TECHNICAL DATA SHEET

- COMPRITOL 888 ATO -

DEFINITION

Glycerol dibehenate EP / Glyceryl behenate NF / Ch. P.

ORIGIN OF THE RAW MATERIALS

The product is manufactured from raw materials of strictly vegetable origin.

MANUFACTURING SITE(S)

This product may be manufactured at several sites.

Quality control and batch release are the responsibility of Gattefossé SAS.

The manufacturing site(s) is (are) indicated in the certificate of analysis.

REGULATORY INFORMATION

Pharmacopeia Conformity: Product conforms to EP, NF, Ch.P.

For information on the regulatory status of this product, please consult the regulatory data sheet (RDS).

FIELD OF USE

This product is a pharmaceutical ingredient. It is recommended for use in pharmaceutical formulations administered by oral, topical and/or rectal/vaginal routes.

This ingredient must be used according to appropriate regulations. Gattefossé accepts no responsibility for the use of this product in applications other than those recommended.

USES

Dermal drug delivery: Consistency agent (thickener).

Oral drug delivery: Modified-release agent.

Oral drug delivery: Lubricant for tablets and capsules.

Oral drug delivery: Excipient for direct compression.

STORAGE RECOMMENDATIONS

Store the product in its original packaging sealed tightly, protected from light and moisture.

Store at a temperature inferior or equal to 30 °C.

During storage at high temperature (> 35°C), there is a risk of powder caking.

Product has a shelf-life of 3 years under the recommended storage conditions and should not be used after its expiry date.

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HANDLING ADVICE

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Presentation: powder.

For additional information, please consult the product handling sheet.

PACKAGING

Bag in cardboard box 25 kg (metal-coated polyester/polyethylene bag) (ACC).

Sample available upon request.

ADDITIONAL TESTS

Nominal average particle size: 50 µm

SAFETY OF USE

For information on the toxicology and safety of this product, please consult the product tox and safety overview.

SOLUBILITIES AT 20°C (Eur. Ph.)

- Ethanol 96°: Insoluble
- Chloroform, Methylene chloride: Soluble under heating conditions
- n-Hexane: Insoluble
- Water: Insoluble
- Mineral oils: Insoluble

GATTEFOSSÉ

Specification number: 3123 / 13
Last specification update: APR 25, 2013
Last document update: APR 25, 2013

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Test	***Specification***
APPEARANCE	Fine powder
ODOUR	Faint
COLOUR (Gardner Scale)	<= 5.0
DROP POINT (METTLER)	69.0 to 74.0 °C
ACID VALUE	<= 4.00 mgKOH/g
SAPONIFICATION VALUE	145 to 165 mgKOH/g
IODINE VALUE	<= 3.0 gI2/100g
PEROXIDE VALUE	<= 6.0 meqO2/kg
TOTAL ASHES CONTENT	<= 0.10 %
WATER CONTENT	<= 1.0 %
HEAVY METALS CONTENT (Pb)	< 10 ppm
TLC (Identification test, USP/NF)	Conforms to the reference standard
ARSENIC CONTENT	< 2 ppm (expressed in AS2O3)
RESIDUE ON IGNITION	<= 0.1 %
1-MONOGLYCERIDES CONTENT	12.0 to 18.0 %
FREE GLYCEROL CONTENT	<= 1.0 %
TOTAL MONOGLYCERIDES CONTENT	15.0 to 23.0 %
TOTAL DIESTERS CONTENT	40.0 to 60.0 %
TOTAL TRIESTERS CONTENT	21.0 to 35.0 %
PALMITIC ACID (C16)	<= 3.0 %
STEARIC ACID (C18)	<= 5.0 %
ARACHIDIC ACID (C20)	<= 10.0 %
BEHENIC ACID (C22)	>= 83.0 %
ERUCIC ACID (C22:1)	<= 1.0 %
LIGNOCERIC ACID (C24:0)	<= 3.0 %
NICKEL CONTENT	< 1 ppm
RESIDUAL SOLVENTS (Eur. Pharm., USP/NF)	Meets the requirements (production without solvent)
EUR. PHARM., USP/NF, JSFA	Conforms to the monographs
POLYOXYLETHYLENE (JSFA)	No change of chloroform layer to blue.
TLC(Identif.test N°1, JSFA, current ed.)	Conforms

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