

QUALITY STATEMENT

Product: Sodium acetate trihydrate

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 2002172/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.

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.

Dioxins

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

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.

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.

OVI and residual solvents

only materials (i. e. starting materials, intermediates, auxiliary agents) being in scope of the EU „Note for Guidance on Impurities: Residual Solvents (CPMP/ICFI/283/95) and EMEA/CVMP/511/03 , CVMP/VICH/502/99, USP <467> Residual Solvents and the requirements of the Ph. Eur, section 5.4 are used.

In accordance with CPMP/ICH/283/95 and CVMP/VICH/502/99 guidelines; only the Class 3 solvent Acetic Acid is likely to be present in this product. Class 1 and/or 2 solvents are not used for manufacturing. Acetic Acid is used as raw material for the production of this product. The level of Acetic Acid in this product is controlled and limited to less than 5000 ppm. If tested, this product will comply with the specified limits for Residual Solvents as given in the USP <467> and Ph.Eur (5.4). We further advise that the content of Acetic acid in this product is tested by acidimetric titration. Using this method the content of Free Acetic acid is measured exclusively.

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

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