



azienda chimica e farmaceutica

SPECIFICA TECNICA

Prodotto **ALCOOL BENZILICO BP-USP**

NOME INCI	Benzyl Alcohol
NOME INCI USA	Benzyl Alcohol
CAS	100-51-6
EINECS / ELINCS	202-859-9
FORMULA	C ₇ H ₈ O
PESO MOLECOLARE	108,1
VALIDITA'	24 mesi

SPECIFICA	METODO	Lim. Inf. - Lim. Sup.	u.m.
Titolo	DSM 3003	≥ 99,90	%
Benzaldeide	DSM 355	≤ 400	ppm
Cloro	DSM 2484	≤ 2	ppm
Acqua	DSM 1797	≤ 0,10	%
Acidità (come acido benzoico)	DSM 1955	≤ 0,05	%
Colore	DSM 1879	≤ 5	APHA
Piombo ¹	NEN 6966	≤ 0,1	ppm
* Aspetto		Liquido incolore	
* Odore		Debolmente aromatico	
* Densità (25 °C)		1,042 - 1,047	g/ml
* Solubilità in acqua (20 °C)		40 g/l (20 °C)	
* Punto di solidificazione		- 15	° C
* Indice di rifrazione (20 °C)		1.540	°
* Residuo non volatile		≤ 0,05	%
* Sostanze correlate		Conforme	
Revisione Capitolato		0	
Data Approvazione		30/09/2010	

* saggi non obbligatori

¹ purity item (EU directive 2008/84/EC)



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This material meets the specifications of FCC, Ph.Eur., BP and USP/NF (not intended for parenteral use).

This material is certified Kosher and Kosher for pass-over and certified Halal.

This material contains < 1 ppm : Ag, As, Bi, Cd, Co, Cr, Cu, Hg, Mn, Ni, Pb, Sb, Sn, Zn.

Stabilizing agents: None

Additives: None

Storage: Under nitrogen

GMO-free declaration:

Benzyl Alcohol is fully synthetic product and do not contain any genetically modified organisms, do not contain genetic material from genetically modified organisms, do not contain proteinacious materials derived from genetically modified organisms, do not contain non-proteinacious material derived from genetically modified organisms, nor have any genetically modified ingredients been used at any time in the synthesis of this material.

Residual solvent:

Solvents that could be present are Benzene (class 1) and Toluene (Class 2).

Benzene is not used. Toluene, however, is used as raw material in the oxidation process of our production, but is removed consistently. No other solvents are likely to be present.

If present, the concentrations are below the limits as set in the abovementioned guideline:

Benzene: < 2 ppm

Toluene: < 890 ppm.

This product is in full compliance with ICH guideline CPMP/ICH/283/95 and the thereto aligned requirements of USP-NF General Chapter <467> Residual Solvents.

Latex: The product as well as the raw materials for production of the above as well as their packaging materials, do not contain Latex rubber.

Origin: Benzyl alcohol is fully synthetic product. Raw materials, additives and catalysts used in the production processes are all synthetic materials.

Irradiation: The product as well as the raw materials for production of the abovementioned materials, have not been subjected to (ionizing) radiation treatment.



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BSE/TSE:

Benzyl alcohol is fully synthetic product. Raw materials, additives and catalysts used in the production processes are all synthetic materials. During production until the packaging of the product, this product can't come into contact with materials from animal or human origin.

Allergens and sensitizers data (In connection with EU Directive 2007/68/EC):

Benzyl Alcohol is fully synthetic product. Raw materials, additives and catalysts used in the production processes are all synthetic materials. During production until the packaging of the product, this product can't come into contact with materials from natural origin.

Allergens and sensitizers listed below are not present in this product, not present on same line and not present in the facility.

Allergens	Sensitizers
Dairy products	Monosodium Glumate
Egg products	Sulphur dioxide (> 10 ppm)
Cereals containing gluten	Sulphites (> 10 ppm)
Soybean product	Yeast
Peanut products	BHA / BHT / TBHQ
Tree nuts	Chocolate derivates
Fish / Shell fish products (crustaceans)	FD&C colors
Sesame seed products	Natural Alcohol
Mustard products	Beef / Pork derivatives
Celery	- Other natural sensitizers
Lupin	
Molluscs	
- Other natural allergens	