Glyceryl Behenate

1 Nonproprietary Names

BP: Glycerol dibehenate
PhEur: Glyceroli dibehenas
USPNF: Glyceryl behenate

2 Synonyms

Compritol 888 ATO; 2,3-dihydroxypropyl docosanoate; docosanoic acid, 2,3-dihydroxypropyl ester; E471; glycerol behenate; glyceryl monobehenate.

Note that tribehenin is used as a synonym for glyceryl tribehenate.

3 Chemical Name and CAS Registry Number

Docosanoic acid, monoester with glycerin [30233-64-8] (glyceryl behenate)
Docosanoic acid, diester with glycerin [94201-62-4] (glyceryl dibehenate)
Docosanoic acid, triester with glycerin [18641-57-1] (glyceryl tribehenate)

4 Empirical Formula Molecular Weight

The PhEur 2002 describes glyceryl dibehenate as a mixture of diacylglycerols, mainly dibehenoylglycerol, together with variable quantities of mono- and triacylglycerols (*see* Section 9). The USPNF 20 describes glyceryl behenate as a mixture of glycerides of fatty acids, mainly behenic acid. It specifies that the content of 1-monoglycerides should be 12.0–18.0%.

5 Structural Formula

See Section 4.

6 Functional Category

Coating agent; tablet binder; tablet and capsule lubricant.

7 Applications in Pharmaceutical Formulation or Technology

Glyceryl behenate is used in cosmetics, foods, and oral pharmaceutical formulations. In cosmetics, it is mainly used as a viscosity-increasing agent in emulsions; *see* Table I.

In pharmaceutical formulations, glyceryl behenate is mainly used as a tablet and capsule lubricant[1–3] and as a lipidic coating excipient; it has been investigated for the encapsulation of various drugs such as retinoids.[4] It has been investigated for use in the preparation of sustained release tablets, [5–8] and as a matrix-forming agent for the controlled release of water-soluble drugs.[9]

Table I: Uses of glyceryl behenate.

Use	Concentration (%)
Lipophilic matrix or coating for sustained-released tablets and capsules	>10.0
Tablet and capsule lubricant	1.0–3.0
Viscosity-increasing agent in silicon gels (cosmetics)	1.0–15.0
Viscosity-increasing agent in w/o or o/w emulsions (cosmetics)	1.0–5.0

8 Description

Glyceryl behenate occurs as a fine white powder or hard waxy mass with a faint odor.

9 Pharmacopeial Specifications

See Table II.

Table II: Pharmacopeial specifications for glyceryl behenate.

Test	PhEur 2002 (Suppl. 4.1)	USPNF 20
Identification	+	+
Characters	+	—
Acid value	⩽4.0	⩽4
Iodine value	⩽3.0	⩽3
Saponification value	145–165	145–165
Residue on ignition	⩽0.1%	⩽0.1%
Nickel	⩽1 ppm	—
Water	⩽1.0%	—
Heavy metals	—	⩽0.001%
Melting point	65–77 °C	—
Content of 1-monoglycerides	—	12.0–18.0%
Content of acylglycerols (glycerides)	+	—
Monoacylglycerols	13–21%	—
Diacylglycerols	40–60%	—
Triacylglycerols	21–35%	—
Free glycerin	⩽1.0%	⩽1.0%
Organic volatile impurities	—	+
Composition of fatty acids	+	—
Arachidic acid	⩽10.0%	—
Behenic acid	⩾83.0%	—
Erucic acid	⩽3.0%	—
Lignoceric acid	⩽3.0%	—
Palmitic acid	⩽3.0%	—
Stearic acid	⩽5.0%	—

10 Typical Properties

Melting point: 65–77 °C
Solubility: soluble, when heated, in chloroform and dichloromethane, practically insoluble in ethanol (95%), hexane, mineral oil, and water.

11 Stability and Storage Conditions

Glyceryl behenate should be stored in a tight container, at a temperature less than 35 °C.

12 Incompatibilities

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13 Method of Manufacture

Glyceryl behenate is prepared by the esterification of glycerin by behenic acid (C_{22} fatty acid) without the use of catalysts. In the case of *Compritol 888 ATO* (Gattefossé), raw materials used are of vegetable origin, and the esterified material is atomized by spray-cooling.

14 Safety

Glyceryl behenate is used in cosmetics, foods and oral pharmaceutical formulations and is generally regarded as a relatively nonirritant and nontoxic material.

LD_{50} (mouse, oral): 5 g/kg[10]

15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantities of material handled. Glyceryl behenate emits acrid smoke and irritating fumes when heated to decomposition.

16 Regulatory Status

GRAS listed. Accepted for use as a food additive in Europe. Included in the FDA Inactive Ingredients Guide (capsules and tablets).

17 Related Substances

Glyceryl palmitostearate.

18 Comments

The EINECS numbers are: 250-097-0 for glyceryl behenate; 303-650-6 for glyceryl dibehenate; 242-471-7 for glyceryl tribehenate.

19 Specific References

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20 General References

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21 Author

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22 Date of Revision

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