



IOI OLEOCHEMICAL

PHARMA

IMWITOR[®] 491

TECHNICAL DATA SHEET

USP (current version): Glyceryl Monostearate

DESCRIPTION

IMWITOR® 491 is a saturated glycerol ester, chiefly based on stearic and palmitic, originating from hydrogenated rape seed oil. Fatty acids and glycerol are derived from vegetable sources. The monoester content is more than 90.0 %.

IMWITOR® 491 is a white to light yellow, waxy powder with a neutral and slightly fatty odour and taste.

APPLICATION

IMWITOR® 491 is often used in formulations of pharmaceuticals. Due to its surface activity IMWITOR® 491 shows the following functions: co-emulsifier, stabilizer, dispersing agent, solubilizer, lubricant, softener, consistency regulator, binding agent and retarding agent. Typical dosage: 1-3 %.

CHEMICAL AND PHYSICAL PROPERTIES

Tests	Values	Typical values	Units	Methods
Melting point	66 – 77	75	°C	Ph. Eur. 2.2.34
Acid value	max. 3	0.9	mg KOH/g	Ph. Eur. 2.5.1
Hydroxyl value	290 – 330	310	mg KOH/g	Ph. Eur. 2.5.3
Monoglycerides	min. 90.0	96	%	Ph. Eur. 2.2.30
HLB value	~ 4			

Above mentioned tests are a selection of relevant parameters and do not represent the complete current sales specification.

IMWITOR® 491 fully complies with the requirements of the current USP monograph “Glyceryl Monostearate”.

IMWITOR® 491 does not contain antioxidants, stabilizers, solvents or other additives.

Solubility

IMWITOR® 491 is insoluble in water, soluble in fatty oils, mineral oil, diethyl ether, acetone and hot ethyl alcohol.



ADDITIONAL INFORMATION

IMWITOR® 491 is generally recognized as safe (GRAS, acc. 21 CFR, §184.1324). It is a non toxic and non irritating excipient for oral, dermal and rectal pharmaceuticals. IMWITOR® 491 is approved as a food additive (E 471).

PACKAGING UNITS

Powder in paper sacks with a PE inliner of 25 kg net.

HANDLING AND SHELF LIFE

If stored longterm in original tightly closed containers, dry, protected from light and moisture and below 25°C, the shelf life then is at least three years.

IOI Oleo GmbH

Hamburg, Germany | +49 40 28 00 31-0
pharma@ioioleo.de | www.ioioleo.de

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