

**94201-CYSTINE-L****1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION.****1.1. Identification of the substance or preparation.**

Name: Cystine-L

Bulk code: 94201

Internal code: 46000

Valid from bulk lot: 0123592

**1.2. Synonyms.**

(R, R) -3,3'-Dithiobis (2-aminopropionic acid)

**2. DESCRIPTION.**

Appearance: Crystal or crystalline powder

Color: White

Smell: Characteristic

Origin: Vegetable.

Geographic origin: China

**3. COMPOSITION/INFORMATION ON COMPONENTS.**Formula:  $C_6H_{12}N_2O_4S_2$ 

CAS: 56-89-3

Molecular weight: 240.3 g/mol

Composition: The product is 100% L-Cystine.

**Obtaining method:** The culture is transferred to a flask and from there to a seeding tank. By adding the culture medium, it is sown and subsequently fermented, applying sterile air. The liquid obtained from the fermentation is passed through a ceramic film, the acid is regulated, it becomes discolored, and an alkali-regulating crystallization subsequently occurs. Crude is centrifuged, dried and packaged.

**4. PHYSICAL-CHEMICAL DATA.**

For more detailed information, consult the analysis bulletin.

**Solubility:** It is soluble in mineral acids and solutions of dilute alkaline hydroxides and practically insoluble in water and alcohol.

**5. PROPERTIES/USES.**

Pharmaceutical use excipient.

Alimentary use.

**94201-CYSTINE-L**

The product complies with the additive declaration and with the Commission Regulation (EU) No. 231/2012 on food additives.

**6. DOSAGE.**

No data available

**7. OBSERVATIONS.**

The product has been handled in a NON-sterile room, therefore the product is NOT STERILE.

**STORAGE:**

Store in a cool, dry place, protected from light and with the container tightly closed, in dry and ventilated places, away from sources of humidity and ignition.

The documentation corresponding to the regulatory part of the product that is available for it is what we reflect below

**BSE/TSE:**

Animal products are not used at any stage of the manufacturing process or in the processing lines to make the product.

**GMO:**

The product is in compliance with the requirements of Regulation (EC) 1829/2003 of the European Parliament and of the Council of September 22, 2003 on genetically modified food and feed. The product is GMO-free and does not contain, does not consist of, and is not produced from genetically modified organisms (GMO).

**NANOMATERIALS:**

The product complies with the requirements of Regulation (EU) 2015/2283 of the European Parliament and of the Council of November 25, 2015 on novel foods and its consequent amendments, so it does not contain engineered nanomaterials .

**PESTICIDES:**

No pesticide is used in the production of L-Cystine, nor in its raw material.

**ADDITIVES:**

The product complies with the additive declaration of compliance with Commission Regulation (EU) No 231/2012 on the requirements for food additives.

**94201-CYSTINE-L****HEAVY METALS:**

The product complies with Commission Regulation (EC) 1881/2006 of 19 September 2006, which establishes maximum levels for certain contaminants in food products and its amendments to Commission Regulation (EC) 629/2008 of July 2, 2008. Therefore, it meets the following requirements:

- Maximum lead (Pb) level: 2.0 mg/kg (ppm)
- Maximum cadmium (Cd) level: 1.0 ppm mg/kg (ppm)
- Maximum mercury level (Hg): 0.1 mg/kg (ppm)

**ALLERGENS:**

- **Food allergens:** The product does not contain any of the allergens listed in Annex II of EU Regulation No. 1169/2011 of the European Parliament and of the Council, nor is it susceptible to cross-contamination with them.

**VEGAN/VEGETARIAN:**

Suitable for vegan/vegetarian consumption.