Castor Oil, Hydrogenated

1 Nonproprietary Names

BP: Hydrogenated Castor Oil

PhEur: Castor Oil, Hydrogenated

USP–NF: Hydrogenated Castor Oil

2 Synonyms

Castorwax; *Croduret*; *Cutina HR*; *Fancol*; 12-hydroxyoctadecanoic acid, 1,2,3-propanetriyl ester; *Kolliwax HCO*; octadecanoic acid, 12-hydroxy-, 1,2,3-propanetriyl ester; 1,2,3-propanetriol tri(12-hydroxystearate); ricini oleum hydrogenatum; trihydroxystearin.

3 Chemical Name and CAS Registry Number

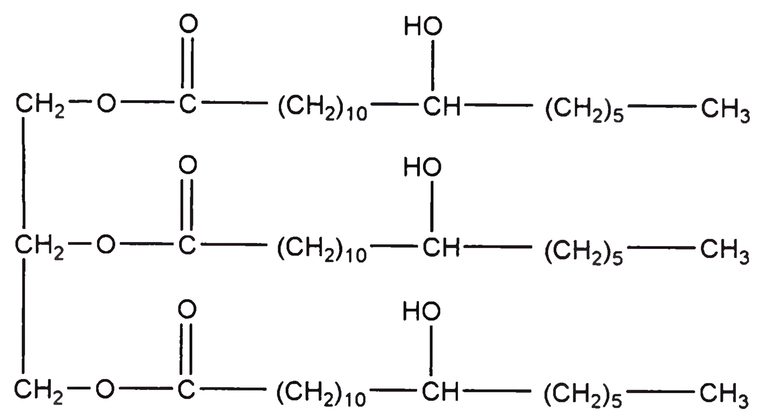
Glyceryl-tri-(12-hydroxystearate) [8001-78-3]

4 Empirical Formula and Molecular Weight

$C_{57}O_9H_{110}$ 939.50

The USP 40–NF 35 S1 describes hydrogenated castor oil as refined, bleached, hydrogenated, and deodorized castor oil, consisting mainly of the triglyceride of hydroxystearic acid.

5 Structural Formula



6 Functional Category

Coating agent; modified-release agent; stiffening agent; tablet and capsule lubricant.

7 Applications in Pharmaceutical Formulation or Technology

Hydrogenated castor oil is a hard wax with a high melting point used in oral and topical pharmaceutical formulations; *see* Table I.

Table I: Uses of hydrogenated castor oil.

Use	Concentration (%)
Coating agent (delayed release)	5.0–20.0
Delayed release drug matrix	5.0–10.0
Tablet die lubricant	0.1–2.0

In topical formulations, hydrogenated castor oil is used to provide stiffness to creams and emulsions.[1] In oral formulations, it is used to prepare sustained-release tablet and capsule preparations,[2–4] and may be used as a coat or to form a solid matrix. Hydrogenated castor oil is additionally used to lubricate the die walls of tablet presses.[5,6]

Studies have shown that hydrogenated castor oil may be used to enhance the stability of moisture-sensitive drug products[7] and it has been used in experimental systems to evaluate nanoemulsions,[8] microemulsions,[9] nanoparticles,[10] and solid dispersion systems[11] as a means to enhance delivery and bioavailability of drugs.

8 Description

Hydrogenated castor oil occurs as a fine, almost white or pale yellow powder or flakes. The PhEur 9.2 describes hydrogenated castor oil as the oil obtained by hydrogenation of virgin castor oil. It consists mainly of the triglyceride of 12-hydroxystearic acid.

9 Pharmacopeial Specifications

See Table II.

Table II: Pharmacopeial specifications for hydrogenated castor oil.

Test	PhEur 9.2	USP 40–NF 35 S1
Characters	+	–
Identification	+	–
Acid value	≤4.0	≤11
Hydroxyl value	145–165	154–162
Iodine value	≤5.0	≤5.0
Saponification value	–	176–182
Alkaline impurities	+	–
Composition of fatty acids	+	–
Palmitic acid	≤2.0%	–
Stearic acid	7.0–14.0%	–
Arachidic acid	≤1.0%	–
12-Oxostearic acid	≤5.0%	–
12-Hydroxystearic acid	78.0–91.0%	–
Any other fatty acid	≤3.0%	–
Nickel	≤1 ppm	–
Heavy metals	–	≤0.001%
Melting range	83–88°C	85–88°C

10 Typical Properties

Acid value ≤5

Density 0.98–1.10 g/cm^3

Flash point 316°C (open cup)

Melting point 87°C for *Castorwax*

Moisture content ≤0.1%

Particle size distribution 97.7% ≥1000 µm in size for flakes.

Solubility Practically insoluble in water; soluble in acetone, chloroform, and methylene chloride.

Specific gravity 1.023 at 25°C for *Castorwax*

11 Stability and Storage Conditions

Hydrogenated castor oil is stable at temperatures up to 150°C.

Clear, stable, chloroform solutions containing up to 15% w/v of hydrogenated castor oil may be produced. Hydrogenated castor oil may also be dissolved at temperatures greater than 90°C in polar solvents and mixtures of aromatic and polar solvents, although the hydrogenated castor oil precipitates out on cooling below 90°C.

Hydrogenated castor oil should be stored in a well-closed container in a cool, dry place.

12 Incompatibilities

Hydrogenated castor oil is compatible with most natural vegetable and animal waxes.