

TECHNICAL DATA SHEET

2389-TDS-ENG-2020

ACEITE DE OLIVA VIRGEN (PH.EUR.)					
DESCRIPTION DCI:		DESCRIPTION DOE:			
CAS Nº: 8001-25-0	EC Nº: 232-277-0		AEMPS CODE:		
MOL. WEIGHT:	MOL. FORMULA:		ARTICLE CODE: 2389		

ATTRIBUTES SHOULD BE

Appearance Clear, transparent, yellow or greenish-yellow liquid

Practically insoluble in ethanol (96 %), miscible with light petroleum Solubility

about 0.913 g/mL Relative density

Identification B Complies

Absorbance

Maximum 270 nm =< 0.20 > 8 Ratio (232/270 nm)

Acid value =< 2.0 mg KOH/g Peroxide value =< 20.0 meq O2/Kg

Unsaponifiable matter =< 1.5 %

Composition of fatty acids

Saturated fatty acids < C16 =< 0.1 % Palmitic acid 7.5 - 20.0 % Palmitoleic acid =< 3.5 % 0.5 - 5.0 % Stearic acid 56.0 - 85.0 % Oleic acid and isomer 3.5 - 20.0 % Linoleic acid Linolenic acid =< 1.2 % Arachidic acid =< 0.7 % Eicosenoic acid =< 0.4 % Behenic acid =< 0.2 % =< 0.2 % Lignoceric acid

Sterols

Cholesterol =< 0.5 % =< 4.0 % Campesterol d7-Stigmasterol =< 0.5 %

the content of stigmasterol is not greater than that of campesterol

Sum of other sterols => 93.0 % Sesame oil Complies Water =< 0.1 % Halogenated solvents =< 1.5 ppm

COMPLIES WITH

European Pharmacopoeia 10.0

STORAGE

Store the container tightly closed. Avoid direct sunlight.



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REMARKS

When cooled, Olive Oil Virgin begins to become cloudy at 10 °C and becomes a butter-like mass at about 0 °C.

Olive Oil Virgin is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.