94289 - CAFFEINE

1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION.

1.1 Identification of the substance or preparation.

Name: Caffeine
Bulk code: 94289

1.2 Synonyms.

Caffeine anhydrous

2. DESCRIPTION

Appearance: crystalline powder or silky crystals
White color
Odor: Odorless
Origin: Chemical synthesis
Geographic origin: China

3. COMPOSITION/INFORMATION ON COMPONENTS.

Chemical name: 1, 3, 7-Trimethyl-3, 7-dihydro-1H-purine-2, 6-dione
Formula: $C_8H_{10}N_4O_2$
Molecular weight: 194.19 g/mol
CAS NO: 58-08-2
CE No.: 200-362-1
Index No.: 613-086-00-5

4. PHYSICAL-CHEMICAL DATA.

For more detailed information, consult the analysis bulletin.

Solubility: Caffeine is barely soluble in water (20 g/L), soluble in boiling water, slightly soluble in ethanol and ether.

5. PROPERTIES/USES.

Pharmaceutical active ingredient.

Cosmetic active ingredient.

Alimentary use.

As a pharmaceutical active:
It is the xanthic base with the greatest stimulating power of the CNS, acting first on the cerebral cortex, later on the medulla and finally on the spinal cord. Its mechanism of action

has to do with its ability to inhibit the enzyme phosphodiesterase , which results in an increase in cAMP ; At low doses it antagonizes adenosine receptors .
It produces cardiac stimulation (positive inotropic effect) and reduction of arteriolar peripheral resistance , which offsets its effects on blood pressure. At the brain level it produces vasoconstriction, which is why its use as an antimigraine has been suggested .
Stimulates skeletal muscles and respiratory control, increases gastric acid secretion and diuresis.
It is administered orally and rectally in the treatment of depressive states and mental fatigue, bronchial asthma, heart failure and headaches.

Topically, it has a local action without a systemic effect, acting on the lipolysis of adipose tissue by inhibiting the enzyme phosphodiesterase . It is also used in atopic dermatitis.

As a cosmetic active:
It is used as a skin conditioning agent and as a perfume .

6. DOSAGE.

As an active pharmaceutical ingredient:

- Orally:
    - Treatment of asthenia: 50-100 mg every 6 hours, which can be increased depending on the clinical response to a maximum of 1200 mg daily.
    - Associated with analgesics with acetylsalicylic acid , paracetamol or codeine in doses of 30-65 mg.
- Topical route:
    - Up to 30% for master formulation in atopic dermatitis therapies.

As a cosmetic active ingredient:

- Calculations of maximum quantities must be calculated based on the NOAEL data established by ECHA. (https://echa.europa.eu/es/brief-profile/-/briefprofile/100.000.329).

7. OBSERVATIONS.

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

STORAGE:
Store at room temperature (25±2ºC), in a cool, dry place, protected from light and with the container tightly closed.

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

The product mentioned above fully complies with REGULATION (EU) No. 231/2012 and its amendments.

BSE/TSE:
The product does not contain ingredients of ruminant origin or materials derived from or exposed to ruminants affected or quarantined by the
Transmissible spongiform encephalopathy (TSE)/Bovine spongiform encephalopathy (BSE) and complies with EU legislation 999/2001.

GMO:
The product or any of its ingredients:
•They are non-GMO and do not contain any GMOs and any GMOs are used in their production .
•The ingredients we supply do not require any mention on their labeling of GMOs, according to Commission Regulation CEC No. 49/2000 dated January 10, and (ECC) No. 1829/2003 and (ECC) No. 1830/ 2003
European Parliament and Council.
•This product has not been genetically modified so there is no obligation for GMO labeling as defined by the aforementioned standards.

NANOMATERIALS:
According to the definition of " nanomaterials " in EU Regulation (EU) No. 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, the manufacturer indicates that no nanomaterials It is used in the formulation or packaging material of the product.

RADIATION:
The product has not been sterilized by ionizing radiation at any point during the entire manufacturing process and therefore fully complies with the relevant legal regulations (Directive 1999/2/EC).

PESTICIDES:
Based on the knowledge of the production process, raw materials and the equipment used, the possible pesticide residues in the product mentioned above comply with the European Legislation on pesticide residues, esp . Regulation (EC) no. 149/2008 and Regulation (EU)

2015/868, of May 26, 2015, amending Annexes II, III and V to Regulation (EC) No. 396/2005.

RESIDUAL SOLVENTS:

The product complies with Directive E 2010/59/EU of August 26
2010 amending Directive 2009/32/EC of the European Parliament and of the Council on the approximation of the laws of the Member States on extraction solvents used in the production of foods and food ingredients. RD1101/2011

CONTAMINANTS:

Based on actual knowledge of the production process, raw materials and equipment used we do not expect any contaminants from dioxins, melamine , polycyclic aromatic hydrocarbons (PAHs) and biphenyls. polychlorinated compounds (PCB) in the product . (REGULATION (EU) 2023/915).

Depending on the knowledge of the production process, raw materials and equipment used, the manufactured product meets the following requirements:

- REGULATION (EC) No- 1881/2006 and subsequent modifications regarding the maximum permitted level of the following contaminants:
  - Aflatoxin B1 <5ppb
  - Aflatoxins B1 + B2 + G1 + G2 <10ppb
  - Ochratoxin A <15ppb
  - Melamine
  - Dioxins
- REGULATION (EC) No. 1933/2015 amending Regulation (EC) No. 1881/2006 with regard to maximum levels of polycyclic aromatic hydrocarbons , in particular:
  - Maximum level of 10 µg / kg benzo (a) pyrene
  - 50 µ g /kg for the sum of PAH4 (PAH4; benzo [a] pyrene , chrysene , benzo [a]anthracene and benzo [b] fluoranthene) in food supplements

ALLERGENS:

The product does not contain any of the following allergenic substances : crustaceans (including shell animals), dairy products, eggs and derivatives, fish, nuts (including all tree nuts), peanuts, soy or derivatives, wheat or derivatives, artificial colors, flavorings, barley/rye or derivatives, bee derivatives, celery, corn or derivatives, fragrances, fruits or derivatives, gluten, grapes, lupine, mollusks, mustard, oats and derivatives, natural or artificial preservatives, rice or derivatives, salt, sesame and derivatives, starch, sugars/alcohols, sugar/sweeteners, sulfur dioxide/sulfites, natural or artificial sweeteners, vegetable or plant derivatives, yeasts or derivatives.

WADA:

According to the current World Anti-Doping Agency list, the ingredient is not a doping substance and is not a combination of doping substances. The ingredient does not contain any doping substances. The ingredient is not the result of a doping substance.

8. BIBLIOGRAPHY:

Pharmaceutical Monographs. COF Alicante, 1998.
" Martindale . The Extra Pharmacopoeia ." 30th Edition . Ed. The Pharmaceutical Press . London. (1993).
https://echa.europa.eu/es/brief-profile/-/briefprofile/100.000.329