Propylene Glycol Alginate

1 Nonproprietary Names

USPNF: Propylene glycol alginate

2 Synonyms

Alginic acid, propylene glycol ester; E405; hydroxypropyl alginate; *Kelcoloid*; *Manucol ester*; *Pronova*; propane-1,2-diol alginate; *Protanal*.

3 Chemical Name and CAS Registry Number

Propylene glycol alginate [9005-37-2]

4 Empirical Formula Molecular Weight

Propylene glycol alginate is a propylene glycol ester of alginic acid, a linear glycuronan polymer consisting of a mixture of β-(1→4)-D-mannosyluronic acid and α-(1→4)-L-gulosyluronic acid residues.

5 Structural Formula

See Section 4.

6 Functional Category

Emulsifying agent; stabilizing agent; suspending agent; viscosity-increasing agent.

7 Applications in Pharmaceutical Formulation or Technology

Propylene glycol alginate is used as a stabilizing, suspending, gelling, and emulsifying agent in oral and topical pharmaceutical formulations. Typically, a concentration of 1–5% is used, although this may vary depending upon the specific application and the grade of propylene glycol alginate used.

Propylene glycol alginate is also used in cosmetics and food products.

8 Description

Propylene glycol alginate occurs as a white to yellowish colored, practically odorless and tasteless, fibrous or granular powder.

9 Pharmacopeial Specifications

See Table I.

Table I: Pharmacopeial specifications for propylene glycol alginate.

Test	USPNF 20
Identification	+
Microbial limits	≤200/g
Loss on drying	≤20.0%
Ash	≤10.0%
Arsenic	≤3 ppm
Lead	≤0.001%
Heavy metals	≤0.004%
Free carboxyl groups	+
Esterified carboxyl groups	+
Assay (of alginates)	+

10 Typical Properties

Solubility: soluble in dilute organic acids and water, forming stable, viscous, colloidal solutions at pH 3. Depending upon the degree of esterification, propylene glycol alginate is also soluble in aqueous ethanol/water mixtures containing up to 60% w/w of ethanol.

Viscosity (dynamic): the viscosity of aqueous solutions depends upon the grade of material used. Typically, a 1% w/v aqueous solution has a viscosity of 20–400 mPa s (20–400 cP). Viscosity may vary depending upon concentration, pH, temperature, or the presence of metal ions. *See* also Sodium Alginate.

11 Stability and Storage Conditions

Propylene glycol alginate is a stable material, although it will gradually become less soluble if stored at elevated temperatures for extended periods.

Propylene glycol alginate solutions are most stable at pH 3–6. In alkaline solutions, propylene glycol alginate is rapidly saponified. Alginate solutions are susceptible to microbial spoilage and should be sterilized or preserved with an antimicrobial preservative. However, sterilization processes may adversely affect the viscosity of propylene glycol alginate solutions, *see* Sodium Alginate.

The bulk material should be stored in an airtight container in a cool, dry place.

12 Incompatibilities

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13 Method of Manufacture

Alginic acid, extracted from brown seaweed, is reacted with propylene oxide to form propylene glycol alginate. Various grades may be obtained that differ in composition according to the degree of esterification and the percentage of free and neutralized carboxyl groups present in the molecule; complete esterification of alginic acid is impractical.

14 Safety

Propylene glycol alginate is used in oral and topical pharmaceutical formulations, cosmetics, and food products. It is generally regarded as a nontoxic and nonirritant material, although excessive oral consumption may be harmful. A study in five healthy male volunteers fed a daily intake of 175 mg/kg body-weight of propylene glycol alginate for 7 days, followed by a daily intake of 200 mg/kg body-weight of propylene glycol alginate for a further 16 days, showed no significant adverse effects.[1]

Inhalation of alginate dust may be irritant and has been associated with industrially related asthma in workers involved in alginate production. However, it appears that the cases of asthma were linked to exposure to seaweed dust rather than pure alginate dust.[2]

LD_{50} (hamster, oral): 7.0 g/kg[3]
LD_{50} (mouse, oral): 7.8 g/kg
LD_{50} (rabbit, oral): 7.6 g/kg
LD_{50} (rat, oral): 7.2 g/kg

15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. Propylene glycol alginate may be irritant to the eyes or respiratory system if inhaled as dust; *see* Section 14. Eye protection, gloves, and a dust respirator are recommended. Propylene glycol alginate should be handled in a well-ventilated environment.

16 Regulatory Status

GRAS listed. Accepted in Europe for use as a food additive. Included in the FDA Inactive Ingredients Guide (oral preparations). Included in nonparenteral medicines licensed in the UK.

17 Related Substances

Alginic acid; sodium alginate.

18 Comments

See Alginic Acid and Sodium Alginate for further information.

19 Specific References

1 Anderson DM, Brydon WG, Eastwood MA, Sedgwick DM. Dietary effects of propylene glycol alginate in humans. *Food Addit Contam* 1991; 8(3): 225–236.
2 Henderson AK, Ranger AF, Lloyd J, *et al.* Pulmonary hypersensitivity in the alginate industry. *Scott Med J* 1984; **29**(2): 90–95.
3 Lewis RJ, ed. *Sax's Dangerous Properties of Industrial Materials*, 10th edn. New York: Wiley, 2000: 3080.

20 General References

McDowell RH. New reactions of propylene glycol alginate. *J Soc Cosmet Chem* 1970; **21**: 441–457.

21 Author

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22 Date of Revision

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