

## Polysorbate 80

<b>CODE ARTICLE:</b> 93476	<b>BATCH:</b> 0124683
<b>TEST DATE:</b> 05/12/2023	<b>TEST:</b> QC-00259333
<b>EXPIRY DATE:</b> 30/06/2026	<b>FABRICATION DATE:</b> 01/06/2023
<b>CAS:</b> [9005-65-6]	
<b>SYNONYMS / BOTANICAL NAME:</b> Tween 80; E-433; Polisorbato 80	
<b>STORAGE:</b> Store in tightly closed containers in a cool, dry place.	

TEST	RESULTS	Units	MIN	MAX	METHOD
APPEARANCE	CONFORM	-		Líquido viscoso oleoso	PH.EUR.*
COLOUR	CONFORM	-		Amarillo	PH.EUR.*
<u>SOLUBILITY</u>					
SOLUBLE	CONFORM			DISPERSIBLE IN WATER, ANHYDROUS ETHANOL, ETHYL ACETATE AND METHANOL	PH.EUR.
INSOLUBLE	CONFORM			FATTY ACIDS AND LIQUID PARAFFIN	PH.EUR.
<u>IDENTIFICATION</u>					
IDENTIFICATION A (IR SPECTRUM)	PASS				PH.EUR.*
IDENTIFICACION B (INDICE DE HIDROXILOS)	71,5 mg KOH/gr		65	80	PH.EUR.
IDENTIFICACION C (INDICE SAPONIFICACION)	50,8 mg KOH/gr		45	55	PH.EUR.
IDENTIFICACION D (COMPOSICIÓN ÁC. GRASOS)	CONFORM				PH.EUR.
IDENTIFICATION E	CONFORM				PH.EUR.
VISCOSITY	CONFORM	mPa*S		400	PH.EUR.
RELATIVE DENSITY	CONFORM	G/ML		APROX. 1,10	PH.EUR.
ACIDITY INDEX	0,5 mg KOH/gr		-	2	PH.EUR.
PEROXIDES INDEX	3,56 meq O2/Kg			10	PH.EUR.
ETHYLENE OXIDE	0 MG/KG			0,2	PH.EUR.
DIOXAN	0,81 ppm			5	PH.EUR.
WATER	2,69 %		-	3	PH.EUR.
SULPHATED ASH	CONFORM %			0,25	PH.EUR.
<u>FATTY ACIDS</u>					
MYRISTIC ACID (C14:0)	CONFORM %			5,0	PH.EUR.
PALMITIC ACID (C16:0)	CONFORM %			16,0	PH.EUR.
PALMITOLEIC ACID (C16:1)	CONFORM %			8,0	PH.EUR.
STEARIC ACID (C18:0)	CONFORM %			6,0	PH.EUR.
OLEIC ACID (C18:1)	CONFORM %		58,0		PH.EUR.
LINOLEIC ACID (C18:2)	CONFORM %			18,0	PH.EUR.
LINOLENIC ACID (C18:3)	CONFORM %			4,0	PH.EUR.
COLOUR	5 Gardner		-	6	Manufacture's Standard
DENSITY	CONFORM	G/ML	1,06	1,10	Manufacture's Standard
IODINE INDEX	CONFORM	g I2/100g	18	24	Manufacture's Standard
REDUCING SUBSTANCES	CONFORM	ML		5,0	Manufacture's Standard
VOLATILE ORGANIC IMPURITIES	CONFORM				Manufacture's Standard

The data expressed in this certificate of analysis is facilitated by our supplier and/or obtained in our control laboratory, in no case being exempted of the controls demanded by each sector. Tests marked with (\*) are verified in Guinama.

Manufacturer Batch: 04231478 Supplier Code: 401338

GUINAMA S.L. C/ OSLO,3 (before C/Praga) POL.IND. GUTENBERG 46185 La Pobra de Vallbona (Valencia) Spain  
Phone: +34 96 186 90 90 / 902 11 98 16 Fax: 96 185 03 52 E-mail: ventas@guinama.com - www.guinama.com



## Polysorbate 80

<b>CODE ARTICLE:</b> 93476	<b>BATCH:</b> 0124683
<b>TEST DATE:</b> 05/12/2023	<b>TEST:</b> QC-00259333
<b>EXPIRY DATE:</b> 30/06/2026	<b>FABRICATION DATE:</b> 01/06/2023
<b>CAS:</b> [9005-65-6]	
<b>SYNONYMS / BOTANICAL NAME:</b> Tween 80; E-433; Polisorbato 80	
<b>STORAGE:</b> Store in tightly closed containers in a cool, dry place.	

TEST	RESULTS	Units	MIN	MAX	METHOD
HEAVY METALS	CONFORM	MG/KG		10	Manufacture's Standard
LEAD	CONFORM	MG/KG		2	Manufacture's Standard
CADMIUM	CONFORM	ppm		1	Manufacture's Standard
ARSENIC	CONFORM	MG/KG		3	Manufacture's Standard
MERCURY	CONFORM	MG/KG		0,1	Manufacture's Standard
ETILENHIDRINA	ABSENCE				Manufacture's Standard
BACTERIAS TOTALES	CONFORM	cfu/g		100	Manufacture's Standard
MOLDS AND YEASTS	CONFORM	cfu/g		10	Manufacture's Standard
PATHOGENS	ABSENCE				Manufacture's Standard
CORRECT BATCH	YES				Manufacture's Standard
SAMPLING	COLLECT				Manufacture's Standard
SPECIFICATION	PH.EUR 11, USP, FCC				Manufacture's Standard

*NON-sterile*

*NOT SUITABLE FOR ORAL USE.*



**Silvia Sancho-Tello Ripoll**  
Technical Director.

The data expressed in this certificate of analysis is facilitated by our supplier and/or obtained in our control laboratory, in no case being exempted of the controls demanded by each sector. Tests marked with (\*) are verified in Guinama.

Manufacturer Batch: 04231478 Supplier Code: 401338

GUINAMA S.L. C/ OSLO,3 (before C/Praga) POL.IND. GUTENBERG 46185 La Pobra de Vallbona (Valencia) Spain  
Phone: +34 96 186 90 90 / 902 11 98 16 Fax: 96 185 03 52 E-mail: ventas@guinama.com - www.guinama.com

