



Specification

Concerning Product:	
Article number	36010
Trade name / designation / denomination	Theobromin rein, sythetisch
CAS number	83-67-0
Other names / synonyms	•Theobromine;
EC number	201-494-2
Customs tariff number / CN code / TARIC	29399900
Molecular weight [g / mol]	180,2
Formula	C ₇ H ₈ N ₄ O ₂
Warning 	
Harmful if swallowed. Do not breathe dust/fume/gas/mist/vapours/spray. Do not get in eyes, on skin, or on clothing. Do not eat, drink or smoke when using this product. Rinse mouth. Remove/Take off immediately all contaminated clothing. Wash hands thoroughly after handling. Dispose of contents/container in accordance with local/regional/national/international regulations.	

Parameter	Test Method	Specification	Unit
Organoleptic test			
Appearance	EP	white or almost white powder	
Physical parameter			
Acidity/Alkalinity	EP	(NaOH 0,01 M) ≤ 0,2	ml
Loss on drying	EP 2.2.32	≤ 0,5	%
Solubility	EP	Very slightly soluble in water and in anhydrous ethanol, slightly soluble in ammonia. It dissolves in dilute solutions of alkali hydroxides and in mineral acids.	
Identity			
Assay	EP 2.2.20	(dried substance) 99,0 – 101,0	%
Identification	EP 2.2.24 2.3.1	complies	
Impurities			
Heavy Metals (as Pb)	EP 2.4.20	conform to EP 5.20	
Sulphated ash	EP 2.4.14	≤ 0,1	%
Related substances	EP 2.2.29	≤ 0,5	% [w/w]
Elemental Impurities			
Arsenic (As)		≤ 1	ppm
Cadmium (Cd)		≤ 1	ppm
Cobalt (Co)		≤ 1	ppm
Mercury (Hg)		≤ 0,1	ppm
Nickel (Ni)		≤ 1	ppm
Lead (Pb)		≤ 1	ppm
Vanadium (V)		≤ 1	ppm

Microbiological data			
Aerobic microorganisms		≤ 100	CFU/g
Escherichia Coli.		neg. in 1 g	
Salmonella		neg. in 25 g	
Yeast and Mould		≤ 10	CFU/g

Supplemental information:

Shelf life: 5 years

Derivation: synthetic

Note:

This product complies to:

- Directive 2009/32/EC on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients
- Regulation (EC) No 1223/2009 on cosmetic products
- Regulation (EC) No 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods
- Regulation (EC) No 1829/2003 on genetically modified food and feed and the Regulation (EC) No 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms (GMO-free)
- Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs (aflatoxin B1 max 2 µg/kg, total aflatoxins B1 B2 G1 G2 max 4 µg/kg)
- Regulation (EC) No 629/2008 amending Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs (Pb max 3 mg/kg, Cd max 1 mg/kg, Hg max 0.1 mg/kg)
- Regulation (EU) 2015/1933 amending Regulation (EC) No 1881/2006 as regards maximum levels for polycyclic aromatic hydrocarbons in cocoa fibre, banana chips, food supplements, dried herbs and dried spices (benzo(a)pyrene max 10 µg/kg, sum of PAH4 max 50 µg/kg)
- Regulation (EU) No 594/2012 amending Regulation (EC) No 1881/2006 as regards the maximum levels of the contaminants ochratoxin A, non dioxin-like PCBs and melamine in foodstuff (ochratoxin A max 10 µg/kg, melamine max 2.5 mg/kg)

Heavy metal specifications have been set considering ICH Q3D (Guideline for Elemental Impurities) option 3. Cd max 1 ppm, Pb max 1 ppm, As max 1 ppm, Hg max 0.1 ppm, Co max 1 ppm, V max 1 ppm, Ni max 1 ppm

The product complies with the microbiological limits: Total aerobic microbial count max 100 CFU/g, Total combined yeasts/moulds count max 10 CFU/g, Escherichia coli absent in 1 g, Salmonella absent in 25 g

Storage conditions: Keep in tightly closed original sealed packing in a cool, clean and dry place, away from direct sunlight and water.

Packing: 25 kg drum

Chemische Werke Hommel GmbH & Co.KG

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Waltrop, 22. Jul. 2024

LF-Basis: Rev 6 (2022-08-30)

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