

PROPYL GALLATE PRODUCT DATA SHEET

A GMP excipient for your most sensitive formulations

Product presentation

Product name : Propyl Gallate GMP

Manufacturer : Minakem Beuvry Production S.A.S

Supplier : Minakem S.A.S

Product grades & references :

- Propyl Gallate standard #700121
- Propyl Gallate milled #700122

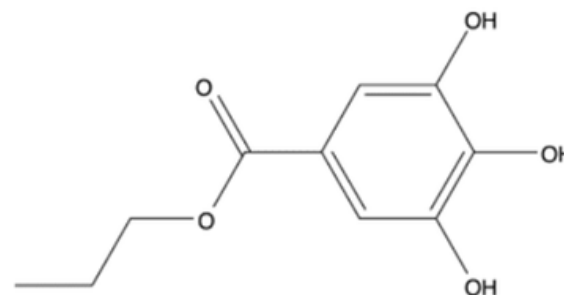
CAS number : 121-79-9

Other names : 3,4,5-Trihydroxybenzoic acid propyl ester, n-Propyl Gallate

Retest date : 4 years

Physico-chemical characteristics:

- Molecular formula : $C_{10}H_{12}O_5$
- Molecular weight : 212.20 g/mol
- Aspect : White to off-white powder



Product application

- **Antioxidant**

Propyl gallate is a well-known safe ingredient to protect oils and fat in products from oxidation. It is widely used as an additive in food, cosmetics and pharmaceutical products as an excipient¹.

- **Inhibitor of nitrosamines formation**

More recently, the risk of nitrosamines impurities in food and drug products has become a critical concern as illustrated by the growing number of publications and patents on the subject. Recent studies now revealed that Propyl Gallate has an effective inhibitory effect on the formulation of Alkyl-Aryl and Dialkyl N-Nitrosamine Derivatives².

¹Int J Toxicol. 2007;26 Suppl 3:89-118 - ²Processes, 2022, 10, 2428

Product conformity

- Both products are fully manufactured, packaged and tested in accordance with **EU GMP Guidelines** Volume 4 Part II (ICHQ7).
- They comply with the requirements of the current monographs of **European Pharmacopeia and US Pharmacopeia**.

Product specifications

Test	PROPYL GALLATE STANDARD #700121	PROPYL GALLATE MILLED #700122
Appearance	White to off-white, crystalline powder	White to off-white, crystalline powder
Identity : IR Spectrum	Complies	Complies
Identity : UV Spectrum	Complies	Complies
Melting range (USP)	146 to 150°C	146 to 150°C
Melting point (EP)	148 to 150°C	148 to 150°C
Clarity of solution	Clear	Clear
Color of solution	Clear, not more intensely colored than BY5	Clear, not more intensely colored than BY5
Total Chlotine	≤ 200 ppm	≤ 200 ppm
Chlorides	≤ 100 ppm	≤ 100 ppm
Zinc content	≤25 ppm	≤ 25 ppm
Heavy metals	≤10 ppm	≤ 10 ppm
Loss on drying	≤ 0.5%	≤0.5%
Residue on ignition	≤ 0.1%	≤ 0.1%
Assay (w) and related substances by HPLC (EP) Propyl Gallate Unspecified imputities Total impurities	98.0 to 102.0% ≤ 0.10% ≤ 0.15%	98.0 to 102.0% ≤ 0.10% ≤ 0.15%
GC residual solvent : • toluene • n-propanol	≤ 890 ppm ≤ 5000 pm	≤ 890 ppm ≤ 5000 pm
PSD	NA	Dv 50 ≤ 150 μm Dv 90≤ 200 μm

Product packaging and storage conditions

The product Propyl Gallate GMP is placed into 2 polyethylene bags, both packed in a plastic drum/keg.

- 20 kg → drum 120 L (Std & Milled)
- 5 kg → keg 15L Std & 20L Milled
- 1 kg (samples)→ keg 6L Std & 10L Milled

Desiccants are placed between the inner bag and outer bag.
The product is stored at room temperature and dry conditions.

Business Manager contact

Minakem SAS - Sébastien JACQUET
Email : sebastien.jacquet@minakem.com