LD_{50} (rabbit, IV): 0.33 g/kg
LD_{50} (rat, IP): 0.88 g/kg
LD_{50} (rat, oral): 3.0 g/kg
LD_{50} (rat, SC): 5.5 g/kg

Comments Anhydrous citric acid is listed in the PhEur 9.2 and USP 40–NF 35 S1. Anhydrous citric acid is one of the materials that have been selected for harmonization by the Pharmacopeial Discussion Group. For further information see the General Information Chapter <1196> in the USP–NF, the General Chapter 5.8 in PhEur, along with the 'State of Work' document on the PhEur EDQM website, and also the General Information Chapter G10 in the JP.

18 Comments

Citric acid monohydrate has undergone harmonization of many attributes for JP, PhEur, and USP–NF by the Pharmacopeial Discussion Group. For further information see the General Chapter 5.8 in PhEur, along with the 'State of Work' document on the PhEur EDQM website, and also the General Information Chapter G10 in the JP.

Citric acid monohydrate has been used experimentally to adjust the pH of tablet matrices in enteric-coated formulations for colon-specific drug delivery.[8]

Therapeutically, preparations containing citric acid have been used to dissolve renal calculi.

A specification for citric acid monohydrate is contained in the *Food Chemicals Codex* (FCC).[9]

The EINECS number for citric acid is 201-069-1. The PubChem Compound ID (CID) for citric acid monohydrate is 22230.

19 Specific References

1 Anderson NR, *et al.* Quantitative evaluation of pharmaceutical effervescent systems II: stability monitoring by reactivity and porosity measurements. *J Pharm Sci* 1982; **71**(1): 7–13.
2 Yanze FM, *et al.* A process to produce effervescent tablets: fluidized bed dryer melt granulation. *Drug Dev Ind Pharm* 2000; **26**(11): 1167–1176.
3 Nykänen P, *et al.* Citric acid as excipient in multiple-unit enteric-coated tablets for targeting drugs on the colon. *Int J Pharm* 2001; **229**(1–2): 155–162.
4 Todo H, *et al.* Improvement of stability and absorbability of dry insulin powder for inhalation by powder-combination technique. *Int J Pharm* 2004; **271**(1–2): 41–52.
5 Anonymous. Citric acid: tooth enamel destruction. *Clin Alert* 1971; 151.
6 Main I, Ward MK. Potentiation of aluminium absorption by effervescent analgesic tablets in a haemodialysis patient. *Br Med J* 1992; **304**: 1686.
7 Lewis RJ, ed. *Sax's Dangerous Properties of Industrial Materials*, 12th edn. New York: Wiley, 2012: 1165.
8 Nykaenen P, *et al.* Citric acid as a pH-regulating additive in granules and the tablet matrix in enteric-coated formulations for colon-specific drug delivery. *Pharmazie* 2004; **59**(4): 268–273.
9 *Food Chemicals Codex*. [online] Bethesda, MD: United States Pharmacopeia. http://publications.usp.org (accessed 31 March 2017).

20 General References

Cho MJ, *et al.* Citric acid as an adjuvant for transepithelial transport. *Int J Pharm* 1989; **52**: 79–81.
European Directorate for the Quality of Medicines and Healthcare (EDQM). European Pharmacopoeia – State Of Work Of International Harmonisation. *Pharmeuropa* 2011; 23(4): 713–714. www.edqm.eu/site/-614.html (accessed 13 December 2011).
Timko RJ, Lordi NG. Thermal characterization of citric acid solid dispersions with benzoic acid and phenobarbital. *J Pharm Sci* 1979; **68**: 601–605.

21 Author

GE Amidon.

22 Date of Revision

4 May 2017.

Coconut Oil

1 Nonproprietary Names

BP: Coconut Oil
JP: Coconut Oil
PhEur: Coconut Oil, Refined
USP–NF: Coconut Oil

2 Synonyms

Aceite de coco; cocois oleum raffinatum; coconut butter; coconut palm oil; copra oil; oleum cocois; *Pureco 76*; refined coconut oil.

3 Chemical Name and CAS Registry Number

Coconut oil [8001-31-8]

4 Empirical Formula and Molecular Weight

Coconut oil contains triglycerides, the fatty acid constituents of which are mainly lauric and myristic acids with smaller proportions of capric, caproic, caprylic, oleic, palmitic and stearic acids.

The PhEur 9.2 and USP 40–NF 35 S1 state that the fatty acid composition for coconut oil is caproic acid (≤1.5%), caprylic acid (5.0–11.0%), capric acid (4.0–9.0%), lauric acid (40.0–50.0%), myristic acid (15.0–20.0%), palmitic acid (7.0–12.0%), stearic acid (1.5–5.0%), arachidic acid (≤0.2%), palmitoleic acid (≤1.0%), oleic acid (4.0–10.0%), linoleic acid (1.0–3.0%), linolenic acid (≤0.2%), and eicosenoic acid (≤0.2%).

5 Structural Formula

See Section 4.

6 Functional Category

Emollient; ointment base.

7 Applications in Pharmaceutical Formulation or Technology

Coconut oil has traditionally been used in ointments where it forms a readily absorbable base. It has been used particularly in preparations intended for application to the scalp, where it could