Quality & Regulatory Product Information

Mfsorb® 509

Product Name: Bemotrizinol

1. Identity and Registrations

INCI Name
Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine

USAN Name
Bemotrizinol

Chemical description
[x] Refer to attached Technical Data Sheet.

Composition
[x] Refer to attached Certificate of Composition.

Process Flow Chart
[x] Refer to attached Process Flow Chart

EU REACH
Compliance with the European Union's Chemicals Legislation (REACH), Regulation (EC)1907/2006.
The REACH registration number is 01-2119777812-28-0006.

Compliance with Global Chemical Inventories
[x] Refer to Safety Data Sheet.

Approval for cosmetic uses
[x] We hereby confirm that the cosmetic raw material marketed by the MFCI Co., Ltd. conforms with the requirements relevant to cosmetic ingredients of the Cosmetics Regulation (EC)1223/2009 and its amendments as currently in force.

2. Manufacturing and raw materials

Type of manufacturing process:
[x] Chemical reaction

Radioactive material:
[x] Based on information concerning the raw materials production process, and equipment used radioactive material is not expected to be present and no irradiation has been used.

Conflict minerals:
[x] No conflict minerals are used throughout the manufacturing process of Bemotrizinol. and Bemotrizinol is free from the conflict minerals: Tin, Tungsten, Tantalum and Gold.

Microplastic:
[x] The Product does not contain any polymer. Consequently, the product cannot be regarded as Microplastic.

Palm-free:
[x] The product does not contain palm and palm derivatives substances.

Raw materials
Based on our actual knowledge, the raw materials are:
[ ] Of vegetable origin
[ ] Derived from non-genetically modified plant.
[ ] GMO(genetically modified DNA)
[ ] Of animal origin
BSE classification:
[x] Synthetic
[ ] Inorganic
[x] produced in China and is origin of China

3. Quality standards
[x] Certified according to ISO 9001/2015
[x] Complied with ICH Q7 (Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients)
[ ] Other:

4. Stabilization of the product
The following substances are added to the product (during or after manufacture) for purposes of stabilization:
[ ] Preservatives:
[ ] Antioxidants :
[ ] Sequestering / complexing agents:
[ ] Others:

5. By-products and impurities

a) Residual solvents
[ ] Based on our actual knowledge of our production process, raw materials and equipment used, no solvent is used in the manufacturing process or, if used, is removed in a final step of the manufacturing process.
[x] The residual solvents in the finished product are N,N-Dimethylformamide and Acetone.
N,N-Dimethylformamide: 880ppm max

Acetone: 5000ppm max

b) Heavy metals

[x] The heavy metal Pb in the products has been controlled within 5ppm, and the heavy metals Hg, Cd, Cr, Co, Ni and Sb have been controlled within 1ppm, and As has been controlled within 2ppm. The total content of heavy metals does not exceed 10ppm.

c) Pesticides

[x] Based on information concerning the raw materials, production process, and equipment used, pesticides are not likely to be present.

d) Aflatoxin/Mycotoxin

[x] Based on information concerning the raw materials, production process, and equipment used Aflataxin/Mycotoxin are not likely to be present.

e) Polycyclic aromatic hydrocarbons

[x] Based on information concerning the raw materials, production process, and equipment used, polycyclic aromatic hydrocarbons are not likely to be present.

f) Residual monomers

[x] Not relevant

g) Other impurities

[ ] 1,4-Dioxane
[ ] Diethylene glycol (sum of ethylene glycol and diethylene glycol)
[ ] Nitrosamines
[ ] Others:

h) Allergens

Fragrance allergens

[x] Based on information concerning the raw materials, production process and equipment used fragrance allergens as of EU Regulation 1223/2009 Annex III, No. 67-92 are not likely to be present.

Food allergens

[x] Based on information concerning the raw materials, production process, and equipment used food allergens as of EU Directive 2000/13/EC(as amended), Annex IIIa, and Regulation(EU)1169/2011, Annex II are not likely to be present.

i) Phthalates

[x] Based on information concerning the raw materials, production process, and equipment used phthalates listed in EU Regulation 1223/2009 Annex II are not likely to be present.

j) CMR substances

[ ] Based on information concerning the raw materials, production process and equipment used CMR substances according to Annex VI of the CLP Regulation (EC)1272/2008) are not likely to be present.

[x] May contain the following CMR substances:
N,N-Dimethylformamide

k) SVHC

[ ] The product does not contain the substances included in the latest candidate list of SVHC.

[x] May contain the following substances in the candidate list of SVHC:
N,N-Dimethylformamide

l) Proposition 65

[ ] Based on information concerning the raw materials, production process, and equipment used substances listed in The Safe Drinking Water and Toxic Enforcement Act of 1986 Proposition 65") are not likely to be present.

[x] May contain the following substances listed in California 65.
N,N-Dimethylformamide

m) Glycol ethers

[x] Based on information concerning the raw materials, production process, and equipment used the following glycol ethers are not likely to be present:
Butyldiglycol (CAS No 112-34-5)
Ethyldiglycol (CAS No 111-90-0)
2-Butoxyethanol (CAS No 111-76-2)

6. Nanomaterials

[x] Concerning new requirements for nanomaterials in cosmetic products, laid down in the Cosmetics Regulation (EC) 1223/2009, the following definition is provided in Article 2,1 (k) of Regulation (EC) 1223/2009:
'Nanomaterial' means an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions. or an internal structure on the scale from 1 to 100 nm'.
The product is not considered as a nanomaterial under this definition.

7. Microbiological information

[x] Based on our current knowledge of our production process, raw materials, and equipment used we do not expect microbiological contamination.

[x] Refer to attached Technical Data Sheet.

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8. Information on animal test

[x] We have not perform animal testing on the Bemotrizinol.

9. Safety and Environment

[x] Current EU Safety Data Sheet available upon request
[x] Toxicological information: Refer to Safety Data Sheet
[x] Ecotoxicological information: Refer to Safety Data Sheet

10. Halal

[x] The product does not contain animal ingredients The source of the product is synthetic. The equipment used for manufacturing these products is not used for the manufacture of other products of animal origin or products containing ingredients of animal origin. The product is stored separately from products of animal origin or products containing such ingredients.

11. Kosher

[x] The product conforms to Jewish living habits and needs on food, medicine, cosmetics and food, medicine, cosmetic additives, etc.

12. Vegan

[x] The product does not contain any animal products and qualify as vegan.
Furthermore, our processing methods do not include the use of bone char or raw materials containing any animal products.

13. CITES

[x] The product is not affected by the Convention on International Trade in Endangered Species of Wild Fauna and Flora.