

Technical package

Dossier Técnico 25/05/2023

HYALURONIC ACID SODIUM (FOOD GRADE)

PRODUCT SPECIFICATION

Product Name	INCI Name	EINECS Number	CAS Code
HYALURONIC ACID SODIUM (FOOD GRADE)	N/A	N/A	9067-32-7

Description	white or similar white powder
Molecular weight	≥0.8×10(6)
Assay of Sodium Hyaluronate %	≥90
Glucuronic acid %	≥44
Loss on drying%	≤10
PH (0.1% Solution))	6.0-7.5
Residue on ignition (500-600°)	≤20%
Heavy Metal	≤10ppm
Lead (Pb)	≤3ppm
Arsenic (As)	≤1ppm
Cadmium (Cd)	≤1ppm
Mercury (Hg)	≤0.1ppm
Chloride (CI)	≤200ppm
Iron(Fe)	≤10ppm
Sulfate (SO4)	≤300ppm
Ammonium	≤200ppm
Proteins %	≤0.1
Transparency%(0.1% Solution)	≥98.5
Total Plate Count	≤1000cfu/g
Yeast and Molds	≤100cfu/g



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Salmonella	Negative in 10g
E.Coli	Negative in 10g
Staphylococcus Aureus	Negative in 10g

Conclusion: Passed the Enterprise standard.

CAS No.: 9067-32-7



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GENERAL PRODUCT INFORMATION		
	00.400	
Mesh of the product	80-100	
Tapped density	0.35-0.5 g/ml	
Bulk density	0.1-0.3 g/ml	
Water solubility	Soluble in water 0.2 g/L at 25 Deg C	
Type of Manufacturing process (Synthesis, Fermentation, Extraction, etc.)	Fermentation	
Specific Origin of the product (Animal, Vegetal, etc.)	From Corn glucose and yeast powder	
Is the product FREE of GLUTEN?	Yes	
Is the product suitable for vegans?	Yes	
Is the product suitable for vegetarians?	Yes	
Is the product free of fructose?	Yes	
Is this product suitable for food?	Yes	
Is this product suitable for feed of animals?	No	
Can the product be used in baby food (according to Regulation (EU) N° 609/2013, Commission Delegated Regulation (EU) 2016/127, Commission Delegated Regulation (EU) 2021/572 and amendments)?	Yes	
Drug indication	Hyaluronic acid sodium (Food grade) is claimed to act as an effective antidepressant, however results are mixed.	
Melting point	298 Deg C	
Country of origin of the raw material/s of the product	Corn Glucose from China	
Storage conditions (in the warehouse)	Dry and cold place	



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GENERAL PRODUCT INFORMATION

Additional information about the product:
Hyaluronic acid sodium(food grade) is produced from Streptococcus Zooepidemicus.

PYRROLIZIDIN ALKALOIDS STATEMENT The product has no Pyrrolizidin alkaloids.

COLOURING FREE STATEMENT This product is colouring free.



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TECHNICAL PRODUCT INFORMATION Name of the product Hyaluronic acid sodium (Food grade) Hyaluronic acid sodium (Food grade) **IUPAC** name Molecular Formula (C14H20NO11Na)n 403.31 g/mol Molecular mass Country of the factory (Manufacturing site) **CHINA** Raw materials used for the manufacture of this product and their Corn Glucose used to ferment the final product function Frequency of analysis of each contaminant? Every batch Frequency of analysis of microbiology? Heavy metals: Every batch, Microbiology: Every 1 Frequency of analysis of each heavy metal? Heavy metals: Every batch, Microbiology: Every 1



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FOREIGN MATERIAL

Explanation of actions taken during the manufacturing process of this product to reduce the risk of appearance of foreign material:

Metal detector	Yes	We use detector to test the foreign bodies.
Sieve	Yes	We use filtrate to the foreign bodies.
Filter	Yes	We use filtrate to the foreign bodies.
X-Ray	No	
Other	No	



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INGREDIENTS

In accordance with the EU Regulation 1169/2011, amending EU Regulation 1924/2006 and EU Regulation 1925/2006, the following ones are the ingredients and their content (in %) in this product.

Hyaluronic acid >= 95%



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BSE/TSE

This product does not contain and is not derived from Specified Risk Material as defined in European Commission Directive (and its amendments) and is therefore conform with the EU legislation relating to the risk of Transmission of Spongiform Encephalopathy (TSE).

GMO

The following EU regulations have been published in the Official Journal of the European Union in this subject:

- Regulation (EC) No.1829/2003 of the European Parliament and the Council of 22 September 2003 on genetically modified food and feed.
- Regulation (EC) No.1830/2003 of the European Parliament and the Council of 22 September 2003 concerning tractability and labeling on genetically modified organisms and tractability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.

This product has not been genetically modified so there is no obligation of GMO labeling as defined by the above mentioned regulations.

NON IRRADIATION/NON IONIZED

According to directives 1992/2/EC and 1999/3/EC, we confirm that this product is not made from irradiated/ionized raw materials and that this product was not irradiated/ionized.



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PESTICIDES

To our actual knowledge of the production process, of the raw materials and of the equipment used, the potential pesticide residues in this product comply with the European legislation on pesticide residues (esp. Regulation (EC) No. 396/2005 and amendments). However, we do not test for pesticide residues on a routine basis.

RESIDUAL SOLVENTS

The product meets with:

- DIRECTIVE 2009/32/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients
- DIRECTIVE 2010/59/EU of 26 August 2010 amending Directive 2009/32/EC of the European Parliament and of the Council on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients.

CONTAMINANTS

The product is in accordance and meets with the Commission Regulation (EU) No. 2023/915 setting maximum levels for certain contaminants in foodstuffs.

PCBS AND MELAMINE

This product is in accordance and meets with the Commission Regulation (EU) No. 2023/915 as regards the maximum levels of the contaminants Ochratoxin A, non-dioxin-like PCBS and melamine in foodstuffs.

ANTI-DOPING

As per the list of 2021 of the World Anti-Doping Agency (WADA), this product is not a doping substance or a combination of doping substances. This product is not manufactured from a doping substance.

NANOMATERIALS

According to the definition of 'Nanomaterials' of the UE Regulation No 1169/2011 of the European Parliament and of the Council of 25th of October 2011 (amending Commission Regulation (EC) 1924/2006 and Commission Regulation (EC) 1925/2006) on the provision of food information to consumers, we hereby attest that no nanomaterials are used in the manufacture, in the formulation nor in the packaging materials of this product.



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HYALURONIC ACID SODIUM (FOOD GRADE)

PACKING

We confirm that the packing used for this product is in compliance with:

- Regulation (EC) No. 1935/2004 of the European Parliament and of the Council of 27th of October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC
- Commission Regulation (EU) No. 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food.

ETHYLENE OXIDE (ETO) & 2-CHLORO-ETHANOL

Ethylene Oxide (& 2-Chloroethanol) is not used in any phases of the process of manufacture or storage of this product. This product does not enter in contact with Ethylene Oxide (& 2-Chloroethanol) in any phases of the process of manufacture or of storage. Therefore, this product is compliant with the limit established in Commission Regulation (EC) No. 396/2005.



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ALLERGENS

In accordance with Regulation (EU) No. 1169/2011, amending Commission Regulation (EC) No. 1924/2006 and Commission Regulation (EC) No. 1925/2006, we confirm the following information:

Does this product contain or is derived from or could be cross-contaminated by any of the following allergens?

Cereals containing gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridised strains) and products thereof	No
Crustaceans and products thereof	No
Eggs and products thereof	No
Fish and products thereof	No
Peanuts and products thereof	No
Soybeans and products thereof (with exceptions established in Annex II)	No
Milk and products thereof (including lactose) (with exceptions established in Annex II)	No
Nuts (i.e. almond, hazelnut, walnut, cashew, pecan nut, Brazil nut, pistachio nut, macadamia nut and Queensland nut) and products thereof (with exceptions established in Annex II)	No
Celery and products thereof	No
Mustard and products thereof	No
Sesame seeds and products thereof	No
Sulphur dioxide and sulphite at concentrations of more than 10 mg/kg or 10 mg/l expressed as SO2	No
Lupine and products thereof	No
Molluscs and products thereof	No



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ALBA LIST (ALLERGENS)

Note: 'Yes' means that there is contamination from

- 1) recipe contents,
- 2) other products handled on the same production line or
- 3) other products handled at same side.

	Cross contamination (mg/kg)?	Where?
Cow milk protein	No	-
Lactose	No	-
Chicken egg	No	-
Soya protein	No	-
Soya oil	No	-
Gluten	No	-
Wheat	No	-
Rye	No	-
Cattle	No	-
Pork	No	-
Chicken	No	-
Fish	No	-
Shellfish and Crustaceae	No	-
Corn	No	-
Cocoa	No	-
Leguminous plants	No	-
Nuts	No	-
Nut oil	No	-
Peanut	No	-
Peanut oil	No	-
Sesame	No	-
Sesame oil	No	-
Glutamate	No	-
Sulphide (E220 to E228)	No	-
Coriander	No	-
Celery	No	-
Carrot	No	-
Lupines	No	-



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NUTRITIONAL INFORMATION

Approximative Nutritional Information of this product is as follows:

Amount 100g

Calories 1292KJ/100g

Total Fat 0g/100g

Saturated Fat 0g/100g

Trans Fat 0g/100g

Cholesterol 0g/100g

Sodium 4.97g/100g

Total Carbohydrate 76g/100g

Dietary Fiber 0g/100g

Sugars 0g/100g

Includes Added Sugars 0g/100g

Moisture 6g/100g

Ash 13g/100g

Protein 0.03g/100g

Vitamin D 0mg/100g

Calcium 0mg/100g

Iron 0mg/100g

Potassium 0mg/100g

*Fat: 9 Calories/g. Carbohydrates: 4 Calories/g. Protein: 4 Calories/g.



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RESIDUE LIMITS (GELATIN, COLLAGEN)

We herewith certify that this product in compliance with: Commission Regulation (EU) No. 2016/355 of 11st of March 2016, amending Annex III to Commission Regulation (EC) No. 853/2004 of the European Parliament and of the Council as regards the specific requirements for gelatine, collagen and highly refined products of animal origin intended for human consumption.

HYGIENE OF FOODSTUFFS

We herewith certify that this product complies with Commission Regulation (EC) No. 852/2004 of the European Parliament on the hygiene of foodstuffs and all its amendments.

FULL TRACEABILITY

This product complies with the full traceability criteria as mentioned in Commission Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28th of January 2002, laying down the general principles and requirements of food law, establishing the European food safety authority and laying down procedures in matters of food safety.



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FACTORY ACCREDITATIONS/CERTIFICATIONS	
ISO 9001	Yes
ISO 22000	Yes
HACCP	Yes
GMP	Yes
FAMIQS	Yes
BRC	Yes
Other accreditations/certifications	HALAL, KOSHER, IP, FSSC 22000, ISO 45001



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NON ANIMAL TESTING

We certify that the product has not been tested on animals.

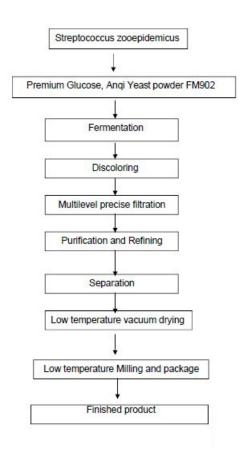


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HYALURONIC ACID SODIUM (FOOD GRADE)

Flow Chart





Material Safety Data Sheet

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HYALURONIC ACID SODIUM (FOOD GRADE)

MSDS (Material Safety Data Sheet)

SECTION 1: Identification of the substance/mixture and of the companylunderlaking

Product Name: HYALURONIC ACID SODIUM (FOOD GRADE)

CAS Number: 9067-32-7

Supplier Information:
Productos Quimicos Gonmisol S.A.
Camino de la Verneda 47-49
08930 - San Adrian del Besos
Barcelona - Spain
Phone +34 933136118
Fax +34 933147427
www.gonmisol.com

1.2 Relevant identified uses of the substance or mixture and uses advised against Application of the substance / the mixture:

Productionlindustrial production of Food, Cosmetics, Pharmaceuticai Industry

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

The substance is not classified according to the CLP regulation.

Information concerning particular hazards for human and environment:

The product has not to be labelled due to the calculation procedure of Regulation (EC) No. 1272/2008.

Classification system:

The classification is according to the latest edition of EU Regulation (EC) No. 1272/2008, and extended by company and literature data.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 Not applicable

Hazard pictograms Not applicable

Signal word Not applicable

Hazard-determining components of labelling: Not applicable

Hazard statements Not applicable

Precautionary statements Not applicable

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable vPvB: Not applicable

Determination of endocrine-disrupting properties Not applicable.



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SECTION 3: Compositionlinformation on ingredients

3.1 Substances

CAS No. Description

9067-32-7 Hyaluronic acid, sodium salt

Remark:

This product contains substance Hyaluronic acid, sodium salt (CAS No.9067-32-7) 100% by weight.

SECTION 4: First aid measures

4.1 Description of first aid measures

General description: No special measures required.

After inhalation: Supply fresh air; consult doctor in case of complaints.

After skin contact:

Wash with water and soap and rinse thoroughly.

If skin irritation continues, consult a doctor.

After eye contact:

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

After swallowing:

Rinse out mouth with water.

Never give anything by mouth to an unconscious person.

Seek medica[treatment.

4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed No further relevant information available.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing agents: Use Jire extinguishing methods suitable to surrounding conditions.

5.2 Special hazards arising from the substance or mixture No further relevant information available.

5.3 Advice for firefighters

Protective equipment:

Mouth respiratory protective device. Wear fully protective suit.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures Ensure adequate ventilation.

A void formation of dust.

Use respiratory protective device against the effects of fumes/dust/aerosol. A void contact with eyes.



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Avoid contact with skin.

6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.

6.3 Methods and material for containment and cleaning up: Pick up mechanically.

Dispose contaminated material as waste according to item 13.

6.4 Reference to other sections

See Section 7 for information on saje handling.

See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

SECTION 7: Handling and storage

7.1 Precautions jor saje handling

Thorough dedusting.

Ensure good ventilationlexhaustion at the workplace.

Keep receptacles tightly sealed.

Keep away from heat and direct sunlight.

Prevent formation of dust.

A void contact with skin and eyes.

For the general occupational hygienic measures refer to section 8.

Information about fire - and explosion protection: Normal measures for preventive fire protection.

7.2 Conditions jor saje storage, including any incompatibilities:

Requirements to be met by storerooms and receptacles: Store in a cool location.

Injormation about storage in one common storage jacility:

Store away from foodstujfs.

Protect from humidity and water.

Further injormation about storage conditions: Store in cool, dry conditions in well sealed receptacles.

7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

DNELs: Data not available PNECs: Data not available

Additional inj ormation: The lists val id during the making were used as basis.

8.2 Exposure controls

Based on the composition shown in Section 3, the jollowing measures are suggested jor occupational sajety measure:

Appropriate engineering controls: See Section 7 for information about design of technical facilities.

Individual protection measures, such as personal protective equipment

Respiratory protection: Suitable respiratory protective device recommended.



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Hand protection

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation! the chemical mixture

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.

Material of gloves:

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

Penetration time of glove material:

The exact break through time has to befound out by the manufacturer of the protective gloves and has to be observed.

Eye/face protection Goggles recommended during refilling

Body protection: Protective work clothing

Thermal hazards: Not required for normal conditions of use.

Environmental exposure controls:

Control measures must be made in accordance with Community environmental protection legislation.

SECTION 9: Physical and chemical properties

Physical state: Solid

Colour: White or almost white

Odour: Odourless

Odour threshold: Data not available

Melting point/freezing point: Data not available

Boiling point or initial boiling point and boiling range: Data not available

Flammability: Data not available

Lower and upper explosion limit: Data not available

Lower: Data not available Upper: Data not available Flash point: Data not available

Auto-Ignition temperature: Data not available Decomposition temperature: Data not available

pH: Data not available Viscosity: Data not available

Kinematic viscosity: Data not available Dynamic viscosity: Data not available Solubility water: Data not available

Partition coefficient n-octanol/water (log value): Data not available

Vapour pressure: Data not available

Density and/or relative density: Data not available

Density: Data not available

Relative density: Data not available

Relative vapour density: Data not available



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Particle characteristics: Data not available

9.2 Other information

Appearance: Form: Powder

Information with regard to physical hazard classes:

Explosives: Not applicable

Flammable gases: Not applicable

Aerosols: Not applicable

Oxidising gases: Not applicable Gases under pressure: Not applicable Flammable liquids: Not applicable Flammable solids: Not applicable

Self-reactive substances and mixtures: Not applicable

Pyrophoric liquids: Not applicable Pyrophoric solids: Not applicable

Self-heating substances and mixtures: Not applicable

Substances and mixtures, which emit flammable gases in contact with water: Not applicable

Oxidising liquids: Not applicable
Oxidising solids: Not applicable
Organic peroxides: Not applicable
Corrosive to metals: Not applicable
Desensitised explosives: Not applicable
Other safety characteristics: Data not available.

SECTION 10: Stability and reactivity

- 10.1 Reactivity No decomposition if used according to specification.
- 10.2 Chemical stability Stable under recommended storage conditions.
- 10.3 Possibility of hazardous reactions No dangerous reactions known.
- 10.4 Conditions to avoid No further relevant information available.
- 10.5 Incompatible materials: No further relevant information available.
- 10.6 Hazardous decomposition products: No dangerous decomposition products known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity Based on available data, the classification criteria are not met.

LD/LC50 values relevant for classification: Data not available

Skin corrosion/irritation: Based on available data, the classification criteria are not met.

Serious eye damage/irritation: Based on available data, the classification criteria are not met.



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Respiratory or skin sensitisation: Based on available data, the classification criteria are not met.

Germ cell mutagenicity: Based on available data, the classification criteria are not met.

Carcinogenicity: Based on available data, the classification criteria are not met.

Reproductive toxicity: Based on available data, the classification criteria are not met.

STOT-single exposure: Based on available data, the classification criteria are not met.

STOT-repeated exposure: Based on available data, the classification criteria are not met.

Aspiration hazard: Based on available data, the classification criteria are not met.

11.2 Information on other hazards

Endocrine disrupting properties

Substance is not listed.

Other information No further relevant information available.

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity: No further relevant information available.

12.2 Persistence and degradability No further relevant information available.

12.3 Bioaccumulative potential No further relevant information available.

12.4 Mobility in soil No further relevant information available.

12.5 Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

12. 7 Other adverse effects No further relevant information available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

Uncleaned packaging:

Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport information 14.1 UN number or ID number ADR/RID/ADN, IMDG, IATA Not applicable 14.2 UN proper shipping name ADR/RID/ADN, IMDG, IATA Not applicable



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14.3 Transport hazard class(es) ADR/RID/ADN, IMDG, IATA Class Not applicable Label Not applicable 14.4 Packing group

ADD/DID/ADN IMDC IATA Not

ADR/RID/ADN, IMDG, IATA Not applicable

14.5 Environmental hazards: Not applicable

14.6 Special precautions for user Not applicable

14. 7 Maritime transport in bulk according to IMO instruments Not applicable

14.8 Transport/Additional information: Not dangerous according to the above specifications

UN "Model Regulation": Not applicable

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specijic for the substance or mixture

Directive 2012/18/EU

Named dangerous substances - ANNEX I Substance is not listed

REGULATION (EU) 2019/1021 on persistent organic pollutants (POP)

Substance is not listed.

Regulation (EU) No 649/2012

Substance is not listed.

REGULATION (EU) 2019/1148

Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))

Substance is not listed.

Annex II - REPORTARLE EXPLOSIVES PRECURSORS

Substance is not listed.

Regulation (EC) No 273/2004 on drug precursors

Substance is not listed.

Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

Substance is not listed.

REGULATION (EC) No 1005/2009 on substances that deplete the ozone layer ANNEX 1 (Ozone-depleting potential)

Substance is not listed.

Other regulations, limitations and prohibitive regulations

SVHC Candidate List of REACH Regulation Annex XIV Authorisation (10/6/2022)

Substance is not listed.

REACH Regulation Annex XVII Restriction (13/12/2021) See Section 16 for information about restriction of use.

Substance is not listed.

REACH Regulation Annex XIV Authorization List (814/2022)

Substance is not listed.

15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out



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MSDS (Material Safety Data Sheet)

SECTION 16: Other information

The contents and format of this SDS are in accordance with Regulation (EC) No 1907/2006, 1272/2008 and Regulation (EU) No 2020/878.

DISCIAIMER OF UABIUTY

The information in this SDS was obtained from sources which we believe are reliable. However, the information is provided without any warranty, express or implied, regarding its correctness. The conditions or methods of handling, storage, use or disposal of the product are beyond our control and may be beyond our knowledge. For this and other reason, we do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the product. This SDS was prepared and is to be used only for this product. If the product is used as a component in another product, this SDS information may not be applicable.

Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

JATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

CAS: Chemical Abstracts Service (division of the American Chemical Society)

DNEL: Derived No-Ejfect Leve! (REACH)

PNEC: Predicted No-Ejfect Concentration (REA CH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic SVHC: Substances of Very High Concem vPvB: very Persistent and very Bioaccumulative