

EXVELIA PS 20

TECHNICAL SPECIFICATION	PRODUCT
NUMBER	STW: EX/2136/1
DATE	2026-07-01
CHEMICAL NAME	Polysorbate 20

TECHNICAL REQUIREMENTS	Identification.....complies with A, B,C,D,E tests (Ph. Eur. 12+ Suppl.)
	Appearance at (20±25)°C.....oily, yellow or brownish – yellow, clear or slightly opalescent liquid (Ph. Eur. 12+ Suppl.)
	Hydroxyl value, mg KOH/g96 ÷ 108 (Ph. Eur. 12+ Suppl.)
	Acid number, mg KOH/gmax. 2.0 (Ph. Eur. 12+Suppl.)
	Water content, %(m/m)max 3.0 (Ph. Eur. 12+ Suppl.)
	Total ash, % (m/m).....max 0.25 (Ph. Eur. 12+ Suppl.)
	Ethylene oxide content, ppm.....≤ 1 (Ph. Eur. 12+Suppl.)
	Dioxane, ppm.....≤ 10 (Ph. Eur. 12+Suppl.)
	Peroxide value, meq O ₂ /1000gmax 10.0 (Ph Eur.12+ Suppl.)
	Saponification value, mg KOH/g.....40 ÷ 50 (Ph. Eur. 12+ Suppl.)
	Fatty acid composition.....conforms
	Caproic C6, %.....max 1.0
	Caprylic C8, %.....max 10.0
	Capric C10, %.....max 10.0
	Lauric C12, %40.0 ÷ 60.0
	Myristic C14, %.....14.0 ÷25.0
	Palmitic C16, %7.0 ÷ 15.0
	Stearic C18, %.....max 7.0
	Oleic C18:1, %.....max 11.0
	Linoleic C18:2, %max 3.0 (Ph. Eur. 12+ Suppl.)

* These informative data are not technical requirements and cannot form the basis for any claims.

USE	Used as an emulsifier for the production of stable O/W emulsions in pharmaceutical applications. Solubilizer for various
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pharmaceutical formulation ingredients, including active substances that are soluble in oils but difficult to dissolve in water. The product meets the quality requirements of the current version of the European Pharmacopoeia. The formaldehyde content may increase with the product's storage time.

PACKAGING

Packaging as agreed with the customer.

STORAGE

EXVELIA PS 20 is stable for 1 year when stored in original, tightly closed containers. It is recommended that the ambient temperature during long-term storage is between 5°C and 25°C, with the extreme acceptable range being between 0°C and 30°C. Storage at higher temperatures is only possible for a short time.

SHELF LIFE

12 months from the date of manufacture

TRANSPORTATION

This product is not regulated for carriage according to ADR/RID, IMDG, ICAO/IATA

CLASSIFICATION AND LABELLING

This technical specification is applicable only if accompanied by the Safety Data Sheet in force. Pursuant to statutory requirements, only the Safety Data Sheet includes updated safety information.

The information contained herein is provided in good faith, based on our state of the art knowledge and experience. We reserve the right to amend this Technical Specification as a result of technological progress and product development by the manufacturer.

This product is intended for the purposes specified herein, for industrial and professional use. To use the product for purposes other than indicated herein, please contact **PCC EXOL SA** for consultation sending an e-mail to: industrial.application@pcc.eu

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