



SterolSure™

Revision: ENB

Supersedes: 01A

Effective: 4/6/2024

Product Code:
EZ891281a

Specification

1. MATERIAL INFORMATION

1.1 **Product Name:** SterolSure™

1.2 **Formula per capsule:**

a. Rice Sterol 210mg

b. Policosanol 30mg

c. Gamma Oryzanol 60mg

1.3 As per the list of 2017 and subsequent amendments of the World Anti-Doping Agency, this material is not a doping substance, nor is it a combination of doping substances.

1.4 This material contains no ingredients of ruminant origin and no materials derived from or exposed to ruminants affected by or under quarantine for Transmitting Transmissible Spongiform Encephalopathy (TSE) / Bovine Spongiform Encephalopathy (BSE) and it is conformed to the EU legislation 999/2001.

2. MATERIAL SPECIFICATIONS

2.1 Physical/Chemical Specifications

Assay/Test	Specification	Test Method
Appearance	Fine powder	Visual
Color	Yellow to brown powder	Visual
Odor and Taste	Characteristic	Organoleptic
Taste	Characteristic	Organoleptic
Loss on Drying	As reported	5g/85°C/2h
Ash	As reported	2g/525 C/4hrs
Assay		
Rice Sterol (Sterol%)	70% ± 2% ≥42%	Calculated proportionally YBH17672005
Policosanol (Octacosanol%)	10% ± 0.1% ≥6%	Calculated proportionally GC
Gamma Oryzanol (Gamma Oryzanol%)	20% ± 0.5% ≥19.8%	Calculated proportionally UV
Total Heavy Metals	≤10.0ppm	USP<231>

APPROVED

Version: EZ2024, 01A

ENZYMOLAB constitutes the R&D Center of **ACERCHEM International Inc.**

Possession of this document is an acknowledgment that all contents herein are the exclusive property of **ACERCHEM International Inc.** The contents may not be reproduced in any form without written permission from **ACERCHEM International Inc.** The possessor must ensure they have the most current revision.

	SterolSure™			Product Code: EZ891281a
	Revision: ENB	Supersedes: 01A	Effective: 4/6/2024	

Arsenic (As)	≤2.0ppm	USP<730>
Lead (Pb)	≤3.0ppm	USP<730>
Mercury (Hg)	≤0.1ppm	USP<730>
Cadmium (Cd)	≤1.0ppm	USP<730>

2.2 Microbiological Specifications

Assay/Test	Specification	Test Method
Total Plate Count	< 3000 CFU/g	USP<2021>
<i>Escherichia coli</i>	Absent in 10g	USP<2021>
<i>Salmonella species</i>	Absent in 10g	USP<2021>
Total Molds/Yeast	< 300 CFU/g	USP<2021>

3. MANUFACTURING

- 3.1 Manufacture material using methods, techniques, and conditions to minimize contamination.
- 3.2 We certify that the identity, potency, purity, and quality of this material meet current MFR specifications.

4. LABELING

- 4.1 Label each container with sufficient information to prevent confusion of identity with other inventory items.
- 4.2 As a minimum, each shipping container clearly states in a conspicuous manner the vendor's name, batch number, product name, product code, quantity per container, and expiration date.

5. PACKAGING/STORAGE

- 5.1 We hereby certify that the packaging used complies with Commission Regulation (EC)No 1935/2004 and Regulation (EU) No 10/2011 Regarding packaging materials and articles intended to come into contact with food.
- 5.2 Material should be packaged in a clean, clear, non-toxic polyethylene or polypropylene bag. The thickness and strength should be sufficient to withstand rupture from routine movement. Net weight: 25 Kg/ Drum
- 5.3 Ship material in a clean, tight, commercially acceptable shipping container and store in a cool, dry, light-resistant environment.
- 5.4 Store material in a dry and protected location at room temperature.

APPROVED	Version: EZ2024, 01A
ENZYMOLAB constitutes the R&D Center of ACERCHEM International Inc. Possession of this document is an acknowledgment that all contents herein are the exclusive property of ACERCHEM International Inc. The contents may not be reproduced in any form without written permission from ACERCHEM International Inc. The possessor must ensure they have the most current revision.	

	SterolSure™			Product Code: EZ891281a
	Revision: ENB	Supersedes: 01A	Effective: 4/6/2024	

5.5 This material has a recommended shelf life of 2 years when stored in a cool, dry, light resistant environment.

APPROVED	Version: EZ2024, 01A
ENZYMOLAB constitutes the R&D Center of ACERCHEM International Inc. Possession of this document is an acknowledgment that all contents herein are the exclusive property of ACERCHEM International Inc. The contents may not be reproduced in any form without written permission from ACERCHEM International Inc. The possessor must ensure they have the most current revision.	