

March 2016

## JMB stearates - BSE, GM, organic solvent, irradiation & allergen status

### THIS STATEMENT COVERS CALCIUM AND MAGNESIUM STEARATES ONLY

Some JMB stearates are used in the production of both pharmaceutical and confectionary products and, in the light of the controversy regarding BSE and the use of genetically-modified materials, many customers are contacting us regarding the status of our products. There has also been recent interest in reducing or eliminating the levels of organic solvents present in pharmaceuticals and whether our products are irradiated. EU legislation requiring allergen labelling has led to customers contacting us for information. Lastly, the EU has recently established legislation covering Erucic acid in foodstuffs.

#### 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.

#### 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 2000/134/EC

Directive 2003/89/EC amends 2000/13/EC and requires, amongst other things, that food products be labelled if they contain any of the allergens listed in Annex IIIa. After 25th November 2005 it becomes unlawful to sell products which do not comply with the Directive. Directive 2006/142/EC further amends 2000/12/EC to add lupins and molluscs to the allergens which have to be declared. We can supply a copy of any of the Directives in electronic form on request.

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

- cereals containing gluten (i.e. 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 i.e. almonds, hazelnuts, walnuts, cashews, pecan, brazil, pistachio, macadamia, 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 SO<sub>2</sub>)
- lupins (added by 2006/12/EC)
- molluscs (added by 2006/12/EC)

#### 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

Some years ago there were concerns about food items imported from China which were found to be contaminated with melamine.

Although no pharmaceutical contaminated with this substance has ever been reported, 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.

**THIS STATEMENT DOES NOT APPLY TO ZINC STEARATE**



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