



Specification

Concerning Product:	
Article number	22839470BLY
Trade name / designation / denomination	Aspartame Fine Granular, E 951
CAS number	22839-47-0
Other names / synonyms	•3-amino-4-[(1-methoxy-1-oxo-3-phenylpropan-2-yl)amino]-4-oxobutanoic acid; •3-amino-N-(?-carbomethoxy-phenethyl)-succinamic acid-N-methyl ester; •3-amino-N-(α-carbomethoxy-phenethyl)-succinamic acid-N-methyl ester; •N-L-?Aspartyl-L-Phenylalanine-1-methyl ester; (3S)-3-Amino-4-[[[(2S)-1-methoxy-1-oxo-3-phenylpropan-2-yl]amino]-4-oxobutanoic acid; •N-L-αAspartyl-L-Phenylalanine-1-methyl ester; (3S)-3-Amino-4-[[[(2S)-1-methoxy-1-oxo-3-phenylpropan-2-yl]amino]-4-oxobutanoic acid; •aspartame;
EC number	245-261-3
Customs tariff number / CN code / TARIC	29242998
Molecular weight [g / mol]	294.30312
Formula	C ₁₄ H ₁₈ N ₂ O ₅

Parameter	Test Method	Specification	Unit
Organoleptic test			
Appearance		Food additive, Aspartame is a Non-Nutrive artificial sweetener based on two amino acids. It is metabolized like a food protein. Aspartame is a white or almost white odourless crystalline substance having a seet tast, slightly hygroscopic, appronimately 200 times as sweet as sucrose. Aspartame provides a clean sugar-like sweetness, without any bitter or metallic aftertaste.	
Colour	visual	white	
Flavor and taste	organoleptic	Approx. 200 times as sweet as sucrose. Clean sugar-like sweetness without aftertaste.	
Odour	organoleptic	odoless	
Physical parameter			
Form		crystalline powder	
Conductivity	conductometric (0.8 g/100 mL)	≤ 30	μS/cm
Loss on drying	gravimetric	≤ 4,5	%
pH value	potentiometric	(1g per 125g H ₂ O) 4,5 – 6,0	
Specific Optical Rotation	polarimetric	[α _D ²⁰] +14.5 – +16.5	°
Bulk density	volumetric	0,45 – 0,65	kg/L
Solubility		Slightly soluble in water and ethanol	
Transmittance	photometric (1-cm cell, 430nm)	(1g in 100g 2N HCl) ≥ 95	%
Identity			
Assay	titrimetric	(dry) 98 – 102	%
Impurities			
Impurity	GC	5-Benzyl-3,6-dioxo-2-piperazineacetic acid ≤ 1,5	%
Elemental Impurities			
Arsenic (As)	acc. to manufacturer	≤ 3	ppm
Lead (Pb)	acc. to manufacturer	≤ 1	ppm
Microbiological data			
Escherichia Coli.	acc. to manufacturer	Negative	/g

Salmonella	acc. to manufacturer	Negative	/25 g
Total Plate Count	acc. to manufacturer	≤ 250	CFU/g
Yeast and Mould	acc. to manufacturer	≤ 100	CFU/g
Particle size distribution			
Particles	sieve analyses	< 150 µm ≤ 50	%
Particles	sieve analyses	< 75 µm ≤ 100	%
Particles	sieve analyses	> 300 µm ≤ 1	%

Regulatory information:

Allergens statement: *Mandatory note:* "Contains a source of phenylalanine"

BSE/TSE statement: The product is a highly purified, high intensity Non-Nutritive dipeptide artificial sweetener and does not contain any components derived from beef or has been in contact with any parts of animals origin during manufacturing, storage or distribution. The product is therefore free of BSE/TSE and fully complies with the Regulation (EC) No. 999/2001 of the European parliament and of the council of 22 May 2001, and with the Note for Guidance reference EMA/410/01 rev.3.

Elemental Impurities: The manufacturer confirms that the product is evaluated according to ICH guideline Q3D and that no Elements are identified to be a potential impurities in it.

GMO statement: The raw materials or any components used for the production of this product are not of animal or plant origin. During manufacturing or storage the final product has not been in contact with any parts of animal or plant origin.

Supplemental information:

Released by manufacturer: 2018-01-01

Shelf life: 5 years under recommended storage conditions

Derivation: produced by a chemical synthesis process from Amino Acids, L-Aspartic acid and L-Phenylalanine

Note: Not subject to authorization, labelling or traceability according to Regulations (EC) No 1829/2003 and No 1830/2003, does not require allergen labelling according to Regulation (EU) No 1169/2011

Storage conditions: Original (unopened) packaging in a dry place (15-30°C; 35-75% relative humidity) protected against odours and pests

Complies with monographie: E 951

Regional origin: EU

Usage: Food additive, Sweetener

Version of manufacturer: 2

Conclusion: European Pharmacopoeia (EP), U.S. Pharmacopeia/National Formulary (USP/NF), Japanese Pharmacopoeia for Excipients (JPE), Commission Regulation (EU) No 231/2012, Food Chemicals Codex (FCC), Joint FAO/WHO Expert Committee on Food Additives (JECFA) and Japanese Standards for Food Additives (JSfA) have set purity criteria for this substance (Heavy metals (as. Lead), Arsenic (As) and Lead (Pb)). Therefore this product fully complies with this requirement.

Product is produced in compliance with applicable European Food Law (e.g. Regulation (EC) No 178/2002, Regulation (EU) No 231/2012). According to the manufacturer the product also meets Ph. Eur. And FAO/WHO Specifications

Chemische Werke Hommel GmbH & Co.KG

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Waltrop, 12. Sep. 2019

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