



Empty Hard Gelatin #00 Capsules  
Royal Purple  
Safety Data Sheet  
Technical Specifications  
Intolerance Data

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# 1. Safety Data Sheet



## 1.1 Description

<b>Product Name</b>	Empty Hard Gelatin #00 Royal Purple Capsules
<b>Product Code</b>	5056206108670 (500 count) 5056206108359 (1000 count) 5056206108366 (5000 count) 5056206108373 (10,000 count) 5056206108380 (70,000 count)
<b>Supplier</b>	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

<b>Composition per capsule part</b>	Body represents about 60% of capsule weight
<b>Name of ingredient(s) and function</b>	Gelatin (bovine), structure Titanium dioxide, opacifier FD&C red #3, colorant FD&C red #40, colorant FD&C blue #1, colorant
<b>Body percentage (mg/body)</b>	Gelatin: qsp 100% (69.9412) Titanium dioxide: 0.9008% (0.6378) FD&C red #3: 0.2423% (0.1716) FD&C red #40: 0.0408% (0.0289) FD&C blue #1: 0.0291% (0.0206)
<b>Cap percentage (mg/cap)</b>	Gelatin: qsp 100% (46.6274) Titanium dioxide: 0.9008% (0.4252) FD&C red #3: 0.2423% (0.1144) FD&C red #40: 0.0408% (0.0192) FD&C blue #1: 0.0291% (0.0137)
<b>Total capsule (mg/capsule)</b>	Gelatin: qsp 100% (116.5686) Titanium dioxide: 0.9008% (1.0630) FD&C red #3: 0.2423% (0.2860) FD&C red #40: 0.0408% (0.0481) FD&C blue #1: 0.0291% (0.0343)
<b>EINECS Number</b>	N/A

## 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 gelatin capsules.

This is based on the following interpretations of European law:

- The empty hard gelatin 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 gelatin 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 gelatin 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 gelatin 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 gelatin capsules.

## 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

<b>Defect Group</b>	<b>Critical Defects</b>	<b>Major Defects</b>	<b>Minor Defects</b>
	<b>Visual</b>	<b>Visual</b>	<b>Visual</b>
AQL	0.01%	0.04%	0.25%
AOQL	0.029%	0.067%	0.36%

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 gelatin	Positive	
Identification of TiO <sub>2</sub>	Conforms to composition	
Identification of dyestuffs	Conforms to composition	
Sulphated ash	Less than 7	%
Disintegration time	Less than 15:00	min/sec
Lubricant content	Less than 0.5	%
Sulphur dioxide	Less than 50	ppm
Loss on drying	Between 13.0 and 16.0	%
Average weight	Between 111 and 125	mg
E. coli	Absence in 1 gram	
Salmonella	Absence in 10 grams	
Staphylococcus aureus	Absence in 1 gram	
Pseudomonas aeruginosa	Absence in 1 gram	
Total yeast and mold count	Less than 100	cfu/g
Total aerobic microbial count	Less than 1000	cfu/g

## 2.2 Metals



<b>Arsenic</b>	<1 ppm
<b>Lead</b>	<1 ppm
<b>Cadmium</b>	<0.5 ppm
<b>Mercury</b>	<0.1 ppm
<b>Cobalt</b>	<5 ppm
<b>Vanadium</b>	<10 ppm
<b>Nickel</b>	<20 ppm
<b>Chromium</b>	<2 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)	NO (bovine)
Free from bovine products or derivatives by using hormones to increase milk yield in cows	NO (bovine)
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	YES
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)	NO
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	NO
Free from glutamates (E620 to E625)	YES
Free from histamine	YES
Free from hickory	YES
Free from honey	YES
Free from lactose	YES



<b>Free from latex</b>	YES
<b>Free from MSG (added and naturally occurring E621)</b>	YES
<b>Free from nucleotides (E627, E630, E631. E635)</b>	YES
<b>Free from polyols</b>	YES
<b>Free from preservatives</b>	YES
<b>Free from starch products (including maltodextrin)</b>	YES
<b>Free from sorbic acid (E200, E203)</b>	YES
<b>Free from sulphur dioxide and sulphites at levels above 10 mg/kg or 10 mg/liter express as SO<sup>2</sup></b>	YES
<b>Free from sweeteners</b>	YES
<b>Free from vanillin</b>	YES
<b>Suitable for diabetics</b>	YES
<b>Suitable for Celiacs</b>	YES
<b>Suitable for Ovo-Lacto Vegetarians</b>	NO
<b>Suitable for Vegans</b>	NO
<b>Kosher Certified</b>	NO
<b>Halal Certified</b>	YES



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