

16 Regulatory Acceptance

GRAS listed. Accepted for use as a food additive in Europe. Included in the FDA Inactive Ingredients Database (oral capsules and tablets). Included in nonparenteral medicines licensed in the UK. Included in the Canadian Natural Health Products Ingredients Database.

17 Related Substances

Calcium phosphate, dibasic anhydrous; calcium phosphate, dibasic dihydrate.

18 Comments

One gram of tribasic calcium phosphate represents approximately 10.9 mmol of calcium and 6.4 mmol of phosphate; 38% calcium and 17.3% phosphorus by weight.⁽³⁾ Tribasic calcium phosphate provides a higher calcium load than dibasic calcium phosphate and a higher Ca/P ratio. Granular and fine powder forms of tribasic calcium phosphate are available from various manufacturers.

A specification for calcium phosphate tribasic is contained in the *Food Chemicals Codex* (FCC).⁽⁶⁾

The EINECS number for calcium phosphate is 231-837-1. The PubChem Compound ID (CID) for tribasic calcium phosphate includes 24456 and 516943.

Tribasic calcium phosphate is a source of both calcium and phosphorus, the two main osteogenic minerals for bone health. The bioavailability of the calcium is well known to be improved by the presence of cholecalciferol. Recent research reports that combinations of tribasic calcium phosphate and vitamin D3 are a cost-effective advance in bone fracture prevention.⁽⁷⁾

19 Specific References

- 1 Delonca H, *et al.* [Effect of excipients and storage conditions on drug stability I: acetylsalicylic acid-based tablets.] *J Pharm Belg* 1969; 24: 243–252[in French].
- 2 Magid L. Stable multivitamin tablets containing tricalcium phosphate. United States Patent No. 3,564,097; 1971.
- 3 Rhodia. Technical literature: Calcium phosphate pharmaceutical ingredients, 1995.

- 4 Magami A. Basic pentacalcium triphosphate production. Japanese Patent 56 022 614; 1981.
- 5 Verrett MJ, *et al.* Toxicity and teratogenicity of food additive chemicals in the developing chicken embryo. *Toxicol Appl Pharmacol* 1980; 56: 265–273.
- 6 *Food Chemicals Codex*. [online] Bethesda, MD: United States Pharmacopeia. <http://publications.usp.org> (accessed 31 March 2017).
- 7 Lilliu H, *et al.* Calcium-vitamin D3 supplementation is cost-effective in hip fractures prevention. *Muturitas* 2003; 44(4): 299–305.

20 General References

- Bryan JW, McCallister JD. Matrix forming capabilities of three calcium diluents. *Drug Dev Ind Pharm* 1992; 18: 2029–2047.
- Chowhan ZT, Amaro AA. The effect of low- and high-humidity aging on the hardness, disintegration time and dissolution rate of tribasic calcium phosphate-based tablets. *Drug Dev Ind Pharm* 1979; 5: 545–562.
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- Pontier C, Viana M. Energetic yields in apatitic calcium phosphate compression: influence of the Ca/P molar ratio. *Polymer International* 2003; 52(4): 625–628.
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21 Author

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22 Date of Revision

4 May 2017.

Ca Calcium Polycarbophil

1 Nonproprietary Names

USP–NF: Calcium Polycarbophil

2 Synonyms

Noveon CA; polycarbophil calcium.

3 Chemical Name and CAS Registry Number

Calcium polycarbophil [9003-97-8] and [126040-58-2]

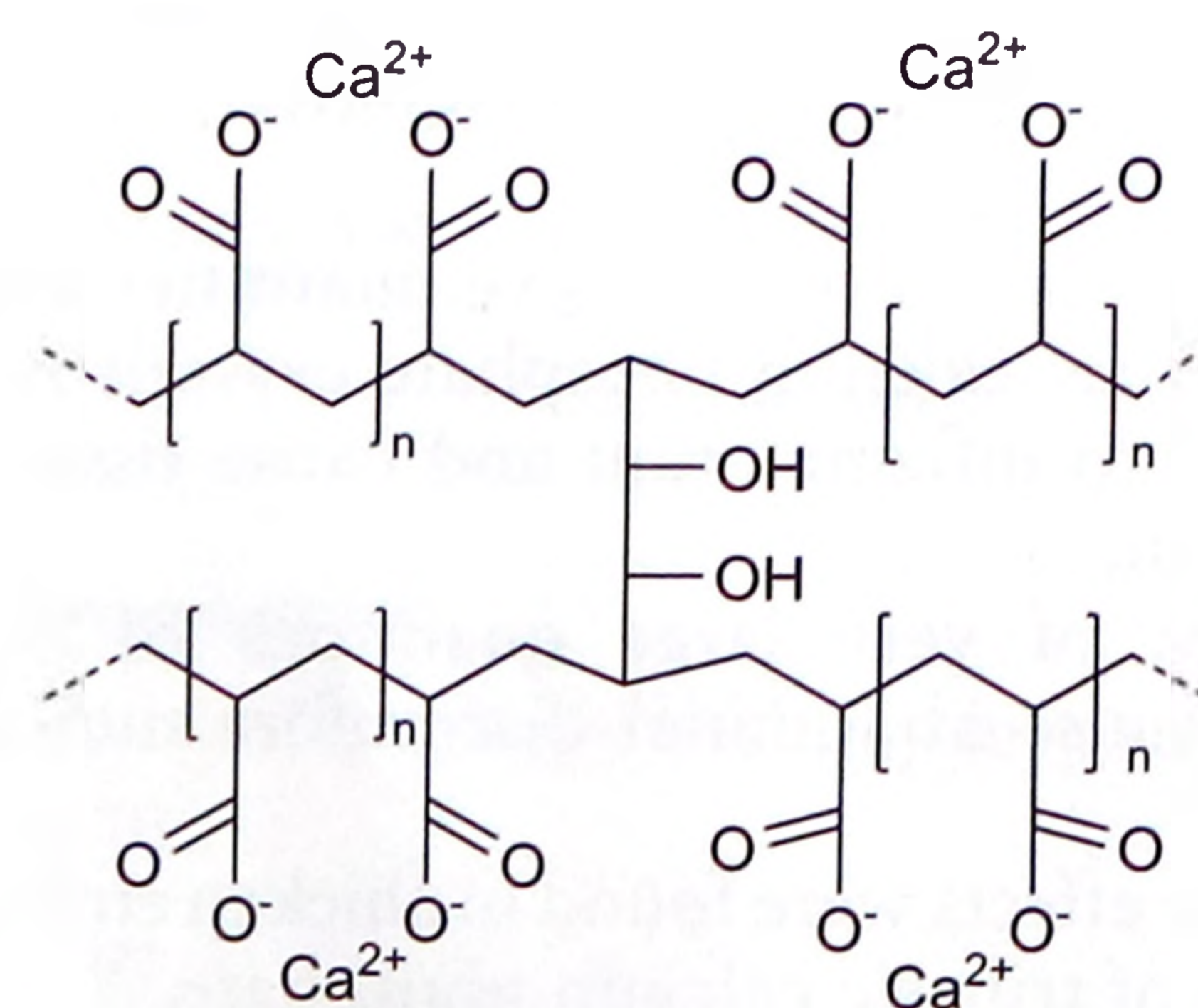
4 Empirical Formula and Molecular Weight

$(C_6H_{10}O_2)_n \cdot (C_3H_3O_2)_n \cdot Ca$

Calcium polycarbophil is the calcium salt of polyacrylic acid polymers crosslinked with divinyl glycol.⁽¹⁾ The molecular weight of these polymers is theoretically estimated to range from 700 000 to 3–4 billion. There are, however, no methods currently available to

measure the actual molecular weight of a crosslinked (i.e. three-dimensional) polymer of this type.

5 Structural Formula



See Section 4.