

March 2021

JMB Metallic Stearates – Regulatory & Position Paper

THIS STATEMENT COVERS CALCIUM STEARATES ONLY

JMB Metallic Stearates find a diverse range of applications in industry, including pharmaceutical and food. Owing to the large number of customer requests regarding the status of our products with respect to various directives, regulations or topical issues, we have put together this document which aims to answer the most common queries. For any specific queries then please do not hesitate to contact us.

MANUFACTURING

JMB calcium stearates are manufactured at the UK production site in Staffordshire, England. They are made from reacting calcium hydroxide with stearic acid in the presence of potable water.

No other additives or excipients are used in the production of JMB metallic stearates.

The stearic acid used is of 100% vegetable origin (palm oil derived) and has Kosher and Halal approval.

JMB metallic stearates are Kosher and Halal approved by the Manchester Beth Din and by Halal Certification Europe respectively.

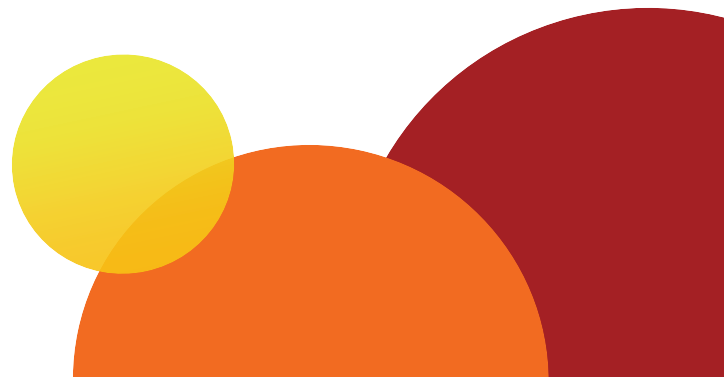
TSE/BSE STATUS in accordance with the EMEA notice for Guidance EMEA 410/01 (current revision)

All stearates manufactured by JMB use stearic acid derived exclusively from plant sources - specifically, the oil palm. We neither use nor store stearic acid from any other source on our site.

There is, therefore, no possible risk of any TSE/BSE material being present in any of our stearates.

"GMO" STATUS

To the best of our knowledge there has not been, and there are no plans for, any experimentation on modifying the genetic make-up of the oil palm. As all other raw materials used in the manufacture of our stearates are of wholly inorganic origin, there are no "GMO" materials present in them.



RESIDUAL SOLVENTS

The International Conference on Harmonisation of technical requirements for registration of pharmaceuticals for human use (ICH) produced its document "Impurities: guidelines for residual solvents" ICH Q3C. This divided a number of organic solvents which might be present in pharmaceuticals into three classes:-

Class 1 - solvents that should be avoided

Class 2 - solvents to be limited

Class 3 - solvents with low toxic potential

We confirm that no organic solvents are used in the production of the stearic acid we use or in the stearate manufacturing process at JMB. We can therefore confirm that JMB stearates are solvent-free.

IRRADIATION

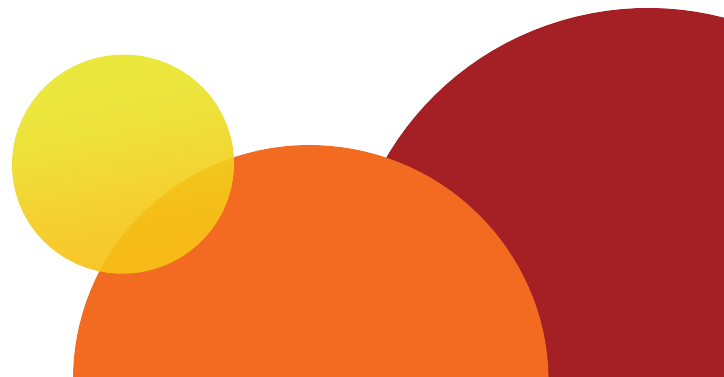
We can confirm that neither our products, nor the ingredients used in their manufacture have been subjected to irradiation.

ALLERGENS - REGULATION 1169/2011 as amended

In order to assist food business operators meet their obligations under the Food Information for Consumers Regulation 1169/2011 as amended;

We can confirm that no JMB stearate contains any of the allergens mentioned in the updated Annex II list: these are as follows:-

- cereals containing gluten namely wheat (such as spelt and Khorasan wheat), rye, barley, oats 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, hazelnuts, walnuts, cashews, pecan, brazil, pistachio, macadamia or Queensland and products thereof
- celery and products thereof
- mustard and products thereof
- sesame seeds and products thereof
- sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre (expressed as SO₂)
- lupin and products thereof
- molluscs and products thereof



Ethylene Oxide Sterilisation

James M. Brown Ltd can confirm that Ethylene oxide is not used in the manufacturing process of the ingredients or in the manufacturing process of the calcium stearate.

NANOPARTICLES – Regulation (EU) 2015/2283 (amending Regulation (EU) 1169/2011)

JMB metallic stearates do not contain nanoparticles.

LATEX

It is the policy of James M. Brown Ltd not to use latex in or during stearate production and, to the best of our knowledge it is not used in the production of the ingredients. Latex gloves are not used in the stearate production plant.

REGULATION EU 2015/1933 (amending regulation EC No. 1881/2006) – Maximum levels for PAH's in Food Supplements

To the best of our knowledge our metallic stearates conform to Regulation EU 2015/1933.

ERUCIC ACID

EU Regulation 696/2014 set limits for the maximum levels of Erucic acid permitted in oils and fats and foods containing oils and fats. Although stearates do not fall into the category 'oils and fats', we thought it wise to investigate the matter. We have been advised by our stearic acid suppliers that Erucic acid is not present in their material and there are no concerns about this substance.

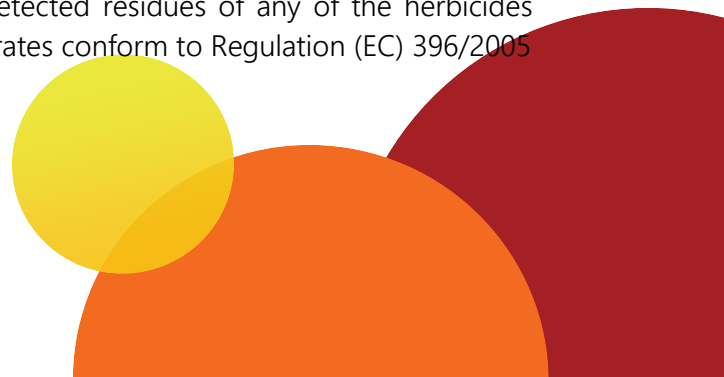
MELAMINE

In the US FDA issued guidance document "Pharmaceutical components at risk for melamine contamination" it contains a list of 'at risk' pharmaceutical components. This list does not include metal stearates.

We are happy to confirm that none of the raw materials we use contain melamine and this substance is not used in any manufacturing process.

PESTICIDES/HERBICIDES

Our suppliers of stearic acid do control the use of herbicides and therefore, test both the crude palm oil and stearic acid for their presence. All suppliers have made it known to James M Brown Ltd that the final product testing regime has not detected residues of any of the herbicides used in their plantations. Therefore JMB metallic stearates conform to Regulation (EC) 396/2005 as amended.



INHERENT PLANT TOXINS

To the best of our knowledge our metallic stearates do not contain any inherent plant toxins. The stearic acid used for the production of JMB metallic stearates is derived solely from the oil palm.

MYCOTOXINS

To the best of our knowledge our metallic stearates do not contain any mycotoxins.

NITRATES

To the best of our knowledge our metallic stearates do not contain any nitrates.

DIOXINS & PCB's

To the best of our knowledge our metallic stearates do not contain any dioxins or PCB's.

HEAVY METALS in accordance with Regulation (EC) 1881/2006

Levels of heavy metals namely Arsenic, Mercury, Cadmium & Lead are tested for in accordance with the specification relevant to the European Pharmacopoeia monograph for calcium stearate and Regulation 231/2012 specification for food additives (see the specific specification for details).

JMB can confirm that the calcium stearate complies with both the specifications contained within the EP monograph and Regulation 231/2012.

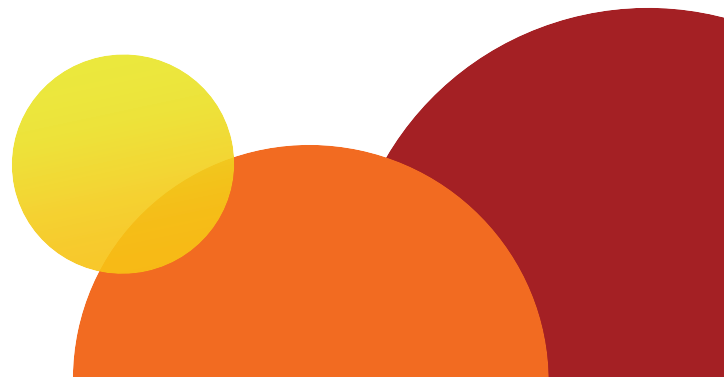
METAL CATALYST/REAGENT RESIDUES in accordance with EMEA/CHMP/SWP/4446/2000 and, ICH Q3D ELEMENTAL IMPURITIES

Please request the JMB Metal Catalyst/Reagent Residue/ICH Q3D Elemental Impurities table for details.

GLUTEN

It is our understanding that gluten is a protein found in wheat, rye, spelt and related plant species. The stearic acid that James M Brown Ltd use for the manufacture of all our stearates is derived exclusively from the oil palm and, to the best of our knowledge, this species – not being a member of the grass family – does not produce gluten.

We have no information as to what, if any, trace levels of gluten might be present in our magnesium stearate.



NUCLEOTIDES/ISOTOPES

James M Brown Ltd can confirm that there are no nucleotides or isotopes in our calcium stearate.

SUITABILITY FOR VEGANS

James M Brown Ltd calcium stearate is made from mineral sourced calcium hydroxide and stearic acid derived from the oil palm. Given that suppliers are selected to meet the required material specifications and the knowledge that we have of the material manufacturing process, we have every confidence that James M Brown Ltd stearates are suitable for vegans.

STABILITY INFORMATION

JMB carry out long-term stability testing in temperate climate conditions and has had accelerated stability testing conducted for climate zone IV. The IPEC Excipient Stability Program Guide 2010 indicates that for products that are deemed stable (as per the criteria), a statement or reference to a stability study in relevant packaging is all that is required to demonstrate stability to users. As is indicated in our specification and on our CoA's for calcium stearate – James M. Brown Ltd has data to support an expiry date of 3 years from the date of manufacture if stored in the original unopened packaging in dry conditions.

SUSTAINABILITY

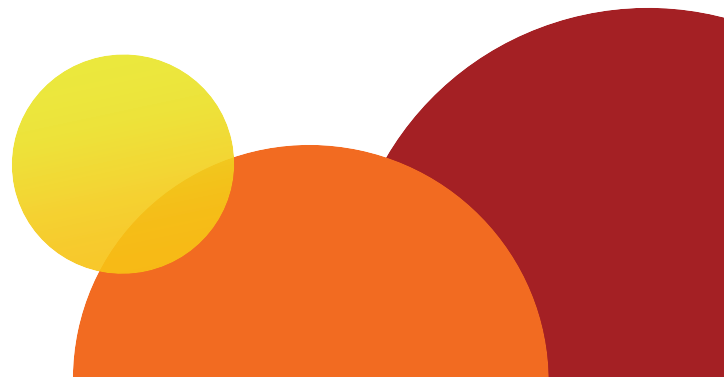
James M. Brown Ltd is an Associate Member of the Roundtable on Sustainable Palm Oil (RSPO) and has achieved Mass Balance RSPO Supply Chain Certification Systems accreditation. Please contact JMB Sales to discuss your RSPO certified requirements. Check our progress on the RSPO website at www.rspo.org.

Excipient Nitrosamines Risk Evaluation

Based on the information provided by our raw material suppliers and our knowledge of the manufacturing processes, we can confirm that there is no risk of nitrosamines being present in JMB calcium stearate.

Glycidyl esters; 2-MCPD esters; 3-MCPD ester

Information provided by our stearic acid suppliers indicates that the JMB manufactured calcium stearate does not contain any Glycidyl esters, 2-MCPD esters or 3-MCPD esters above 0.1mg/Kg.



Proposition 65 Chemical Ingredients

James M. Brown Ltd can confirm that the calcium stearate it manufactures does not contain any chemicals known to the State of California to cause Cancer, Reproductive or Developmental harm.

WADA Prohibitive Substances List

James M. Brown Manufactured Calcium Stearate is not on the list of prohibitive substances as maintained by WADA.



Dave Cooper
Quality Systems Manager

