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21 Author

S Driver.

22 Date of Revision

4 May 2017.

Propylene Glycol Alginate

1 Nonproprietary Names

USP–NF: Propylene Glycol Alginate

2 Synonyms

Alginic acid, propylene glycol ester; E405; hydroxypropyl alginate; *Kelcoloid*; *Kimiloid*; *Manucol Ester*; *PGA*; *Profoam*; propane-1,2-diol alginate; *TIC Pretested*.

P

3 Chemical Name and CAS Registry Number

Propylene glycol alginate [9005-37-2]

4 Empirical Formula and 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; foam 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 0.3–5.0% w/v is used, although this may vary depending upon the specific application and the grade of propylene glycol alginate used.

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. *See also* Section 18.

Table I: Pharmacopeial specifications for propylene glycol alginate.

Test	USP 40–NF 35 S1
Identification	+
Microbial limits	≤200 cfu/g
Loss on drying	≤20.0%
Ash	≤10.0%
Arsenic	≤3 ppm
Lead	≤10 ppm
Heavy metals	≤40 ppm
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 (95%). The interfacial and foaming properties of propylene glycol alginate aqueous solutions have been studied, and were found to be affected by the degree of esterification and molecular weight.[1]

Spectroscopy

NIR spectrum *see* Figure 1.

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.