

## QUALITY STATEMENT

Product: Sodium hydrogen phosphate 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 2002/72/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 immediately after receiving of these changes from manufacturer.

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.

### **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.

### **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.

### **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.

### **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.

#### **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.

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

Material does not contain carcinogenic, mutagenic, toxic to reproduction (CMR) substances nor substances having endocrine-disrupting properties. The regulations



**Macco Organiques, s.r.o.**

involved with this are the Regulation (EC) No 1272/2008; Regulation (EC) No 1907/2006; Regulation (EU) No 528/2012 and the SCHEER guideline.

February 25<sup>th</sup>, 2021



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**Macco Organiques, s.r.o.**  
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