



## TECHNICAL DATA SHEET

### DEFINITION

Glycerol dibehenate EP10.0 / Glyceryl dibehenate NF38 / Glyceryl behenate CP2020 /Eicosadioate

### PACKAGING

1kg/bag, 5kg/carton, 20kg/drum

Bag in cardboard drum 20 kg (polyethylene bag).

Sample available upon request.

### APPEARANCE

White or off-white powder or hard wax block; it has a slight odor.

Soluble in chloroform and almost insoluble in water or ethanol.

### RIGIN OF THE RAW MATERIALS

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

### DESCRIPTION

CAS: 77538-19-3 (or 91052-55-0) (or 30233-64-8) (or 94201-62-4)

EINECS: 278-717-5 (or 293-216-1) (or 250-097-0) (or 303-650-6)

### ADDITIONAL TESTS

Average particle size: D97=187μm

### SOLUBILITIES AT 20°C(Eur. Ph.)

Ethanol 96°: Partly soluble in hot ethanol 96°

Chloroform, Methylene chloride: Soluble under heating conditions

n-Hexane: Insoluble

Water: Insoluble

Mineral oils: Insoluble

### QUALITY STANDARD: ChP2020; USP43-NF38; EP9.0; GB1886.65-2015

TEST	SPECIFICATION
Melting Point	65~77°C
Acid Value	NMT 4 mg KOH/g
Saponification Value	145-165 mg KOH/g
Iodine Value	NMT 3 gl2/100g
Peroxide Value	NMT 6 meqO2/kg
Free Glycerin	NMT 1.0%
Water Content	NMT 1.0%
Residue On Ignition	NMT 0.1%
Total Ashes Content	NMT 0.1%
Nickel Content	NMT 1 Ppm
Heavy Metals(Pb)	NMT 10 ppm
Arsenic Content	NMT 2 ppm(expressed in AS2O3)
Palmitic Acid(C16)	NMT 3.0%
Stearic Acid(C18)	NMT 5.0%
Arachidic Acid(C20)	NMT 10.0%



Behenic Acid(C22)	NLT 83.0%
Erucic Acid(C22:1)	NMT 3.0%
Lignoceric Acid(C24:0)	NMT 3.0%
Monoglycerides	15.0-23.0%
Diglycerides	40.0-60.0%
Triglycerides	21.0-35.0%
Residual Solvents (EP/NF)	Production without solvents

**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.

**USES**

Dermal drug delivery: consistency agent (thickener) for silicone gelling agents and emulsions Oral drug delivery: modified-release agent.

Oral drug delivery: lubricant for tablets and capsules.

Oral drug delivery: excipient for direct compression.

Taste masking agent

Emulsifier in food.

Daily chemical products such as facial cleanser, toner, shampoo, toothpaste.

Application	Dosage/ %	Examples
Sustained release skeleton material	>10.0	Loratadine and Pseudoephedrine Sulfate Sustained Release Tablets
Fat-soluble coating material	>10.0	
Lubricants for tablets, etc	1.0-3.0	Captopril Tablets
Taste-masking agent		Amoxicillin Dry Suspension
Adhesives for tablets, etc	1.0-3.0	
Thickeners for gels, emulsions, etc	1.0-15.0	

**BENEFITS:**

1. As a sustained release skeleton material: Suitable for a wide range of tableting process: direct tableting, wet granulation, dry granulation and hot melt granulation; PH-independent drug release; Burst-free drug release related to ethanol; Drug release through diffusion mechanism to avoid burst effect; Without digestion and high physiological tolerance.
2. As a lubricant: No effect on disintegration time and drug release; Improve compressibility in tablet and capsule production; Do not interfere with drug testing; Do not reduce tablet hardness; Acid drugs can use it.

**SAFETY:** Generally considered non-toxic and non-irritating.

**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 2 years under the recommended storage conditions and should not be used after its expiry date.

**SHELF LIFE:** 2 years.