

### **GMO, Allergen and Food Status of Hygiene Technologies Ltd Tech 30AF Antifoam**

The suppliers of the major components of the above antifoam have verified that to the best of their knowledge and according to all their manufacturing controls there are no GMO components in the materials they supply. The major materials in the mixture apart from water are inorganic man-made products and have no GMO component. The second and less used type of ingredients are surfactants and the suppliers have verified that these chemicals do not contain GMO materials to the best of their knowledge. The minor ingredients are biocide chemicals. Those of potential plant origin have been certified as not containing GMO's. The rest are purely synthetic chemicals and thus have no reason to contain GMO's. Thus, to the best of our knowledge and ability to ascertain, this product does not contain any genetically modified organisms.

No materials used in the manufacture of these products contain any allergenic materials to the best of our knowledge. They do not contain sulphur dioxide, nor products derived from cereals containing gluten, crustaceans, eggs, fish, peanuts, soybeans, milk, nuts, celery, mustard, sesame seeds, lupin or molluscs. All materials used are specified by the suppliers as food ingredients to FDA guidelines, and the products are manufactured using sterilised, stainless steel vessels under food grade conditions. The products are packaged into new, sterile HDPE packages made from virgin plastic.

#### Components:

##### Active Component

Silicone fluid (10 – 40%) : The supplier has confirmed that the material supplied consists only of dimethylpolysiloxane, and complies with the requirements from the following provisions of FDA 21 CFR.

FDA compliance (food additive to 10ppm)

§ 173.340: Defoaming agents

FDA compliance (food contact)

§ 173.340: Defoaming agents

§ 175.105: Adhesives

§ 175.300: Resinous and polymeric coatings (release agent)

§ 176.170: Components of paper and paperboard in contact with aqueous and fatty foods

§ 176.180: Components of paper and paperboard in contact with dry food

§ 176.200: Defoaming agents used in coatings

§ 176.210: Defoaming agents used the manufacture of paper and paperboard

§ 177.1200: Cellophane

§ 177.2260: Filters, resin-bonded

§ 177.2800: Textiles and textile fabrics

§ 178.3120: Animal glue

§ 178.3570: Lubricants with incidental food contact

§ 181.28: Release agents (prior sanction)

Emulsifiers (< 10%) : The supplier has confirmed the material supplied complies with the requirements from the following provisions of FDA 21 CFR.

§ 178.3400 "Emulsifiers and/or surface-active agents"

§ 181.30 "Substances used in the manufacture of paper and paperboard products used in food packaging"

Biocides (<1.0%) : FDA approved additives to prevent biocidal growth.

Every batch is subjected to a set of quality assurance tests to ensure conformity to its specified physical properties. As part of this, each batch is subjected to a spore count (100 µL on 80mm diam. DRBC plate, maximum count = 5., normal result = 0) and a microorganism count (100 µL on 80mm diam. nutrient agar, maximum count = 5, normal result = 0). The products are manufactured in designated equipment unique to these products and without cross contamination from other products or raw materials. The manufacturing processes are clearly defined and documented and validated for each batch. Records are made for each batch to ensure that the processes are adhered to. Any changes to the processes are validated and full testing undertaken to confirm that there are no changes to the quality or effectiveness of the product. Distribution records are kept at all times and a recall procedure is in place if any fault is discovered.