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4 May 2017.

Starch, Modified

1 Nonproprietary Names

USP–NF: (a) Modified Starch
(b) Pregelatinized Modified Starch

Both monographs in the USP 40–NF 35 S1 describe a vast family of food modified starches, all conforming to the US Code of Federal Regulations 21 CFR 172.892. The two monographs cover either the granular and cold-water-insoluble starches or the cold-water-soluble pendants, obtained via an additional pregelatinization process. Hydroxypropylated starches and pregelatinized hydroxypropylated starches are described in several specific USP–NF monographs. Some specific pharmaceutical starches without food conformity are described in separate monographs (e.g. *see* Sodium Starch Glycolate).

The PhEur 9.2 describes only hydroxypropylated (food modified) starches in a dedicated monograph (*see* Hydroxypropyl Starch).

2 Synonyms

Amprac; *amylum modificatum*; *C*Pharm*; *Capsul*; *Clearam*; *Cleargum*; E1401–1452; *Hi-Cap*; *Instant Pure-Cote*; *Lycoat*; *Pure-Cote*; *Pure-Gel*; *Purity*; *Purity Gum*; *Uni-Pure*.

According to the International Numbering System (INS) for Food Additives⁽¹⁾ the following starches should comply with food legal regulations:

- 1400 Dextrin roasted starch
- 1401 Acid-treated starch
- 1402 Alkaline-treated starch
- 1403 Bleached starch

- 1404 Oxidized starch
- 1405 Starches, enzyme-treated
- 1410 Monostarch phosphate
- 1412 Distarch phosphate
- 1413 Phosphated distarch phosphate
- 1414 Acetylated distarch phosphate
- 1420 Starch acetate
- 1422 Acetylated distarch adipate
- 1440 Hydroxypropyl starch
- 1442 Hydroxypropyl distarch phosphate
- 1450 Starch sodium octenyl succinate
- 1451 Acetylated oxidized starch

3 Chemical Name and CAS Registry Number

The chemical name and the corresponding CAS number depend on the botanical origin of the starch and the nature of the chemical modification(s). Some examples are given in this nonexhaustive list:

- Acetylated distarch adipate, waxy corn basis [63798-35-6]
- Acid-treated corn starch [65996-63-6]
- Acid-treated waxy corn starch [68909-37-5]
- Distarch phosphate, waxy corn basis [55963-33-2]
- Oxidized waxy corn starch [65996-62-5]
- Sodium octenyl succinate starch [66829-29-6]

4 Empirical Formula and Molecular Weight

$(C_6H_{10}O_5)_n$ where $n = 300-10\,000$