



Empty Hard Pullulan #0 Capsules
Safety Data Sheet
Technical Specifications
Intolerance Data

We don't just sell machines—
we provide service.

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1. Safety Data Sheet



1.1 Description

| | |
|---------------------|---|
| Product Name | Empty Hard Pullulan #0 Capsules |
| Product Code | 5056206116934 (5,000 count) 5056206116941 (100,000 count) |
| Supplier | LFA Machines Oxford Ltd. Unit 4b, 26-27 Murdock Road Bicester, Oxfordshire OX26499 United Kingdom Tel: +44 (0) 1869 250 234 |

1.2 Ingredients/Identity Information

| | |
|---|---|
| Composition per capsule part | Body represents about 60% of capsule weight |
| Name of ingredient(s) and function | Pullulan, structure |
| Body percentage (mg/body) | qsp 100% (73.2000) |
| Cap percentage (mg/cap) | qsp 100% (48.8000) |
| Total capsule (mg/capsule) | qsp 100% (122.0000) |
| E Number | E1204 |
| CAS Number | 9057-02-7 |

1.3 Hazards Identification



The European Regulations on Material Safety Data Sheets (MSDS), Classification, Labeling and Packaging of hazardous substances or mixtures do not apply to empty hard pullulan capsules.

This is based on the following interpretations of European law:

- The empty hard pullulan capsules supplied by LFA Machines correspond to the definition of 'Articles' as described in article 3 of the European Regulation (EC) No 1907/2006. An 'article' means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition. As a result, empty hard pullulan capsules are neither substances or mixtures.
- Article 31 of the European Regulation (EC) No 1907/2006 requires that the supplier of a substance or mixture shall provide the recipient of a substance or preparation with a safety data sheet complied in accordance with Annex II. It is not required to provide safety data sheets for articles. As a result, LFA Machines does not provide safety data sheets for empty hard pullulan capsules.
- Article 33 of the European Regulation (EC) No 1907/2006 requires that any supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) in a concentration above 0.1% weight by weight (w/w) shall provide the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of the substance. LFA Machines certifies that the empty hard pullulan capsules are free of substances meeting the criteria in Article 57 and identified in accordance with Article 59.
- The European Regulation (EC) No 1272/2008 on classification, labeling and packaging of substances and mixtures is not applicable for articles. As a result, this regulation is not applicable for empty hard pullulan capsules.

To the best of our knowledge, our products do not contain any contaminants or by-products known to the State of California that cause cancer or reproductive toxicity as listed under Proposition 65 Drinking Water and Toxic Enforcement Act.

1.4 Storage



LFA recommends capsules to be stored in the closed containers in which they are received. They should be kept in areas where the ambient temperature is 15°C to 25°C with a relative humidity of 35% to 65%. Following these environmental conditions will lead to 5 years shelf life for the capsules.

1.5 Additional Information

| Defect Group | Critical Defects | Major Defects | Minor Defects |
|--------------|------------------|---------------|---------------|
| | Visual | Visual | Visual |
| AQL | 0.01% | 0.04% | 0.25% |
| AOQL | 0.029% | 0.067% | 0.36% |

| Additional Specifications | | |
|---|--------|---------------|
| Ingredient/Reference | EEC No | Function |
| Carrageenan (not to exceed 0.5%) | E407 | Gelling agent |
| Potassium chloride (not to exceed 2.0%) | E508 | Gelling agent |

This advice is given by LFA Machines Oxford Ltd., who accept no legal liability for it. The information contained herein is based on the present state of our knowledge and is intended to describe our products from the point of view of safety requirements. It should not therefore be construed as guaranteeing specific properties.

Individuals working with chemicals should consider all chemicals to be potentially hazardous even if their individual hazards may be uncharacterized or unknown.

We confirm that the information above is sourced from the original manufacturers/suppliers.

2. Technical Specifications

2.1 Product Data



| Characteristics | Specifications | Units |
|-------------------------------|-----------------------|--------------|
| Identification of Pullulan | Positive | |
| Sulphated ash | Not more than 4 | % |
| Disintegration time | Less than 15 | min |
| Loss on drying | Between 10 and 14 | % |
| Average weight | Between 115 to 129 | mg |
| E. coli | Absence in 1 gram | |
| Salmonella | Absence in 10 grams | |
| Staphylococcus aureus | Absence in 1 gram | |
| Total aerobic microbial count | Less than 1000 | cfu/g |
| Total yeast and mold count | Less than 100 | cfu/g |

2.2 Metals



| | |
|-----------------|----------|
| Arsenic | <1.5 ppm |
| Lead | <1 ppm |
| Cadmium | <0.5 ppm |
| Mercury | <0.1 ppm |
| Cobalt | <5 ppm |
| Vanadium | <10 ppm |
| Nickel | <20 ppm |

There are no nuts in this recipe, and there are no nuts on site. However, we cannot guarantee that the raw materials entering the site are nut free.

3. Intolerance Data

3.1 Intolerance Data Table



| | |
|---|-----------------|
| Free from all animal products (beef, pork, poultry, or other) | YES |
| Free from bovine products or derivatives by using hormones to increase milk yield in cows | YES |
| Free from bone meal | YES |
| Free from peanuts and peanut derivatives (including possible cross contamination) | YES |
| Free from other nut and nut derivatives | YES |
| Free from nut derived oil | YES |
| Free from sesame seeds and sesame seed derivatives | YES |
| Free from poppy seeds and poppy seed derivatives | YES |
| Free from sunflower seeds and sunflower seed derivatives | YES |
| Free from other seeds and seed derivatives | YES |
| Free from milk and milk derivatives | YES |
| Free from egg and egg derivatives | YES |
| Free from cereals containing gluten (wheat/rye/oats/barley/spelt/kamut or their hybridized strains) and derivatives | YES |
| Free from soya and soya derivatives | YES |
| Free from maize and maize derivatives | YES |
| Free from corn and corn derivatives | YES |
| Free from lupin and lupin derivatives | YES |
| Free from yeast and yeast derivatives | YES |
| Free from cotton seeds (flour) and cotton seed derivatives | YES |
| Free from rice and rice derivatives | YES |
| Free from mustard and mustard derivatives | YES |
| Free from celery and celery derivatives | YES |
| Free from celeriac and celeriac derivatives | YES |
| Free from fruit and fruit derivatives | YES |
| Free from vegetable and vegetable derivatives | NO (tapioca) |
| Free from carrot and carrot derivatives | YES |
| Free from legumes/pulses | YES |



| | |
|---|-----|
| Free from fish and fish derivatives | YES |
| Free from crustaceans and/or molluscs and their derivatives | YES |
| Free from additives | YES |
| Free from added salt | YES |
| Free from added sugar | YES |
| Free from antioxidants | YES |
| Free from artificial glutamates | YES |
| Free from aspartame | YES |
| Free from Azo and coal tar dyes | YES |
| Free from benzoates (E210/E219) | YES |
| Free from BHA/BHT (E320/E321) | YES |
| Free from caffeine | YES |
| Free from cinnamon | YES |
| Free from cocoa | YES |
| Free from colors (artificial/nature identical/natural/smoked) | YES |
| Free from dextrose | YES |
| Free from dioxins | YES |
| Free from ethanol | YES |
| Free from ethylene oxide | YES |
| Free from flavorings (artificial/nature identical/natural/smoked) | YES |
| Free from garlic | YES |
| Free from gelatine | YES |
| Free from glutamates (E620 to E625) | YES |
| Free from histamine | YES |
| Free from hickory | YES |
| Free from honey | YES |
| Free from lactose | YES |



| | |
|--|---|
| Free from latex | YES |
| Free from MSG (added and naturally occurring E621) | YES |
| Free from nucleotides (E627, E630, E631. E635) | YES |
| Free from polyols | YES |
| Free from preservatives | YES |
| Free from starch products (including maltodextrin) | NO (produced from starch by <i>Aureobasidium pullulans</i>) |
| Free from sorbic acid (E200, E203) | YES |
| Free from sulphur dioxide and sulphites at levels above 10 mg/kg or 10 mg/liter express as SO² | YES |
| Free from sweeteners | YES |
| Free from vanillin | YES |
| Suitable for diabetics | YES |
| Suitable for Celiacs | YES |
| Suitable for Ovo-Lacto Vegetarians | YES |
| Suitable for Vegans | YES |
| Kosher Certified | YES |
| Halal Certified | YES |



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