_8O_2$
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 $\pm$ 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)
Identification (double bonds)	Positive (USP)
Residual solvents	According to the requirements of the USP

Purity

Assay	99 % to 101 % of $C_6H_8O_2$, on dry weight basis	
Loss on drying	Not more than 0.5 % (Karl Fischer method)	
Heat resistance	No discoloration after 90 minutes at 105 °C	
Melting range	133 - 135 °C (EU/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

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

Nutrinova® Sorbic Acid Pharma Grade meets the requirements of the European Pharmacopoeia and the US Pharmacopoeia.

Nutrinova® Sorbic Acid Pharma Grade conforms also to the purity specifications published by FAO/WHO, those of the US Food Chemicals Codex, those of the JSFA, and the EC/EFSA. Any existing legal restrictions for the use in foods, drugs, feeding stuff and cosmetics must be observed by users of Nutrinova® Sorbic Acid.

Nutrinova® Potassium Sorbate – Pharma 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	$C_6H_7KO_2$
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 $\pm$ 2 nm (solution of 0.002 g/L in water at pH <3)
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 K2CO3)	Not more than 0.1	%
Aldehydes	Not more than 0.15	% (as acetaldehyde)
Identification (double bonds)	Positive (USP)	
Residual solvents	According to the requirements of the USP	

Purity

Assay	99 % to 101 % of $C_6H_7KO_2$, 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	133 - 135 °C (EU/FCC)
Alkalinity (calc. as K2CO3)	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	

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

Nutrinova® Potassium Sorbate Pharma Grade meets the requirements of the European Pharmacopoeia and US Pharmacopoeia.

Nutrinova® Potassium Sorbate Pharma Grade conforms also to the purity specifications published by FAO/WHO, those of the Food Chemicals Codex, those of the JSFA and the EC/EFSA. Any existing legal restrictions for the use in foods, drugs, feeding stuff and cosmetics must be observed by users of Nutrinova® Potassium Sorbate.

15. Certificate of Analysis (CoA): Nutrinova® Sorbic Acid and Nutrinova® Potassium Sorbate Food Grade and Pharma Grade - examples

Nutrinova® Sorbic Acid Food Grade:

Certificate of Analysis

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

Cert Issue Date: 26 Mar 2014

Material No.: 20008714
Produced at: Frankfurt am Main
Produced on: 28 Feb 2014
Best before date: 27 Feb 2017
Country of origin: Germany

Batch 0000681355
On the batch, of which the consignment is a part, the following values were determined.

Characteristic	(Method)	UoM	Value	Limits
Abs. max. (in Water)	(UV)	nm	263,8	262,0 - 266,0
Appearance	VISUAL		white, crystalline powder	
Assay	(FCC, Titrimetric)	%	99,8	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)		%	< 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, JSFA)	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

Nutrinova® Sorbic Acid meets the purity specifications of the FAO/WHO, those of the Food Chemicals Codex, those of the JSFA, the guidelines of the Council of Ministers of the EC, the regulations on preservatives applicable in the Federal Republic of Germany and other national food laws. The existing legal restrictions for the use in foods, drugs and cosmetics must be observed.
Nutrinova® Sorbic Acid and its raw materials are manufactured synthetically. Nutrinova® Sorbic Acid is as a component of food fit for human consumption.

Allergens Status:
Nutrinova® Sorbic Acid does not contain substances having allergenic properties, for which labelling is required, as listed in Annex IIIa of the Directive 2000/13/EC and subsequent amendments.

Nutrinova® Sorbic Acid complies further on with the Regulation (EU) 1169/2011, the US Food Allergen Labeling and Consumer Protection Act of 2004 and the Japanese Food Sanitation Law.

GMO Status:
Nutrinova® Potassium Sorbate is considered NOT genetically modified or NOT derived from a genetically modified organism as defined by the EC regulations 1830/2003/EC on labeling and traceability and 1829/2003/EC on genetically modified food and feed and their amending legislation.

The test results refer exclusively to the examined sample taken from the above-mentioned lot. Any copying of the test report, whether in part or in full, is not allowed without Nutrinova's permission.

Retain sample policy:
Please be informed, that since January 1st, 2012 we store retain samples of Nutrinova® Sorbic Acid and Nutrinova® Potassium Sorbate for 4 years from date of manufacture.

Nutrinova® Potassium Sorbate Food Grade:

Certificate of Analysis

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

Cert Issue Date: 26 Mar 2014

Material No.: 20008709
Produced at: Frankfurt am Main
Produced on: 22 Mar 2014
Best before date: 21 Mar 2017
Country of origin: Germany

Batch 0000686303
On the batch, of which the consignment is a part, the following values were determined.

Characteristic	(Method)	UoM	Value	Limits
Abs. max. (in Water)	(UV)	nm	263,2	262,0 - 266,0
Alkalinity (calc. as K2CO3)	(FCC, Titrimetric)	%	0,05	max. 0,10
Appearance	VISUAL		white to yellowish-white granular	
Assay	(FCC, Titrimetric)	%	100,2	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)	%	0,06	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, JSFA)	ppm	25,8	0,0 - 100,0
Sulfate	(IC)	ppm	< 150,0	0,0 - 150,0

Nutrinova® Potassium Sorbate conforms to the purity specifications published by FAO/WHO, those of the Food Chemicals Codex, those of the JSFA, the guidelines of the Council of Ministers of the EC, the regulations on preservatives applicable in the Federal Republic of Germany and other national food laws. The existing legal restrictions for the use in foods, drugs and cosmetics must be observed. Nutrinova® Potassium Sorbate is as a component of food fit for human consumption.
Nutrinova® Potassium Sorbate and its raw materials are manufactured synthetically.

Allergens Status:
Nutrinova® Potassium Sorbate does not contain substances having allergenic properties, for which labelling is required, as listed in Annex IIIa of the Directive 2000/13/EC and subsequent amendments.

Nutrinova® Potassium Sorbate complies further on with the Regulation (EU) 1169/2011, the US Food Allergen Labeling and Consumer Protection Act of 2004 and the Japanese Food Sanitation Law.

GMO Status:
Nutrinova® Potassium Sorbate is considered NOT genetically modified or NOT derived from a genetically modified organism as defined by the EC regulations 1830/2003/EC on labeling and traceability and 1829/2003/EC on genetically modified food and feed and their amending legislation.

The test results refer exclusively to the examined sample taken from the above-mentioned lot. Any copying of the test report, whether in part or in full, is not allowed without Nutrinova's permission.

Retain sample policy:
Please be informed, that since January 1st, 2012 we store retain samples of Nutrinova® Sorbic Acid and Nutrinova® Potassium Sorbate for 4 years from date of manufacture.

Certificate of Analysis (Examples Pharma Grade)

Nutrinova® Sorbic Acid Pharma Grade:

Certificate of Analysis

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

Cert Issue Date: 26 Mar 2014

Material No.: 20008717
Produced at: Frankfurt am Main
Produced on: 02 Dec 2013
Best before date: 01 Dec 2016
Country of origin: Germany

Batch 0000665746
On the batch, of which the consignment is a part, the following values were determined.

Characteristic	(Method)	UoM	Value	Limits
Abs. max (in Isopropanol)	(UV)	nm	254,6	252,0 - 256,0
Abs. max. (in Water)	(UV)	nm	263,3	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)	%	0,10	max. 0,10
Assay	(FCC, Titrimetric)	%	99,6	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
Organic volatile impurities	(USP,GC)		Pass	
Water content	(Karl Fischer)	%	0,22	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	(PH.EUR)		< 10 CFU / 1g	
Pseudomonas aeruginosa	(PH.EUR)		neg. / 1g	
Escherichia coli	(PH.EUR)		neg. / 1g	
Salmonella bacilli	(PH.EUR)		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

Methods are validated against official PH.EUR. and USP methods.
Nutrinova® Sorbic Acid Pharma Grade meets the requirements of the European Pharmacopoeia 8.0, the US Pharmacopoeia USP 37-NF 32 and the Monograph of the Japanese Pharmaceutical Excipients List in the updated version.

Nutrinova® Sorbic Acid Pharma Grade conforms also to the purity specifications published by FAO/WHO, those of the Food Chemicals Codex, those of the JSFA, the guidelines of the Council of Ministers of the EC, the regulations on preservatives applicable in the Federal Republic of Germany and other national food laws. The existing legal restrictions for the use in foods, drugs and cosmetics must be observed. Nutrinova® Sorbic Acid is as a component of food fit for human consumption.

The test results refer exclusively to the examined sample taken from the above-mentioned lot. Any copying of the test report, whether in part or in full, is not allowed without Nutrinova's permission.
Retain sample policy:
Please be informed, that since January 1st, 2012 we store retain samples of Nutrinova® Sorbic Acid and Nutrinova® Potassium Sorbate for 4 years from date of manufacture.

Nutrinova® Potassium Sorbate Pharma Grade:

Certificate of Analysis

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

Cert Issue Date: 26 Mar 2014

Material No.: 20008711
Produced at: Frankfurt am Main
Produced on: 22 Jan 2014
Best before date: 21 Jan 2017
Country of origin: Germany

Batch 0000674569
On the batch, of which the consignment is a part, the following values were determined.

Characteristic	(Method)	UoM	Value	Limits
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 K2CO3)	(FCC, Titrimetric)	%	0,06	max. 0,10
Appearance	VISUAL		white to yellowish-white granular	
Appearance of Solution	(EP)		clear and colourless	
Assay	(FCC, Titrimetric)	%	100,3	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	132,1	132,0 - 135,0
Organic volatile impurities	(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	(PH.EUR)		< 10 CFU / 1g	
Moulds	(PH.EUR)		< 10 CFU / 1g	
Yeasts	(PH.EUR)		< 10 CFU / 1g	
Staphylococcus aureus	(PH.EUR)		neg. / 1g	
Enterobacteriaceae	(PH.EUR)		< 10 CFU / 1g	
Pseudomonas aeruginosa	(PH.EUR)		neg. / 1g	
Escherichia coli	(PH.EUR)		neg. / 1g	
Salmonella bacilli	(PH.EUR)		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

Methods are validated against official PH.EUR. and USP methods.
Nutrinova® Potassium Sorbate Pharma Grade meets the requirements of the European Pharmacopoeia 8.0, the US Pharmacopoeia 37-NF 32 and the Monograph of the Japanese Pharmaceutical Excipients (JPE) in the updated version.

Nutrinova® Potassium Sorbate Pharma Grade conforms also to the purity specifications published by FAO/WHO, those of the Food Chemicals Codex, those of the JSFA, the guidelines of the Council of Ministers of the EC, the regulations on preservatives applicable in the Federal Republic of Germany and other national food laws. The existing legal restrictions for the use in foods, drugs and cosmetics must be observed. Nutrinova® Sorbic Acid is as a component of food fit for human consumption.

The test results refer exclusively to the examined sample taken from the above-mentioned lot. Any copying of the test report, whether in part or in full, is not allowed without Nutrinova's permission.

Retain sample policy:
Please be informed, that since January 1st, 2012 we store retain samples of Nutrinova® Sorbic Acid and Nutrinova® Potassium Sorbate for 4 years from date of manufacture.

16. 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 wear appropriate 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

17. 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 accredited 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 accredited laboratory)

Retain sample policy: Since January 1st, 2012 we store retain samples of Nutrinova® Sorbic Acid and Nutrinova® Potassium Sorbate for 4 years from date of manufacture.

18. 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.

19. Allergens

19.1. 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.

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 Sanitation Law, and does not contain any ingredients listed as following:

- Cereals containing gluten namely wheat, rye, barley, oats, spelt, kamut or their hybridised 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 illinoinensis* (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

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

garlic	buckwheat
millet	stone fruits
vanillin	glutamate
seasonings	rice
benzoic acid	maize and products thereof

19.2. Allergens in Cosmetics

Nutrinova® Sorbic Acid and Nutrinova® Potassium Sorbate are produced synthetically and do not contain any perfumes or other substances mentioned in Annex III of the Regulation (EC) No 1223/2009 of 30 November 2009 on cosmetic products listing substances which cosmetic products must not contain except subject to the restrictions laid down there.

20. CMR substances in Cosmetics

Sorbic acid or potassium sorbate has not been classified as carcinogen, mutagenic or reproductive toxicant known as CMR by any regulatory agency worldwide.

Nutrinova® Sorbic Acid and Nutrinova® Potassium Sorbate are approved in Cosmetic products referring to Regulation (EC) No 1223/2009 of 30 November 2009 on cosmetic products, article 14, Annex V and are permitted with 0,6 % (maximum concentration in the ready for use preparation; calculated as acid) in cosmetic products.

21. 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 No. 258/97, 1139/98, 49/2000, 50/2000 or 1829/2003 and 1830/2003 respectively nor according to the Japanese Food Sanitation Act.

22. Irradiation

Neither the starting materials nor our end products 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.

23. Pest Control

Nutrinova 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:	U.V. 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 will be archived for ten years.

24. Foreign Object Recognition and Avoidance 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 will be conducted in special filling rooms according to the food GMP standard. 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 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.

25. 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, FDA regulations and the Japanese Food Sanitation Law.

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.

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

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, FDA regulations and the Japanese Food Sanitation Law.

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.

26. 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
- E number
- Company name and address
- Date of manufacturing
- Best-before date
- Country of origin

The finished products are stored at Nutrinova under GMP conditions. 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.

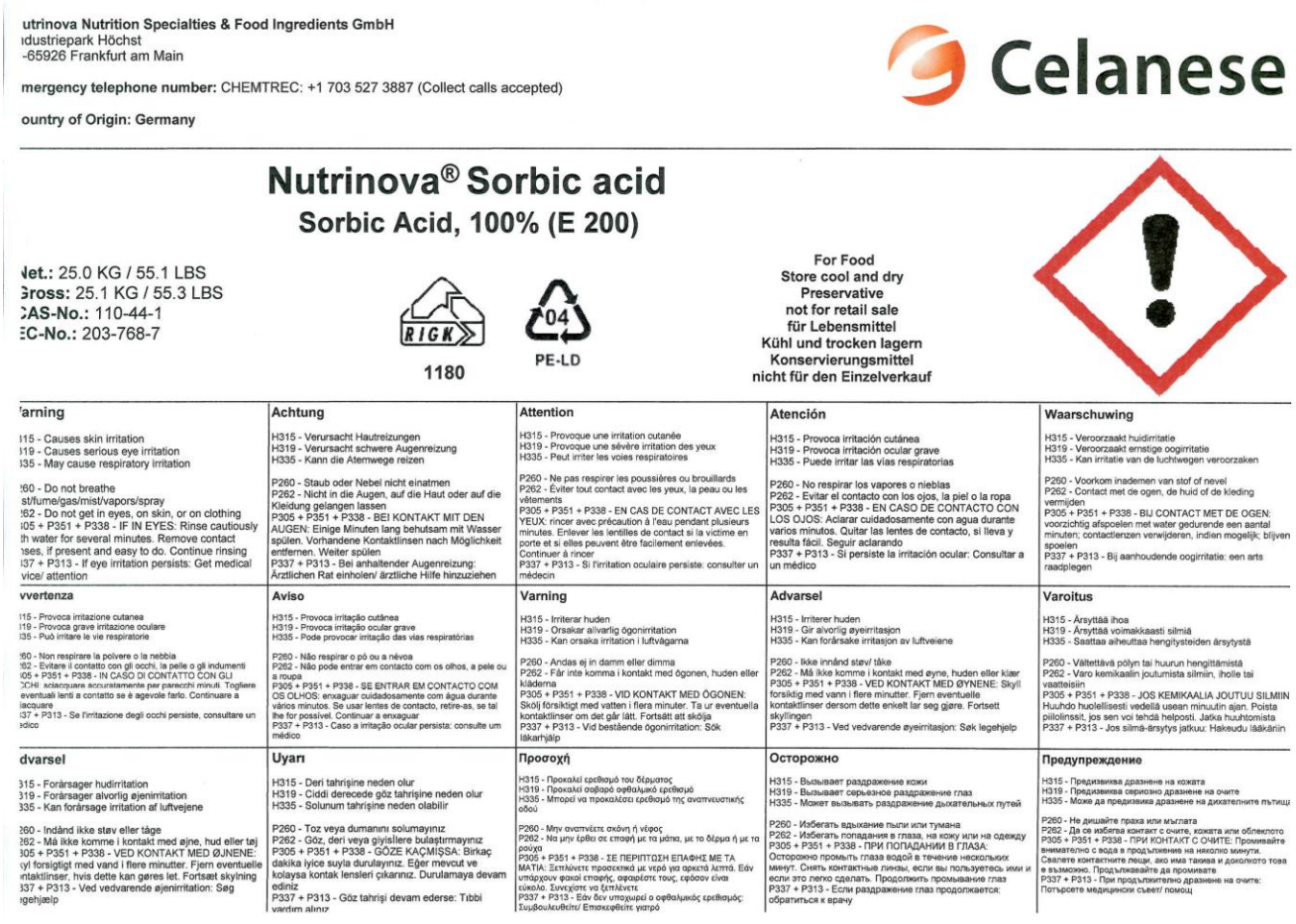
During the storage of our products the following requirements must be fulfilled:

- 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.

27. Product Label – examples

Labeling according to GHS-Regulation (Regulation (EC) No 1272/2008 on classification, labeling and packaging of substances and mixtures)



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ıdustriepark Höchst
-65926 Frankfurt am Main

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

ountry of Origin: Germany

Celanese

Nutrinova® Sorbic acid

Sorbic Acid, 100% (E 200)

let.: 25.0 KG / 55.1 LBS
Gross: 25.1 KG / 55.3 LBS
CAS-No.: 110-44-1
EC-No.: 203-768-7

RIGK
1180

04
PE-LD

For Food
Store cool and dry
Preservative
not for retail sale
für Lebensmittel
Kühl und trocken lagern
Konservierungsmittel
nicht für den Einzelverkauf

'arning	Achtung	Attention	Atención	Waarschuwing
315 - Causes skin irritation 319 - Causes serious eye irritation 335 - May cause respiratory irritation 260 - Do not breathe st/fume/gas/mist/vapors/spray 262 - Do not get in eyes, on skin, or on clothing 305 + P351 + P338 - IF IN EYES: Rinse cautiously th water for several minutes. Remove contact ıses, if present and easy to do. Continue rinsing 337 + P313 - If eye irritation persists: Get medical vice/ attention	H315 - Verursacht Hautreizungen H319 - Verursacht schwere Augenreizung H335 - Kann die Atemwege reizen P260 - Staub oder Nebel nicht einatmen P262 - 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	H315 - Provoque une irritation cutanée H319 - Provoque une sévère irritation des yeux H335 - Peut irriter les voies respiratoires P260 - Ne pas respirer les poussières ou brouillards P262 - Éviter tout 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 porte et si elles peuvent être facilement enlevées. Continuer à rincer P337 + P313 - Si l'irritation oculaire persiste: consulter un médecin	H315 - Provoca irritación cutánea H319 - Provoca irritación ocular grave H335 - Puede irritar las vías respiratorias P260 - No respirar los vapores o nieblas P262 - 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	H315 - Veroorzaakt huidirritatie H319 - Veroorzaakt ernstige oogirritatie H335 - Kan irritatie van de luchtwegen veroorzaken P260 - Voorkom inademen van stof of nevel P262 - Contact met de ogen, de huid of de kleding vermijden P305 + P351 + P338 - BIJ CONTACT MET DE OGEN: voorzichtig afspoelen met water gedurende een aantal minuten; contactlenzen verwijderen, indien mogelijk; blijven spoelen P337 + P313 - Bij aanhoudende oogirritatie: een arts raadplegen
vvertenza	Aviso	Varning	Advarsel	Varoitus
315 - Provoca irritazione cutanea 319 - Provoca grave irritazione oculare 335 - Può irritare le vie respiratorie 260 - Non respirare la polvere o la nebbia 262 - Evitare il contatto con gli occhi, la pelle o gli indumenti 305 + P351 + P338 - IN CASO DI CONTATTO CON GLI CCHI: sciacquare accuratamente per parecchi minuti. Togliere eventuali lenti a contatto se è agevole farlo. Continuare a lacquare 337 + P313 - Se l'irritazione degli occhi persiste, consultare un dico	H315 - Provoca irritação cutânea H319 - Provoca irritação ocular grave H335 - Pode provocar irritação das vias respiratórias P260 - Não respirar o pó ou a névoa P262 - Não pode entrar em contacto com os olhos, a pele ou a roupa P305 + P351 + P338 - SE ENTRAR EM CONTACTO COM OS OLHOS: enxaguar cuidadosamente com água durante vários minutos. Se usar lentes de contacto, retire-as, se tal lhe for possível. Continuar a enxaguar P337 + P313 - Caso a irritação ocular persista: consulte um médico	H315 - Irriterar huden H319 - Orsakar allvarlig ögonirritation H335 - Kan orsaka irritation i luftvägarna P260 - Andas ej in damm eller dimma P262 - Får inte komma i 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 läkarhjälp	H315 - Irriterer huden H319 - Gir alvorlig øyeirritasjon H335 - Kan forårsake irritasjon av luftveiene P260 - Ikke innånd støv/ tåke P262 - Må ikke komme i kontakt med øyne, huden eller klær P305 + P351 + P338 - VED KONTAKT MED ØYNENE: Skyll forsiktig med vann i flere minutter. Fjern eventuelle kontaktlinser dersom dette enkelt lar seg gjøre. Fortsett skyllingen P337 + P313 - Ved vedvarende øyeirritasjon: Søk legehjelp	H315 - Ärsyttää ihoa H319 - Ärsyttää voimakkaasti silmiä H335 - Saattaa aiheuttaa hengitysteiden ärsytystä P260 - Vältettävä pölyn tai huurun hengittämistä P262 - Varo kemikaalin joutumista silmiin, iholle tai vaatteisiin P305 + P351 + P338 - JOS KEMIKAALIA JOUTUU SILMIIN Huuhdo huolellisesti vedellä usean minuutin ajan. Poista piilolinssit, jos sen voi tehdä helposti. Jatka huuhtomista P337 + P313 - Jos silmä-ärsytys jatkuu: Hakeudu lääkäriin
dvarsel	Uyarı	Προσοχή	Осторожно	Предупреждение
315 - Forårsager hudirritation 319 - Forårsager alvorlig øjenirritation 335 - Kan forårsage irritation af luftvejene 260 - Indånd ikke støv eller tåge 262 - Må ikke komme i kontakt med øjne, hud eller tøj 305 + P351 + P338 - VED KONTAKT MED ØJNENE: yl forsigtigt med vand i flere minutter. Fjern eventuelle ntaktlinser, hvis dette kan gøres let. Fortsæt skylning 337 + P313 - Ved vedvarende øjenirritation: Søg gehjælp	H315 - Deri tahrişine neden olur H319 - Ciddi derecede göz tahrişine neden olur H335 - Solunum tahrişine neden olabilir P260 - Toz veya dumanını solumayınız P262 - Göz, deri veya giysilere bulaştırmayınız P305 + P351 + P338 - GÖZE KAÇMIŞSA: Birkaç dakika iyice suyla durulayınız. Eğer mevcut ve kolaysa kontak lensleri çıkarınız. Durulamaya devam ediniz P337 + P313 - Göz tahrişi devam ederse: Tıbbi yardım alınız	H315 - Προκαλεί ερεθισμό του δέρματος H319 - Προκαλεί σοβαρό οφθαλμικό ερεθισμό H335 - Μπορεί να προκαλέσει ερεθισμό της αναπνευστικής οδού P260 - Μην αναπνέετε σκόνη ή νέφος P262 - Να μην έρθει σε επαφή με τα μάτια, με το δέρμα ή με τα ρούχα P305 + P351 + P338 - ΣΕ ΠΕΡΙΠΤΩΣΗ ΕΠΑΦΗΣ ΜΕ ΤΑ ΜΑΤΙΑ: Ξεπλύνετε προσεκτικά με νερό για αρκετά λεπτά. Εάν υπάρχουν φακοί επαφής, αφαιρέστε τους, εφόσον είναι εύκολο. Συνεχίστε να ξεπλένετε P337 + P313 - Εάν δεν υποχωρεί ο οφθαλμικός ερεθισμός: Συμβουλευθείτε/ Επισκεφθείτε γιατρό	H315 - Вызывает раздражение кожи H319 - Вызывает серьезное раздражение глаз H335 - Может вызывать раздражение дыхательных путей P260 - Избегать вдыхание пыли или тумана P262 - Избегать попадания в глаза, на кожу или на одежду P305 + P351 + P338 - ПРИ ПОПАДАНИИ В ГЛАЗА: Осторожно промыть 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	H315 - Предизвиква дразнене на кожата H319 - Предизвиква сериозно дразнене на очите H335 - Може да предизвика дразнене на дихателните пътищ P260 - Не дишайте праха или мъглата P262 - Да се избягва контакт с очите, кожата или облеклото P305 + P351 + P338 - ПРИ КОНТАКТ С ОЧИТЕ: Промивайте внимателно с вода в продължение на няколко минути. Свалете контактните лещи, ако има такива и доколкото това е възможно. Продължавайте да промивате P337 + P313 - При продължително дразнене на очите: Потърсете медицински съвет/ помощ

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ıdustriepark Höchst
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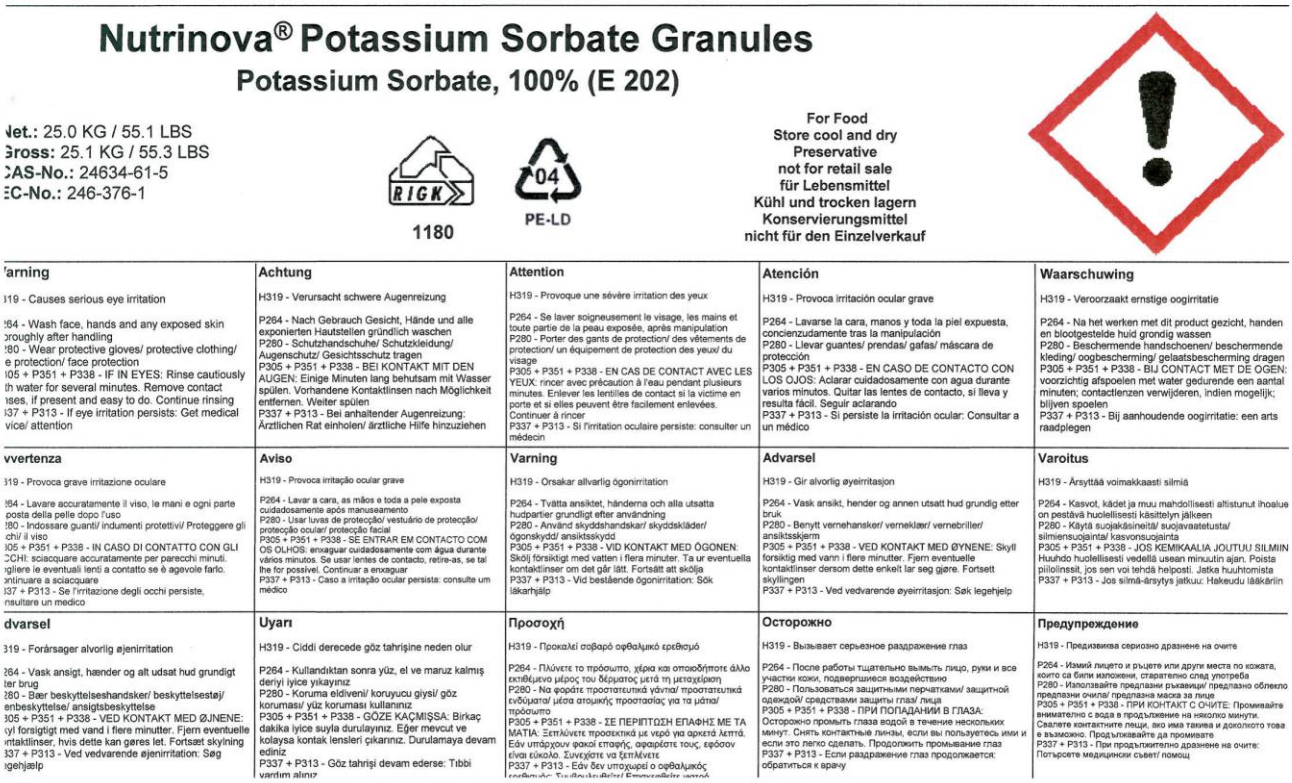
mergency telephone number: CHEMTREC: +1 703 527 3887 (Collect calls accepted)

ountry of Origin: Germany

Celanese



Nutrinova® Potassium Sorbate Granules

Potassium Sorbate, 100% (E 202)

let.: 25.0 KG / 55.1 LBS
Gross: 25.1 KG / 55.3 LBS
CAS-No.: 24634-61-5
EC-No.: 246-376-1

RIGK
1180

04
PE-LD

For Food
Store cool and dry
Preservative
not for retail sale
für Lebensmittel
Kühl und trocken lagern
Konservierungsmittel
nicht für den Einzelverkauf

'arning 319 - Causes serious eye irritation 264 - Wash face, hands and any exposed skin oroughly after handling 280 - Wear protective gloves/ protective clothing/ e protection/ face protection 305 + P351 + P338 - IF IN EYES: Rinse cautiously th water for several minutes. Remove contact ises, if present and easy to do. Continue rinsing 337 + P313 - If eye irritation persists: Get medical vice/ attention	**Achtung** H319 - Verursacht schwere Augenreizung P264 - Nach Gebrauch Gesicht, Hände und alle exponierten Hautstellen gründlich waschen P280 - Schutzhandschuhe/ Schutzkleidung/ 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	**Attention** H319 - Provoque une sévère irritation des yeux P264 - 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/ 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 porte et si elles peuvent être facilement enlevées. Continuer à rincer P337 + P313 - Si l'irritation oculaire persiste: consulter un médecin	**Atención** H319 - Provoca irritación ocular grave P264 - Lavarse la cara, manos y toda la piel expuesta, concienzudamente 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	**Waarschuwing** H319 - Veroorzaakt ernstige oogirritatie P264 - Na het werken met dit product gezicht, handen en blootgestelde huid grondig wassen P280 - Beschermende handschoenen/ beschermende kleding/ oogbescherming/ gelaatsbescherming dragen P305 + P351 + P338 - BIJ CONTACT MET DE OGEN: voorzichtig afspoelen met water gedurende een aantal minuten; contactlenzen verwijderen, indien mogelijk; blijven spoelen P337 + P313 - Bij aanhoudende oogirritatie: een arts raadplegen
vvertenza 319 - Provoca grave irritazione oculare 264 - Lavare accuratamente il viso, le mani e ogni parte posta della pelle dopo l'uso 280 - Indossare guanti/ indumenti protettivi/ Proteggere gli chi/ il viso 305 + P351 + P338 - IN CASO DI CONTATTO CON GLI CCHI: sciacquare accuratamente per parecchi minuti. ıgliere le eventuali lenti a contatto se è agevole farlo. ntinuare a sciacquare 337 + P313 - Se l'irritazione degli occhi persiste, nsultare un medico	**Aviso** H319 - Provoca irritação ocular grave P264 - Lavar a cara, as mãos e toda a pele exposta cuidadosamente após manuseamento P280 - Usar luvas de protecção/ vestuário de protecção/ protecção ocular/ protecção facial P305 + P351 + P338 - SE ENTRAR EM CONTACTO COM OS OLHOS: enxaguar cuidadosamente com água durante vários minutos. Se usar lentes de contacto, retire-as, se tal lhe for possível. Continuar a enxaguar P337 + P313 - Caso a irritação ocular persista: consulte um médico	**Varning** H319 - Orsakar allvarlig ögonirritation P264 - 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 läkarhjälp	**Advarsel** H319 - Gir alvorlig øyeirritasjon P264 - Vask ansikt, hender og annen utsatt hud grundig etter bruk P280 - Benytt vernehansker/ verneklær/ vernebriller/ ansiktsskjerm P305 + P351 + P338 - VED KONTAKT MED ØYNENE: Skyll forsiktig med vann i flere minutter. Fjern eventuelle kontaktlinser dersom dette enkelt lar seg gjøre. Fortsett skyllingen P337 + P313 - Ved vedvarende øyeirritasjon: Søk legehjelp	**Varoitus** H319 - Ärsyttää voimakkaasti silmiä P264 - Kasvot, kädet ja muu mahdollisesti altistunut ihoalue on pestävä huolellisesti käsittelyn jälkeen P280 - Käytä suojakäsineitä/ suojavaatetusta/ silmiensuojaintа/ kasvonsuojainta P305 + P351 + P338 - JOS KEMIKAALIA JOUTUU SILMIIN Huuhdo huolellisesti vedellä usean minuutin ajan. Poista piilolinssit, jos sen voi tehdä helposti. Jatka huuhtomista P337 + P313 - Jos silmä-ärsytys jatkuu: Hakeudu lääkäriin
dvarsel 319 - Forårsager alvorlig øjenirritation 264 - Vask ansigt, hænder og alt udsat hud grundigt ter brug 280 - Bær beskyttelseshandsker/ beskyttelsestøj/ enbeskyttelse/ ansigtsbeskyttelse 305 + P351 + P338 - VED KONTAKT MED ØJNENE: ıyl forsigtigt med vand i flere minutter. Fjern eventuelle ıntaktlinser, hvis dette kan gøres let. Fortsæt skylning 337 + P313 - Ved vedvarende øjenirritation: Søg ıgehjælp	**Uyarı** H319 - Ciddi derecede göz tahrişine neden olur P264 - Kullandıktan sonra yüz, el ve maruz kalmış deriyi iyice yıkayınız P280 - Koruma eldiveni/ koruyucu giysi/ göz koruması/ yüz koruması kullanınız P305 + P351 + P338 - GÖZE KAÇMIŞSA: Birkaç dakika iyice suyla durulayınız. Eğer mevcut ve kolaysa kontak lensleri çıkarınız. Durulamaya devam ediniz P337 + P313 - Göz tahrişi devam ederse: Tıbbi yardım alınız	**Προσοχή** H319 - Προκαλεί σοβαρό οφθαλμικό ερεθισμό P264 - Πλύνετε το πρόσωπο, χέρια και οποιοδήποτε άλλο εκτεθέμενο μέρος του δέρματος μετά τη μεταχείριση P280 - Να φοράτε προστατευτικά γάντια/ προστατευτικά ενδύματα/ μέσα ατομικής προστασίας για τα μάτια/ πρόσωπο P305 + P351 + P338 - ΣΕ ΠΕΡΙΠΤΩΣΗ ΕΠΑΦΗΣ ΜΕ ΤΑ ΜΑΤΙΑ: Ξεπλύνετε προσεκτικά με νερό για αρκετά λεπτά. Εάν υπάρχουν φακοί επαφής, αφαιρέστε τους, εφόσον είναι εύκολο. Συνεχίστε να ξεπλένετε P337 + P313 - Εάν δεν υποχωρεί ο οφθαλμικός	**Осторожно** H319 - Вызывает серьезное раздражение глаз P264 - После работы тщательно вымыть лицо, руки и все участки кожи, подвергшиеся воздействию P280 - Пользоваться защитными перчатками/ защитной одеждой/ средствами защиты глаз/ лица P305 + P351 + P338 - ПРИ ПОПАДАНИИ В ГЛАЗА: Осторожно промыть 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	**Предупреждение** H319 - Предизвиква сериозно дразнене на очите P264 - Измий лицето и ръцете или други места по кожата, които са били изложени, старателно след употреба P280 - Използвайте предпазни ръкавици/ предпазно облекло предпазни очила/ предпазна маска за лице P305 + P351 + P338 - ПРИ КОНТАКТ С ОЧИТЕ: Промивайте внимателно с вода в продължение на няколко минути. Свалете контактните лещи, ако има такива и доколкото това е възможно. Продължавайте да промивате P337 + P313 - При продължително дразнене на очите: Потърсете медицински съвет/ помощ

28. Nutritional Data

Nutrinova® Sorbic Acid has the following nutritional values:

Based on 100 g	Sorbic Acid
Energy value (kcal) (KJ)	 330* 1380*
Carbohydrates	0
Fat (g)	0
Protein (g)	0
Potassium (g)	0
Calcium (g)	0
Dietary fiber (g)	0

*based on literature data

Nutrinova® Potassium Sorbate has the following nutritional values:

Based on 100 g	Potassium Sorbate
Energy value (kcal) (KJ)	 246* 1030*
Carbohydrates	0
Fat (g)	0
Protein (g)	0
Potassium (g)	26
Calcium (g)	0
Dietary fiber (g)	0

*based on literature data

29. Kosher Certification

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

30. 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.

31. Vegan Certification

1. Nutrinova® Sorbates are manufactured without the use of animal matter or products derived from animal origin.
2. We do not use any material from
   - egg and egg derivatives
   - milk and dairy derivatives
   - onion, shallot, leek, garlic
   - liquor

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

32. Quality and Safety System for Specialty Feed Ingredients (FAMI QS) Certification

Nutrinova has implemented and maintains a Feed Safety Management System including Good Manufacturing Practice (GMP) for Nutrinova® Sorbates. The current certificate for the Quality and Safety System for Specialty Feed Ingredients and their Mixtures (FAMI QS) is available on http://www.celanese.com/food-ingredients/products/Nutrinova-Sorbic-Acid/media-literature.aspx.

33. Traceability / Retained sample

The European General Law Regulation 178 / 2002 requires a system for traceability for food ingredients and primary packaging. Nutrinova 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.

Nutrinova 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.

34. Non-containing Dioxins or PCBs

Our products do not contain Dioxins (PCDD / FCDF) or PCBs.

35. 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

36. Certificate of Compliance to CPMP/ICH/283/95 ("Residual Solvents")

Nutrinova® Sorbic Acid and Nutrinova® Potassium Sorbate are manufactured synthetically according to a process developed by Hoechst/Nutrinova Nutrition Specialties & Food Ingredients GmbH, Frankfurt, Germany.

According to the ICH Harmonised Tripartite Guideline for residual solvents (CPMP/ICH/283/95) 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.

37. Specification Limits for Residues of Metal Catalysts or Metal Reagents (The European Agency for the Evaluation of Medicinal Products Evaluation of Medicines for Human Use, EMEA/CHMP/SWP/4446/2000

In accordance to this Guideline zinc (Zn)-compounds are used as metal catalysts (Class 3-Classification) in the Nutrinova® Sorbates production process.

38. Non-containing Substances mentioned in the World Anti Doping Agency (WADA) Regulation

No substances mentioned in the WADA regulation 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 regulation can also be ruled out.

39. Certificate of Suitability

Animal Spongiform Encephatology - Guideline CPMP/BWP/1230/98

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 the above mentioned guideline and a Certificate of Suitability are not applicable for our products.

40. Nitrofen

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

41. Latex

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

42. 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.

43. Personal and Plant Hygiene Program

The personal and plant hygiene program conforms to the requirements of the FSSC 22000:2010 standard and other food safety standards, e.g. BRC, GMA-Safe etc.

44. 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 and do not require a warning label.

45. Compliance with Toxic Substance Control Act (TSCA)

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

46. 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 on animals after January 1st, 1998, nor do they contain any material from animal origin.

47. 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 Nutrinova's 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 Nutrinova Hazards Analysis Critical Control Point Team (HACCP) led by Nutrinova Quality Management.

48. Food Safety and Security Management System

Nutrinova 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 22000:2010 (Food Safety Security System)

ISO 9001:2008 (Quality Management)

Food Defense of IFS Food (2013)

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 (2013)

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 6 years

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

Customer audits upon request

Complete control of the manufacturing process

FDA Food Security Preventive Measures Guidance (March 21, 2003)

Crisis Management

Emergency Availability 24 hours 7 days a week

49. Questions & Answers

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?	Head of Global Quality Management reports to Managing Director
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 GMO-Regulations e.g. EC No 50/2000, EC No 49/2000, IKS 224.14?	N/A*, synthetically manufactured product
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 Institute Fresenius, Taunusstein, Germany: Microbiological testing CLAS Laboratory, Industriepark Höchst, Germany: Heavy metals testing
How have you qualified/ evaluated these contract laboratories?	Both labs are accredited according to ISO 17025

*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 ▪ 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 ▪ 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 ▪ 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?	Managing Director
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 all 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 22000:2010 Registration No. 003122 FSSC
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” (tab water regulation) purified and filtered
Please state the physical/ chemical and the micro-biological quality of this type of water.	According to German “Trinkwasserverordnung” (tab 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

ICH Q3C - Residual Solvents

Nutrinova@ Sorbates comply with the Guideline CPMP/ICH/283/95.

Supplier Trade Name	Nutrinova® Sorbic Acid, Nutrinova® Potassium Sorbate
Company Name of Manufacturer	Nutrinova Nutrition Specialties &Food Ingredients GmbH 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 x No

Class 2 Solvents

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

☐ Yes x No

Class 3 Solvents

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

x Yes ☐ No

If YES, please fill out the table below!

Name of Class 3 Solvent	Maximum Concentration [ppm]	Complies with Guideline CPMP/ICH/283/95
Acetone	200	Yes

GMO Questionnaire

Does the product conforms to the current EU food regulations*?

x Yes ☐ No

Does the product contain genetically modified material?

☐ Yes x No

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

☐ Yes x 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)?

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

*based on the following European Laws: Regulation No. 258/97 of 27 January 1997, Council Regulation (EC) No 1139/98 of 26 May 1998, Commission Regulation (EC) No 50/2000 of 10 January 2000, Commission Regulation (EC) No 49/2000 of 10 January 2000;