



azienda chimica e farmaceutica

SPECIFICA TECNICA

TECHNICAL SPECIFICATION

Prodotto: **SACCARINA SODICA BP**
Product **SACCHARIN SODIUM BP**

NOME INCI INCI NAME	Sodium Saccharin
NOME INCI USA INCI NAME USA	Sodium Saccharin
CAS CAS NUMBER	6155-57-3
EINECS / ELINCS EINECS / ELINCS	204-886-1
FORMULA FORMULA	$C_7H_4NNaO_3S \cdot 2H_2O$
PESO MOLECOLARE MOLECULAR WEIGHT	241.19

SPECIFICA SPECIFICATION	METODO METHOD	Lim. Inf. - Lim. Sup. Lower Lim. - Upper Lim.	u.m.
Aspetto Aspect		Polvere cristallina bianca o quasi bianca o cristalli incolori, efflorescenti in aria secca. <i>White or almost white, crystalline powder or colourless crystals, efflorescent in dry air.</i>	
* Solubilità Solubility		Facilmente solubile in acqua, poco solubile in alcool, praticamente insolubile in etere. <i>Freely soluble in water, slightly soluble in alcohol, practically insoluble in ether.</i>	
Punto di fusione Melting point		226,0 - 230,0	° C
Identificazione Identification		Conforme Conform	
Aspetto della soluzione Appearance of solution		Chiara ed incolore Clear and colourless	
Acidità o alcalinità Acidity or alkalinity		Conforme Conform	

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o-Toluenesulfonamide <i>o-Toluenesulfonamide</i>		<=10	ppm
p-Toluenesulfonamide <i>p-Toluenesulfonamide</i>		<=10	ppm
Metalli pesanti <i>Heavy metals</i>		<=20	ppm
Acqua <i>Water</i>		<=15,00	%
Benzoati e Salicilati <i>Benzoate and Salicylate</i>	Non appare precipitato o violetto di colore <i>No precipitate or violet color appears</i>		ppm
* p-Solfonamide dell'acido benzoico <i>p-Sulfonamide benzoic acid</i>		<=25	ppm
Sostanze facilmente carbonizzabili <i>Readily carbonizable substances</i>	Conforme <i>Conform</i>		
Arsenico <i>Arsenic</i>		<=3,0	ppm
Selenio <i>Selenium</i>		<=30	ppm
Piombo <i>Lead</i>		<=1,00	ppm
Titolo <i>Assay</i>		99,00 - 101,00	%
Impurezze organiche volatili (O.V.I.) <i>Organic volatile impurities (O.V.I.)</i>	Conforme <i>Conform</i>		
Sali d'ammonio <i>Ammonium salts</i>		<=25,0	ppm
* pH <i>pH</i>	Conforme <i>Conform</i>		
* Acido benzoico e salicilico <i>Benzoic and salicylic acid</i>	Conforme <i>Conform</i>		
Revisione Capitolato <i>Specification Revision</i>		5	

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Data Approvazione Approval Date		20/09/2016	
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* saggi non obbligatori
test not required

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GENETICALLY MODIFIED ORGANISMS – GMO

According to the EU regulations concerning the traceability and labelling of Genetically Modified Organisms (GMO), and the traceability of food products produced from GMO (Regulation N°1829/2003/EC and N°1830/2003/EC and amendments), we confirm that the product :

1.	Contains ingredient(s) from Maize and/or Soya origin	Yes	No X
	Contains no material which contains, consists of or is produced from authorized GMOs in proportion higher than 0,9 % . This presence is adventitious or technically unavoidable	Yes X	No
	is GMO or contains or consists of GMOs	Yes	No X
	is produced from GMOs or contains ingredients produced from GMOs	Yes	No X
2.	Contains ingredient(s) from other potential GMO-risk raw material(s) (rice, beet, cotton ...)	Yes	No X
	Contains no material which contains, consists of or is produced from evaluated GMOs in proportion higher than 0,5 % . This presence is adventitious or technically unavoidable	Yes X	No
3.	For information about processing aids, is produced or contains ingredient(s) produced with GMOs or Genetically Modified Microorganisms processing aids (bacteria, yeast...) or derived from GMOs or GMMs (including enzymes)	Yes	No X

We confirm that the ingredient supplied is compliant in all respects with the Regulations N°1829/2003/EC and N°1830/2003/EC where applicable

SUBSTANCES OR PRODUCTS CAUSING ALLERGIES OR INTOLERANCES

According Regulation (EU) N° 1169/2011 as regards indication of ingredients present in foodstuffs

The modification of the 2000/13 European directive about the labelling aims at the obligation of labelling clearly the allergen below used in food products production and still present in the product, even in a modified form, including additives and processing aids.

Allegen	Yes	No
Cereals containing gluten(1) and products thereof		X
Crustaceans and products thereof		X
Eggs and products thereof		X
Fish and products thereof (2)		X
Peanuts and products thereof		X
Soybeans and products thereof (3)		X
Milk and products thereof (including lactose) (4)		X
Nuts (5) or products thereof		X
Celery and products thereof		X

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Mustard and products thereof		X
Sesame seeds and product thereof		X
Sulphur dioxide and sulphites at concentrations of more than 10mg/kg or 10 mg/l expressed as SO ₂		X
Lupines and products thereof		X
Mollusc and product thereof		X

- (1) Cereals which contain gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridised strains) except: wheat-based glucose syrups including dextrose, wheat-based maltodextrins, glucose syrups based on barley, cereals used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages;
- (2) Except: fish gelatine used as carrier for vitamin or carotenoid preparations, fish gelatine or Isinglass used as fining agent in beer and wine;
- (3) Except fully refined soybean oil and fat, natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, natural D-alpha tocopherol succinate from soybean sources; vegetable oils derived phytosterols and phytosterol esters from soybean sources; plant stanol ester produced from vegetable oil sterols from soybean sources;
- (4) Except when used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages, lactitol;
- (5) almond (*Amygdalus communis* L.) hazelnuts (*Corylus avellana*), walnut (*Juglans regia*), cashew (*Anacardium occidentale*), pecan nuts (*Carya illinoensis*), brazil nut (*Bertholletia excelsa*), pistachio nut (*Pistacia vera*), macadamia nut and queensland nut (*Macadamia terniflora*) and products thereof, except nuts used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages;

ALLERGENS & FOOD INTOLERANCE

Allegen	Yes	No
Gluten		X
Yeasts and hydrolysates, cardamom, vanilla, cinnamon, cocoa, leguminosae; benzoic acid, benzoate, parabens, phenylalanine, glutamate, coriander and product thereof.		X
Bovine, porcine, ovine, fish and by-products		X
Exotics fruits (kiwi, banana, mango, ...) and products thereof		X
Strawberry and others berries		X
Azo-colorants		X
Others:		X

NON IRRADIATION

Has this raw material or one of its ingredients been irradiated or ionised?

No

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NANOMATERIAL

Does this raw material contain or can be considered as engineered nanomaterial*? No

Does this raw material have been made with nanotechnology? No

Does the product contain nanotechnology as defined by the French decree n°2012-232? No

*'engineered nanomaterial' means any intentionally produced material that has one or more dimensions of the order of 100 nm or less or that is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic of the nanoscale

RESIDUAL SOLVENTS According to UE Directive 2009/32 modified by (UE) 2010/59

Does the raw material contain some residual solvent? YES

If yes, please give:

- names of extraction solvents used: Methyl alcohol
- percentage of extraction solvents used:
- quality of extraction solvents used: food grade
- level of residual solvents : <3000 ppm

FOOD CERTIFICATE

Is the raw material Food Grade? YES

Is the product conforming to commission regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety?

Manufacturer' quality certificates ISO 9001

Can the product be used in babyfood (Directive 2006/141/CE)? NA

Is the product used in the European food industry before May 1997? YES

Is this product:

- Kosher certified YES

- Halal certified YES

Is this product suitable for:

- Vegetarians (free of all animals and fish products and derivatives thereof, except for honey, egg, milk and milk products)? YES

- Vegans (no product issued from animals, including honey, egg, milk, and milk products)? YES

ORIGIN

Synthetic YES

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CONTAMINANTS

Is the product conforming to UE regulations No 1881/2006 and No 629/2008 setting maximum levels for certain contaminants in foodstuffs, as amended?

YES

Contaminants	Tested
Pesticides (please precise)	No
Dioxins and dioxin like PCBS	No
PAH's (polycyclic aromatic hydrocarbons)	No
PCB's (polychlorobiphenyls)	No
Benzopyrens	No
Melamine	No
Mycotoxins and 3-MCPD	No
Doping like substances	No

Is the product conforming to UE regulations No 396/2005 about maximum residue levels of pesticides?

In riferimento all'oggetto Vi confermiamo che, salvo contaminazioni accidentali indipendenti dalla scrivente, il prodotto in oggetto NON contiene ftalati.

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