

## QUALITY STATEMENT

Product: Magnesium sulfate heptahydrate

### **Bovine Spongiform Encephalopathy (BSE)/ Transmissible Spongiform Encephalopathy (TSE) status**

We herewith confirm that above mentioned product provides no risk of TSE and BSE. Neither source materials nor production processes as defined in section 2 of the "Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Products (EMEA/410/01 Rev. 03) are used in the manufacture.

### **Genetically Modified Organisms (GMO) status**

We herewith confirm that above mentioned product is non – GMO by origin, because is manufactured by chemical synthesis from raw materials, which are pure chemical substances, and do not need to be labeled, as GMO or produced from GMO, according to EC regulations 1829/2003/EC.

Non – GMO by origin means:

Identity preserved raw materials of non – GMO of origin are used throughout the manufacturing process, that traceability is assured and that measures are in place to prevent cross contamination with GMO products.

### **Allergenic properties status**

We herewith confirm that above mentioned product complies with the requirements of Directive 2000/13/EC of the European Parliament and of the Council last amended by Regulation (EU) No. 1169/2011 as regards certain food ingredients. The above mentioned product does not contain Allergens listed within Annex IIIa

### **Additives**

We herewith confirm that above mentioned product does NOT contain any additives. The packaging complies with Directive 94/62/EC, Directive 2002/172/EC and Regulation (EC) no. 1935/2004 and does not contain any restricted additives.

### **Halal status**

Hereby we declare that the the above mentioned product is non-Haram (minimum requirement) and is Halal using Codex Alimentarius Commission Guidelines.

This means that the products we supply you with is:

1. Free from animal origin, alcohol and genetic modified products (as defined by Halal terms, as defined in CAC/GL 24/1997) and there is not any cross contamination with Haram products,
2. Halal as defined in the Codex general guidelines CAC/GL 24-1997 (Link: <http://www.fao.org/DOCREP/005/Y2770E/y2770e08.htm>) with the exception on labelling.

### **Change control notification status**

Herewith we confirm that Macco Organiques, s.r.o., Czech Republic will inform customer about all significant changes in production, purification process or packaging material of above mentioned product, that may have influence on its quality, safety or stability three months before change implementation.

We also commit ourselves to inform whether any changes are made in the specification.

### **Radiation certificate status**

We herewith confirm that above mentioned product and starting raw materials also are not exposed to source of radiation during the production, storage or transport.

### **Process Water Statement**

Herewith we declares that no process water is used in the manufacturing process of the above mentioned product.

Moreover, we confirm that to the best of our knowledge no substances are used or produced in the manufacturing process of the above mentioned product, that are not covered by the monograph for this product of the European Pharmacopeia.

### **Impurities**

According to the "Note for Guidance on Summary of Requirements for active substances in part II of the dossier (CPMP / QWP / 297 / 97)" herewith we confirm that for the production of the product mentioned above no process is used, which may leave impurities less than 0.1% not adequately controlled in the current edition of the Ph.Eur. monograph. Therefore, the Ph.Eur. monograph is suitable to control the purity of the above mentioned raw material."

### **Animal Testing**

We herewith confirm that above mentioned product is not tested on animals.

### **Ionisation Radiation**

We hereby certify that our above mentioned product is not treated by ionising radiation. Legal reference: Directive 1999/2/EC dated 22 February 1999 on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionising radiation.

### **Melamine, Cyanuric Acid**

We hereby certify that the product mentioned above is free from Melamine, Cyanuric acid.

### **Kosher**

We hereby certify that our above mentioned product is manufactured by chemical process with mineral raw materials. The product does not contain any ingredient of animal origin, any blood or blood by-products or any alcohol. Alcohol has not been used in the manufacturing process. The equipment used for manufacturing and packaging the above

mentioned product is not used for the manufacture and packaging of products of animal origin or products containing animal or animal-derived ingredients.

#### **Contact materials**

We hereby certify that the used contact materials are in compliance to Regulation (EC) 1935/2004 (adopted 27 October 2004) repeals Directives 80/590/EEC and 89/109/EEC.

#### **Traceability**

Traceability measurements are requested through regulation (EC) No. 178/2002 as an imposed obligation to secure food safety along the whole food supply chain. We hereby assure to fulfil the requirements of regulation (EC) No. 178/2002 with regard to the product itself and to its contact materials.

#### **Asbestos**

We hereby certify that the product mentioned above does not contain any asbestos.

#### **Dioxins**

Hereby we declare that the product mentioned above and associated packaging, does NOT contain any dioxins.

#### **Latex**

Hereby we declare that the product mentioned above and associated packaging, does NOT contain any latex.

#### **Mycotoxins**

Hereby we declare that the product mentioned above is mycotoxins free.

#### **Pesticides**

Hereby we declare that the product mentioned above and starting raw materials also are not exposed to source of pesticides.

#### **Phthalates**

Hereby we declare that the product mentioned above and starting raw materials and associated packaging, does NOT contain any phthalates.

#### **Aflatoxins**

Hereby we declare that the product mentioned above and starting raw materials and associated packaging are free of aflatoxins.

#### **Animal free**

Hereby we declare that the product mentioned above and starting raw materials and associated packaging does not contain any substances of animal or biological origin. During the manufacturing process no raw materials of biological origin are used.

#### **Nanomaterials**

Hereby we declare that the product mentioned above provides no risk of contamination by nanomaterials.

Neither source materials nor production processes are used in the manufacture.

#### **Packaging materials**

Hereby we declare that the packaging material used as primary packaging for the product mentioned above fulfils the requirements CPMP/QWP/4359/03 for plastic immediate packaging materials.

#### **HACCP**

Hereby we confirm to our customer that we established quality assurance system and the product mentioned above fulfill the requirements of the quality assurance system in view of health safety of product according to HACCP is implemented.

#### **OVI and residual solvents**

Hereby we declare that the product mentioned above is free from the Residual Organic Solvents and meet the OVI & Residual Solvents requirements as outlined in the USP, EP and CPMP/ICH/28 260/06 Guidelines.

#### **Residues of metal catalysts or metal reagents**

Hereby we declare that the product mentioned above is free from the Residues of metal catalysts or metal reagents and meet the Residues of metal catalysts or metal reagents requirements as outlined in current ICH Q3D guideline

#### **SVHC**

Hereby we declare that the product mentioned above is free of Substance of very high concern stated in Annex XIV of Reach and SVHC candidate list.

#### **California List of Chemicals, Proposition 65**

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

#### **C.M.R. classified substances**

material does not contain carcinogenic, mutagenic, toxic to reproduction (CMR) substances nor substances having endocrine-disrupting properties. The regulations involved with this are the Regulation (EC) No 1272/2008; Regulation (EC) No 1907/2006; Regulation (EU) No 528/2012 and the SCHEER guideline.

**Special Diets**

Suitable for celiacs	YES
Suitable for vegans	YES
Suitable for vegetarians	YES
Suitable for ova-lacto vegetarians	YES
Suitable for diabetics	YES

**Nutritional value**

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

Listed In Amounts Per 100 Grams

Calories	0	Kcal	Vit. E. – Alpha Eq	0	mg
Protein	0	g	Calcium	40	mg
Total	0	g	Copper	0	mg
Carbohydrates			Iron	0	mg
Dietary Fiber	0	g	Magnesium	9756	mg
Fat Total	0	g	Phosphorus	0	mg
Saturated Fat	0	g	Potassium	0.4	mg
Mono Fat	0	g	Sodium	0	mg
Poly Fat	0	g	Zinc	0	mg
Cholesterol	0	mg	Total Sugars	0	g
Total Vit. A	0	mcg	Vitamin D	0	mcg
Thiamine –B1	0	mg	Starch	0	g
Riboflavin-B2	0	mg	Water (moisture)	51.2	g
Niacin – B3	0	mg	Vitamin C	0	mg
Vitamin B6	0	mg	Insol. Fiber	0	g
Vitamin B12	0	mcg	Sol. Fiber	0	g
Ash	49.8	g	Crude Fiber	0	g
Alcohol	0	g	Biotin	0	mg
Sugar Alcohol	0	mcg	Iodine	0	mg
Folic Acid	0	mcg	Trans Fat	0	g
Pantothenic Acid	0	mg	Added Sugars	0	g
Chromium	0	mcg	Vitamin K	0	mcg
Molybdenum	0	mcg	Manganese	0	mg
Selenium	0	mcg			
Chloride	3	mg			

March 4, 2020



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