

JMB JAMES M. BROWN LTD.

NAPIER STREET, FENTON, STOKE-ON-TRENT, STAFFS. ST4 4NX
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VAT Reg. No: GB 238 5019 63

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JMB Metallic Stearates – Regulatory & Position Paper

THIS STATEMENT COVERS CALCIUM AND MAGNESIUM 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

James M Brown metallic stearates are made from reacting magnesium oxide or calcium hydroxide (depending upon the required metal stearate) 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 Halaal approval and is sourced from Malaysia.

The magnesium oxide is sourced from mineral deposits and the calcium hydroxide is derived from mineral deposits in the UK.

JMB metallic stearates are Kosher and Halaal approved by the Manchester Beth Din and by The Muslim Food Board respectively.

TSE/BSE STATUS

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 potentially-infectious material being present in any of our stearates.

"GM" 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 "GM" materials present in them.

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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". 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 are pleased to be able to 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 stearic acid used in their manufacture, have been subjected to irradiation.

ALLERGENS - DIRECTIVES 2006/142/EC, 2003/89/EC and 2000/13/EC AND REGULATION 1169/2011

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

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, rye, barley, oats, spelt, kamut 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

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- 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

REGULATION EU 2015/1933 (amending regulation EC Mo. 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 August 2009 the US FDA issued its guidance document "Pharmaceutical components at risk for melamine contamination".

The FDA document contains a list of 'at risk' pharmaceutical components and this does not include metal stearates. Despite this, 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

Our suppliers of stearic acid do use herbicides and therefore, test both the crude palm oil and stearic acid for their presence. Both suppliers have made it known to James M Brown Ltd that the testing regime has not detected any herbicide residues in their products.

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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.

SUITABILITY FOR VEGANS

James M Brown Ltd stearates are made from mineral sourced magnesium oxide or 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

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 stated in our specification and on our CoA's for magnesium & calcium stearates – 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 for the manufacture of its metallic stearates. Check our progress on the RSPO website at www.rspo.org.

THIS STATEMENT DOES NOT APPLY TO JMB ZINC STEARATE



Dave Cooper
Quality Systems Manager