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## 13 Method of Manufacture

Acetyltriethyl citrate is prepared by the esterification of citric acid with ethanol followed by acylation with acetic anhydride.

## 14 Safety

Acetyltriethyl citrate is used in oral pharmaceutical formulations and is generally regarded as a nontoxic and nonirritating material. However, ingestion of large quantities may be harmful.

The Cosmetic Ingredient Review Expert Panel has assessed acetyltriethyl citrate and concluded that the material is safe as used in cosmetics and personal care products.[8]

$LD_{50}$ (mouse, IP): 1.15 g/kg[7]
$LD_{50}$ (rat, oral): 7 g/kg[7]

## 15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled.

Acetyltriethyl citrate may be irritating to the eyes or the respiratory system as a mist or at elevated temperatures. Gloves and eye protection are recommended for normal handling and a respirator is recommended if used at elevated temperatures.

## 16 Regulatory Status

Approved in the USA for direct food contact in food films.

## 17 Related Substances

Acetyltributyl citrate; tributyl citrate; triethyl citrate.

## 18 Comments

The EINECS number for acetyltriethyl citrate is 201-066-5. The PubChem Compound ID (CID) for acetyltriethyl citrate is 6504.

## 19 Specific References


1 Jensen JL, *et al.* Variables that affect the mechanism of drug release from osmotic pumps coated with acrylate/methacrylate copolymer latexes. *J Pharm Sci* 1995; **84**: 530–533.
2 Gutierrez-Rocca JC, McGinity JW. Influence of water soluble and insoluble plasticizer on the physical and mechanical properties of acrylic resin copolymers. *Int J Pharm* 1994; **103**: 293–301.
3 Lehmann K. Chemistry and application properties of polymethacrylate coating systems. In: McGinity JW, ed. *Aqueous Polymeric Coatings for Pharmaceutical Dosage Forms*. New York: Marcel Dekker, 1989: 153–245.
4 Steurnagel CR. Latex emulsions for controlled drug delivery. In: McGinity JW, ed. *Aqueous Polymeric Coatings for Pharmaceutical Dosage Forms*. New York: Marcel Dekker, 1–61.
5 Gutierrez-Rocca JC, McGinity JW. Influence of aging on the physical-mechanical properties of acrylic resin films cast from aqueous dispersions and organic solutions. *Drug Dev Ind Pharm* 1993; **19**(3): 315–332.
6 Siepmann J, *et al.* Diffusion-controlled drug delivery systems: calculation of the required composition to achieve desired release profiles. *J Control Release* 1999; **60**(2–3): 379–389.
7 Lewis RJ, ed. *Sax's Dangerous Properties of Industrial Materials*, 12th edn. New York: Wiley, 2012: 70–71.
8 Johnson W Jr. Final report on the safety assessment of acetyl triethyl citrate, acetyl tributyl citrate, acetyl trihexyl citrate, and acetyl trioctyl citrate. *Int J Toxicol* 2002; **21**(Suppl 2): 1–17.


## 20 General References


Fadda HM, *et al.* The use of dynamic mechanical analysis (DMA) to evaluate plasticization of acrylic polymer films under simulated gastrointestinal conditions. *Eur J Pharm Biopharm* 2010; **76**(3): 493–497.

Vertellus Specialties Inc. Material safety data sheet: *Citroflex A-2*, November 2010.


## 21 Author

ME Quinn.

## 22 Date of Revision

4 May 2017.

# Adipic Acid

## 1 Nonproprietary Names

PhEur: Adipic Acid
USP–NF: Adipic Acid

## 2 Synonyms

Acidum adipicum; acifloctin; acinetten; adilactetten; asapic; 1,4-butanedicarboxylic acid; E355; 1,6-hexanedioic acid; *Inipol DS*.

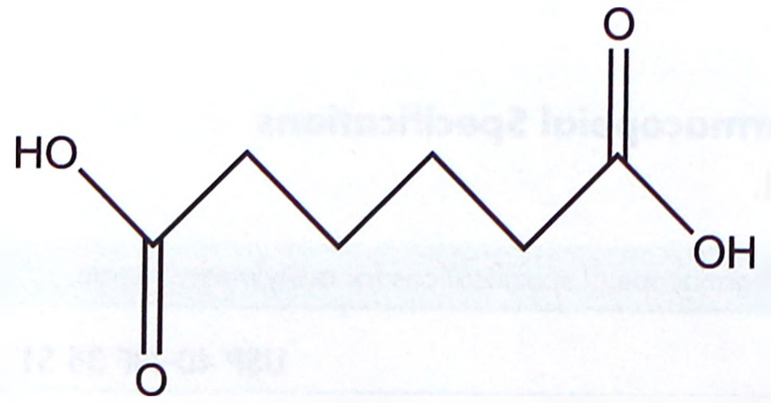
## 3 Chemical Name and CAS Registry Number

Hexanedioic acid [124-04-9]

## 4 Empirical Formula and Molecular Weight

$C_6H_{10}O_4$ 146.14

## 5 Structural Formula




## 6 Functional Category

Acidulant; buffering agent; flavoring agent; modified-release agent.