



Società per Azioni
Eigenmann & Veronelli

Cap. int. vers. € 15.600.000

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SORBITAL T 80 PH (PHARMA GRADE)

Rev5 23/05/2018

Trade name SORBITAL T 80 PH
Raw material category Pharmaceutical excipient
Product Description POLYSORBATE 80

Composition

Components	Source of raw materials
100% Polysorbate 80	vegetable / synthetic

Solvents, preservatives and other additives

Ingredient	CAS No.	EINECS / EC No.	content [%]	Function
no additives				
no BHA/BHT				

Information on production process

The product is not irradiated.

The product is manufactured in the strictest absence of any animal derived material of any type.

TSE/BSE Status: TSE/BSE FREE

Origin of vegetable starting material: palm oil or palm oil derivatives

GMO-Status: GMO FREE



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Byproducts

Residual solvents	not present
Parabens	not present
1,4-Dioxane	max 10 ppm
Ethylene Oxide	max 1 ppm
Latex	not present
Phthalates	Based on our knowledge we do not expect to be present
Nanomaterials	not present
VOC	not present
Diethylene glycol	not present
Pesticides	compliance with the requirements of European Regulation (EC) No. 396/2005/EC with modifications, concerning «maximum limits applicable to pesticide residues present in or on foodstuffs and feed of plant and animal origin»
HEAVY METALS	10 ppm (as Pb)

Food Ingredients listed in Annex II REGULATION (EU) No 1169/2011

None of these substances have been intentionally added to our raw materials or are formed during the manufacturing process according to our knowledge of the chemistry.

* Purified product derived from maize starch and/or wheat starch hydrolysis. Absence of Wheat gluten when tested with the best available technique R5 Sandwich ELISA Kit. In Europe, this product does not have to support any allergen labeling according to the 2007/68/EC directive.

The product is considered GLUTEN FREE.

Regulatory Status

Regulatory status (chemical regulations) Europe

Components	REACH status	CAS No.	EINECS / EC No.
POLYSORBATE 80	COMPLIANT	9005-65-6	Polymer

Shelf life / storage conditions

36 months after production (unopened original packaging)



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Listing on National Inventories

Country/State	Inventory	Listed under	Remark
Australia	AICS	yes	
Philippine	PICCS	yes	
Canada	DSL	yes	
Usa	TSCA	yes	
Japan	MITI/ENCS	yes	No. 8-55 X
China	EICSC	yes	
NewZeland	NZIoC	yes	
Taiwan	ECL	Yes	KE-25511

Pharmacopoeia

The above mentioned product fulfils the analytical requirements of the currently valid versions of the European Pharmacopoeia (Ph. Eur.), United States Pharmacopoeia (USP / NF) and is tested and certified according to pharmacopoeiamethods.

Quality System

The above mentioned product is manufactured according to ISO 9001, ISO 14001, OHSAS 18001, EMAS.

GMP

NOTAVAILABLE

Kosher and Halal-Certificates

NOTAVAILABLE

Information on REACH / Substances of Very High Concern (SVHC)

During the production process of the above mentioned product we do not intentionally use or add any SVHC (according to current release of the candidate list) above the threshold limit of 0,1% w/w. Testing of these substances is not part of our standard routine quality control and production testing procedures.

Information on REACH / PBT- and vPvB - substances

Above mentioned products is not a PBT, vPvB substance as per the criteria of the REACH Regulation.



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Aflatoxins

The product is chemically produced but the raw material is in compliance with the maximum residues levels for certain contaminants in food set in Commission Regulation 1881/2006 as amended, replacing Regulation 466/2001, sets maximum levels in certain foods for the following mycotoxins - aflatoxins, ochratoxin A, patulin, deoxynivalenol, zearalenone, fumonisins, T-2 and HT-2-toxin.

The analysis on Aflatoxins is not part of our standard quality and production analyses.

Melamine

We do not use or add intentionally melamine in the above mentioned product, therefore we have no reason to expect the possibility of contamination.

World Anti-Doping List (WADA)

We confirm that during the production of above mentioned product intentionally we do not use or add any substances from World Anti-Doping List (WADA).

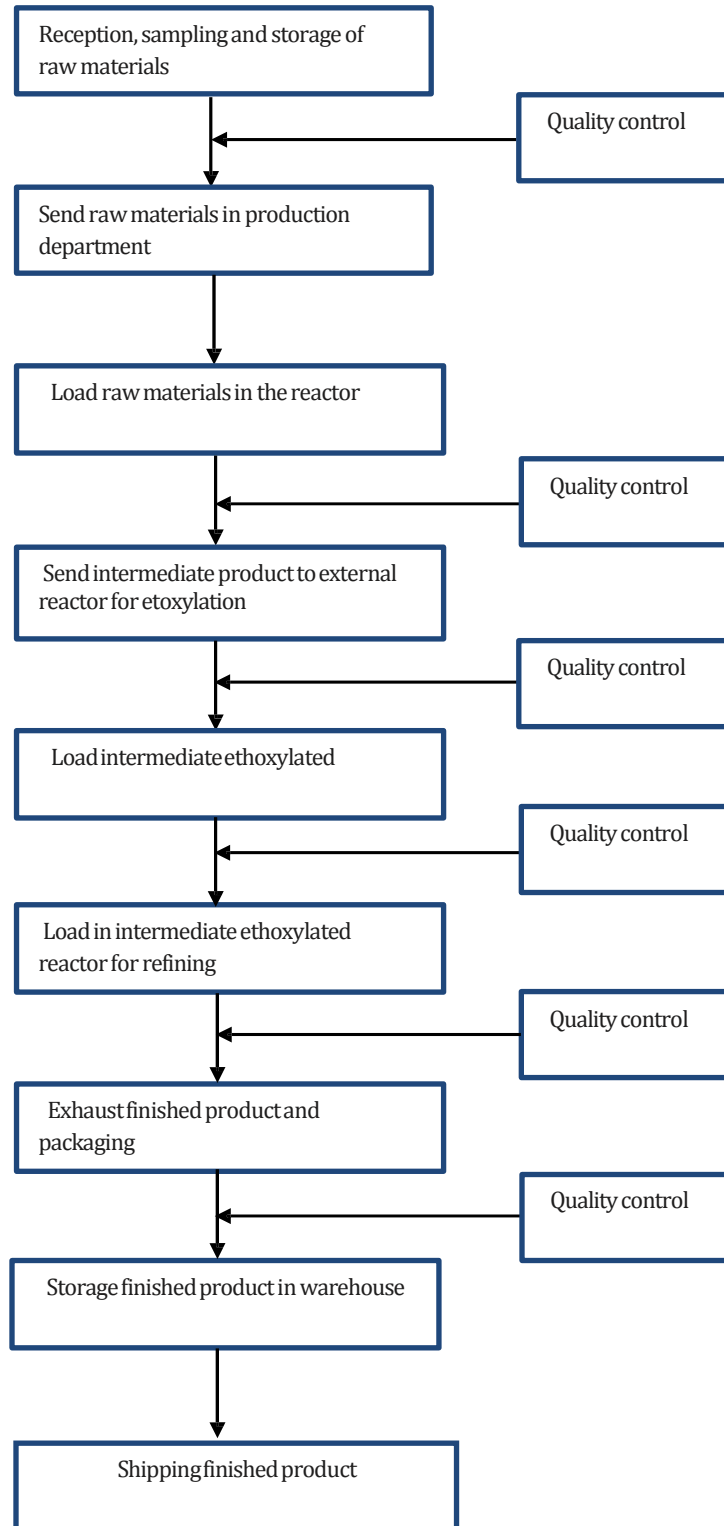
Indirect Food Contact Regulations

Country/ State	Regulation	
USA	FDA 21 CFR	172.515, 172.836, 172.838, 172.840, 172.842, 173.340, 175.105, 176.180, 178.3400, 573.860, 73.1, 73.1001
ITALY	DM 21/03/1973	Positive list under Rif. No. 85360
EUROPE	10/2011	Positive list under No. 242, Rif. No. 85360
GERMANY	BfR Recommendations on Food Contact Materials	XXXVI, XLIV
SWITZERLAND	SR 817.023.21	Listed in Annex 6, List of additives, Part A : evaluated substances





Manufacturing flowchart





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Rev 0 10/06/2015
Rev 1 02/07/2015 TSE/BSE Status
Rev 2 26/01/2016 DIETHYLENE GLYCOL
Rev 3 25/02/2016 Pesticides statement
Rev 4 27/06/2016 Heavy metals



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