

Shenzhen Youpuhui Pharmaceutical Co. Ltd Shenkeng, Liuyue Henggang Longgang District Jirong Road 18 518173 Shenzhen City CHINA

Statement concerning the regulatory status of Tricalcium phosphate according to the Chinese Pharmacopoeia

Herewith we, Chemische Fabrik Budenheim KG (Germany), want to inform you that the "Calcium Phosphate" monograph in the Chinese Pharmacopoeia (ChP) refers Beta-Tricalciumphosphate with the CAS number 7758-87-4. The chemical formula is $Ca_3(PO_4)_2$.

The following products sold by Chemische Fabrik Budenheim KG (Germany) with the product names

- TRI-CAFOS® 250
- TRI-CAFOS® 350
- TRI-CAFOS® 500
- TRI-CAFOS® 200-7

however are pentacalcium hydroxide tris(orthophosphate) with the chemical formula $Ca_5(PO_4)_3OH$, which are listed under the CAS number 12167-74-7. To best of our knowledge no monograph exists for these products in the Chinese Pharmacopoeia (ChP).

Named TRI-CAFOS[®] products comply to the monographs as provided in the US Pharmacopoeia (USP-NF) and in the European Pharmacopoeia (Ph. Eur.).

Please note this non-transferable confirmation is restricted to aforementioned amounts/products and cannot be transferred to other products/lots or other clients than the client mentioned in the recipient's box.

*** This statement is computer generated and therefore not signed ***

Any information contained herein and any advice given by Budenheim is made to the best of our ability on the basis of current industrial practice and our own knowledge and experience. Any responsibility for damages resulting from the use of or reliance upon such information or products such information refers to is limited pursuant to our Conditions of sale and supply. Neither our advice nor any information contained herein shall cause the purchaser or any other person or entity using or intending to use our products to refrain from testing our products, verifying any suggestions contained in our information and/or reviewing (and, if relevant, respecting) any conflicting patent and other proprietary rights; relevant to the specific products for the specific products to respect and pulciation intended and to review (and, if relevant, to respect) any conflicting patent and other proprietary rights relevant to the specific product and/or use.

File Name: created by: approved by: QA review by: valid until further notice from:	TCF_Shenzen_regulatory_status_ChP.pdf Sebastian Siegling / Product Management Udo Arenz / Head of Marketing Sonja Schlarb / Quality Assurance December / 2017	Date: Date: Date: until:	Version: 001 December 04 th 2017 December 08 th 2017 December 08 th 2017 November / 2019	
--	---	-----------------------------------	---	--