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Nutrition & Health

Quality & Regulatory Product Information

L-Menthol FCC

Date: 15 Nov 2023

PRD 30564715

With the rising complexity of the regulatory environment and customers' growing demand for product quality and safety worldwide, companies need to provide information related to an increasing number of different regulatory issues.

At the same time fast information flow is a key requirement for success.

In order to assist you in a rapid execution, BASF Nutrition & Health established a Quality & Regulatory Product Information package (Q&R PI) which will provide you with a comprehensive summary of all required regulatory, quality, and safety information.

We have gained positive feedback from a large number of our customers who were able to accelerate their submission process. We are convinced that this package will also support you in your daily business.

If you have any further questions or need additional support, please contact your BASF sales representative.

Status: 15 Nov 2023

Quality & Regulatory Product Information
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1. Identity

INCI (CTFA) Name: MENTHOL

CAS-No: 2216-51-5

Listing in Chemical Inventories

(x) Europe
EINECS/ELINCS/NLP: 218-690-9
(x) Japan (ENCS/ISHL)
(x) Australia (AICS)
(x) China (IECSC)
(x) Philippines (PICCS)
(x) USA (TSCA)
(x) Canada (DSL/NDSL)
(x) New Zealand (NZIOC)
(x) Switzerland (CHEMINV)

(Pre-)registration by BASF*

(x) Korea (K-REACH)
(x) Turkey (KKDIK)
(x) Great Britain - DUIN submitted, registration under UK-REACH planned
(x) Taiwan (TCSI)
( )
( )

* please note, (pre-)registration in these countries is not transferable to / valid for other companies

Additional Identification Numbers

(x) CoE-No: 63
(x) FEMA: 2665
(x) CFR 172.515 listed
(x) JECFA (WHO) No: 427
(x) FL-Number (EU Union List): 02.015
(x) FCC, see current Food Chemical Codex Literature

Custom Tariff code

290611

2. REACH

(x) Registered (see attached statement)
( ) Not registered due to:

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3. Production

a. Manufacturer
(x) BASF : BASF SE site Ludwigshafen (Germany) or BASF Petronas Chemicals SDN BHD, Kuantan (Malaysia)
( ) The product is manufactured by a contract manufacturer according to the BASF specification

b. Country of origin: Germany or Malaysia

c. Manufacturing Process
(x) synthetic
( ) by fermentation
( ) mineral
( ) animal
( ) plant
( ) renewable feedstock
(x) other: without palmoil or derivatives thereof

4. Storage conditions and temperature

( ) No special storage conditions
(x) Storage temperature 15-25 °C (optimum storage temperature)
( ) Store refrigerated (+2 to +8 °C)
(x) Carefully reseal the container after opening
(x) Store the substance under inert gas
(x) Storage temperatures (> 35°C) lead to the following phenomena: melting
(x) which is reversible, if cooled down
( ) which is irreversible
( ) Others

Retest date / Best before (if the above storage conditions are maintained):
60 months after production date

5. Product Details/Composition

a. BSE/TSE risk

(x) Based on our current knowledge we hereby confirm that we do not expect a BSE/TSE risk that results from our production process and the used raw materials and equipment

b. GMO Material (Genetically Modified Organism)

(x) No genetic engineering involved
(x) No GM(O) DNA present
(x) Not subject to GM(O)-labelling according to Regulation (EC) No 1829/2003
( ) See attached statements

c. Vegetarian / vegan status

( ) not applicable
(x) suitable for vegetarians according to ISO 23662
(x) suitable for vegans according to ISO 23662
( ) other:

d. Stabilization of the Product

The following substances are added to the product (during or after manufacture) for purpose of stabilization at indicated levels

(x) No additives
( ) Preservatives:
( ) Antioxidants:
( ) Sequestering agents (complexing agents):
( ) Other substances:

e. Solvents

(x) Based on our current knowledge of our production process, raw materials and equipment used we do not expect solvents to be present
(x) Ethanol not used for synthesis
( ) May contain solvents:

f. Catalysts

(x) Based on our current knowledge of our production process, raw materials and equipment used we do not expect catalysts to be present

g. CMR Substances (Carcinogenic, Mutagenic or Toxic for Reproduction)

( ) The above mentioned substance is listed as CMR substance in Annex VI of Regulation (EC) No 1272/2008
( ) The above mentioned substance is a CMR substance based on self-classification:

(x) Based on our current knowledge of our production process, raw materials and equipment used we do not expect CMR substances (according to Regulation (EC) No 1272/2008 as amended) to be present in concentrations >=0.1%.
( ) Please refer to section 3 of the material safety datasheet (MSDS) for information regarding the presence of CMR substances present in this product in concentrations >=0.1%.

6. Contaminants

(x) We hereby confirm that the above mentioned substance is in compliance with Commission Regulation (EC) No 2023/915 setting maximum levels for certain contaminants in foodstuffs

a. Heavy Metals

(x) Based on our current knowledge of our production process, raw materials and equipment used we do not expect lead, cadmium, mercury and arsenic to be present

b. Polycyclic aromatic hydrocarbons (US EPA 16-PAH emission factors)

(x) Based on our current knowledge of our production process, raw materials and equipment used we do not expect any of the 16 polycyclic aromatic hydrocarbons as defined by US EPA (EPA Identification Number: E17134016) to be present

c. Dioxins and polychlorinated biphenyls (PCB)

(x) Based on our current knowledge of our production process, raw materials and equipment used we do not expect dioxins and PCB to be present

d. Mycotoxins

(x) Based on our current knowledge of our production process, raw materials and equipment used we do not expect Aflatoxine, Ochratoxin A, Patulin, Deoxynivalenol, Zearalenon, Fumonisine or T-2- and HT-2-Toxin to be present

e. Phthalates

(x) Based on our current knowledge of our production process, raw materials and equipment used we do not intentionally add phthalates

f. Glycol ether

(x) Based on our current knowledge of our production process, raw materials and equipment used, we do not expect any glycol ethers as listed in Regulation (EC) No 1223/2009 on cosmetic products (as amended) to be present.

g. Pesticides Residues

( ) We hereby confirm that the above mentioned substance is in compliance with Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin (as amended)

(x) Based on our current knowledge of our production process, raw materials and equipment used we do not expect pesticides to be present

( ) Additional comments:

h. Other impurities

(x) Based on our current knowledge of our production process, raw materials and equipment used we do not expect any of the following substances to be present

Free ethylene oxide
Sulfite
Nitrosamines
Aromatic amines
Acrylamide

( ) additional comments:

7. Allergens

a. Fragrance Allergens listed in Annex III of the Regulation (EC) No 1223/2009 on cosmetic products (as amended)

(x) Based on our current knowledge of our production process, raw materials and equipment used we do not expect fragrance allergens to be present

( ) See attached statement

b. Food allergens according to Annex II of Regulation (EC) No 1169/2011(Annex IIIa of Directive 2000/13 respectively) (as amended) and in the US Food Allergen Labelling and Consumer Protection Act (FALCPA)

( ) Not applicable

(x) See attached statement

8. Microbiological Information

(x) Based on our current knowledge of our production process, raw materials and equipment used we do not expect microbiological contaminations
( ) Additional comments:

9. Compliance Statements

a. Cosmetic Legislation

(x) We hereby confirm that the above mentioned substance is in compliance with Regulation (EC) No 1223/2009 on cosmetic products (as amended)

b. IFRA Recommendation

(x) Product is in conformity with IFRA Guidelines (http://www.ifraorg.org/)
( ) IFRA Standard available, download possible on IFRA homepage (https://ifrafragrance.org/safe-use/library)

c. IOFI Recommendation

(x) Product is in conformity with IOFI Code of Practice (Details: http://www.iofi.org/)

d. EU-Regulation on flavorings

(x) We hereby confirm that above mentioned substance complies with the definition of a "flavoring substance", according to Article 3 of Regulation (EC) No 1334/2008 (as amended) on flavorings and certain food ingredients with flavoring properties for use in and on foods. It is listed in Annex I of Regulation (EC) No 1334/2008.

e. Proposition 65

(x) Based on our current knowledge of our production process, raw materials and equipment used we do not expect substances listed in The Safe Drinking Water and Toxic Enforcement Act of 1986 ("Proposition 65") (as amended) to be present
( ) May contain:

10. Other Statements and Specifications

(x) Product specification
(x) Technical information
(x) Material safety datasheet
(x) Social and environmental standards
(x) Kosher certificate
(x) Halal certificate or statement
(x) ISO 9001
(x) ISO 50001
( ) HACCP
(x) FSSC 22000
( ) Others

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Issued by:
BASF SE
Nutrition and Health

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Nutrition & Health

Statement on L-Menthol for use in Ayurveda

CAS Number: 2216-51-5
EC Number: 218-690-9
Chemical name: Cyclohexanol, 5-methyl-2-(1-methylethyl)-, (1R,2S,5R)-

Our product **L-Menthol** has been exclusively produced via a synthetic route and therefore, does not qualify for any claims regarding “natural”.

This means further, that any changes in the product name, which would lead to a misinterpretation regarding the origin of the product, cannot be supported by BASF SE.

If you have any further questions or need additional support, please contact your BASF sales representative.

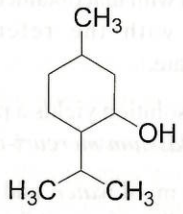
Statement on L-Menthol for use in Ayurveda

response in all of the rats. Use doses in geometric progression. As an initial approximation, total doses of 7, 14 and 28 IU may be tried although the dose will depend on the sensitivity of the animals used, which may vary widely. Dissolve separately the total quantities of the preparation being examined and of the standard Preparation corresponding to the daily doses to be used in sufficient albumin phosphate buffer pH 7.2 so that the daily dose is about 0.2 ml. Add a suitable antimicrobial preservative such as 0.4 per cent w/v of *phenol* or 0.002 per cent w/v of *thiomersal*. Store the solutions at a temperature of 2° to 8°, Inject subcutaneously into each rat the daily dose allocated to its group on 4 consecutive days at the same time each day. On the fifth day, about 24 hours after the last injection, euthanize the rats and remove the seminal vesicles or the prostate gland. Remove any extraneous fluid and tissue and weigh immediately the seminal vesicles or the prostate gland. Calculate the result of the assay by standard statistical methods, using the weight of the vesicles or the prostate gland as the response. (The precision of the assay may be improved by a suitable correction of the organ weight with reference to the weight of the animal from which it was taken; an analysis of covariance may be used). The fiducial limits of error are not less than 64 per cent and not more than 156 per cent of stated potency.

Storage. Sealed container, store protected from light in containers at a temperature not exceeding 20°.

Labelling. The label states (1) the number of IU (units) of follicle stimulating hormone activity; (2) the number of IU (units) of luteinizing hormone activity and (3) where applicable, the number of IU (units) of chorionic gonadotrophin activity contained in it.

Menthol



$C_{10}H_{20}O$ Mol. Wt.156.3

Menthol is 2-isopropyl-5-methylcyclohexanol. It is obtained from the volatile oils of various species of *Mentha* or prepared synthetically. It may be levo-rotatory [(–)-menthol] or racemic [(±)-menthol].

Category. Topical antipruritic.

Description. Colourless, hexagonal or needle-like crystals, or infused masses or a crystalline powder.

Identification

A. Determine by infrared absorption spectrophotometry (2.4.6). Compare the spectrum with that obtained with *menthol IPRS* or with the reference spectrum of menthol.

B. Dissolve 10 mg in 1 ml of *sulphuric acid* and add 1 ml of a 1 per cent w/v solution of *vanillin* in *sulphuric acid*; an orange-yellow colour is produced. Add 1 ml of *water*; the colour changes to violet (distinction from thymol).

C. When triturated with about an equal weight of *camphor* or *chloral hydrate* or *phenol*, the mixture liquefies.

Tests

Appearance of solution. Dissolve 1.0 g in 10 ml of *ethanol (95 per cent)*. The solution is not more opalescent than opalescence standard OS4 (2.4.1), and not more intensely coloured than reference solution RS6 (2.4.1).

Acidity. To 1.0 g in a 100-ml glass-stoppered conical flask add 20 ml of *water*, boil until dissolution is complete, cool, stopper the flask and shake vigorously for 1 minute. Add a few crystals of the substance under examination to initiate crystallisation, shake vigorously for 1 minute and filter. To 5 ml of the filtrate add 0.05 ml of *methyl red solution* and 0.05 ml of *0.01M sodium hydroxide*; the solution is yellow.

Specific optical rotation (2.4.22). (for (–)-menthol) –51.0° to –49.0°; (for (±)-menthol) –2.0 ° to +2.0°, determined in a 10.0 per cent w/v solution in *ethanol (95 per cent)*.

Congealing range (2.4.10). (for (±)-menthol) 27.0° to 28.0°; on prolonged stirring, the temperature rises 30° to 32°.

Related substances. Determine by gas chromatography (2.4.13).

Test solution. Dissolve 0.1 g in sufficient *ethanol (95 per cent)* to produce 10 ml.

Reference solution (a). Dilute 1 ml of the test solution to 100 ml with *ethanol (95 per cent)*.

Reference solution (b). Dilute 1 ml of reference solution (a) to 20 ml with *ethanol (95 per cent)*.

Chromatographic system

- a glass or stainless steel column 4 m x 2 mm, packed with diatomaceous support (125 to 180 mesh) impregnated with 5 per cent carbowax 20 M (Polyethylene glycol compund 20 M),
- temperature :
  column 80°, after 2 minutes, increase the temperature of the column to 240° at a rate of 8° per minute and maintain at this temperature for 15 minutes,
  injection port at 250° and the detector at 240°,
- flow rate: 30 ml per minute of the carrier gas.

Inject 1 µl of each solution. Run the chromatogram obtained with the test solution for 3 times the retention time of the principal peak. In the chromatogram obtained with the test solution the sum of the areas of all the secondary peaks is not more than the area of the principal peak in the chromatogram obtained with reference solution (a) (1.0 per cent). Ignore any peak with an area less than the principal peak in the chromatogram obtained with reference solution (b) (0.05 per cent).

Residue on evaporation. Evaporate 2.0 g on a water-bath and heat at 105° for 1 hour. The residue weighs not more than 1.0 mg (0.05 per cent).

Storage. Store protected from light and moisture at a temperature not exceeding 30°.

Labelling. The label states whether the contents are levo-rotatory or racemic menthol.

Menthol and Benzoin Inhalation

Menthol and Benzoin Inhalation is an inhalation vapour, solution of racementhol or levomenthol 20 g in sufficient benzoin inhalation to produce 1000 ml.

Menthol and Benzoin Inhalation contains not less than 2.8 per cent w/v of total balsamic acids, calculated as cinnamic acid, $C_9H_8O_2$.

Tests

Total solids (2.6.5). 9.0 per cent to 12.0 per cent w/v, determined on 2 ml of the solution by drying at 105° for 4 hours.

Other tests. Comply with the tests stated under Inhalation Preparations.

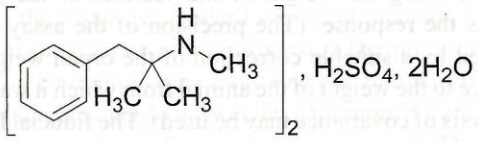
Follow the procedure described under Assay with suitable dilution of the reference solution wherever the amount of active substance is to be determined in any test.

Assay. Boil 10 ml with 25 ml of *ethanolic potassium hydroxide solution* under a reflux condenser for 1 hour. Evaporate the *ethanol (95 per cent)*, disperse the residue in 50 ml of hot *water*, cool, add 80 ml of *water* and 1.5 g of *magnesium sulphate* dissolved in 50 ml of *water*. Mix thoroughly and allow to stand for 10 minutes. Filter, wash the residue on the filter with 20 ml of *water*, acidify the combined filtrate and washings with *hydrochloric acid* and extract with four 40 ml quantities of *ether*. Discard the aqueous solution, combine the ether extracts and extract with successive quantities of 20, 20, 10, 10 and 10 ml of *sodium hydrogen carbonate solution*, washing each aqueous extract with the same 20 ml of *ether*. Discard the ether layers, carefully acidify the combined aqueous extracts with *hydrochloric acid* and extract with successive quantities of 30, 20, 20 and 10 ml of *chloroform*, filtering each extract through *anhydrous sodium sulphate* supported on absorbent cotton. Distil the *chloroform* from the combined filtrates until 10 ml remains and remove the remainder in a current of air. Dissolve the residue, with the aid of gentle heat, in 10 ml of *ethanol (95 per cent)*, previously neutralised to *phenol red solution*, cool and titrate with *0.1 M sodium hydroxide* using *phenol red solution* as indicator.

1 ml of *0.1 M sodium hydroxide* is equivalent to 0.01482 g of total balsamic acids, calculated as cinnamic acid, $C_9H_8O_2$.

Labelling. The label states the amount of active ingredient delivered per inhalation.

Mephentermine Sulphate



$(C_{11}H_{17}N)_2,H_2SO_4,2H_2O$ Mol. Wt.460.6

Mephentermine Sulphate is *N*,α,α-trimethylphenethylamine sulphate dihydrate.

Mephentermine Sulphate contains not less than 98.0 per cent and not more than 102.0 per cent of $(C_{11}H_{17}N)_2,H_2SO_4$, calculated on the dried basis.

Category. Sympathomimetic.

Description. A white crystals or a white crystalline powder.

Identification

A. Determine by infrared absorption spectrophotometry (2.4.6). Compare the spectrum with that obtained with *mephentermine sulphate IPRS* or with the reference spectrum of mephentermine sulphate.

B. A 0.2 per cent w/v solution yields a precipitate with *iodine solution* and with *potassium mercuri-iodide solution*.

C. Dissolve 0.1 g in 5 ml of *water*, add with stirring 10 ml of *picric acid solution*. Allow to stand for 30 minutes, filter and wash the precipitate with small quantities of cold *water* until the last washing is colourless; the precipitate, after drying at 105° melts at 154° to 158° (2.4.21).

D. It gives the reactions of sulphates (2.3.1).

Tests

pH (2.4.24). 4.0 to 6.5, determined in a 2.0 per cent w/v solution in *carbon dioxide-free water*.