



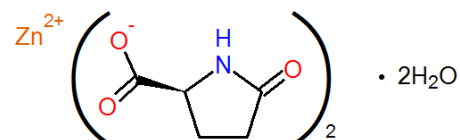
Zinc PCA

Zinc Pyroglutamate Dihydrated

TECHNICAL DOSSIER

QUALITY AND REGULATORY STATEMENTS

Product: **ZINC PCA**
 Substance: **Zinc Pyroglutamate Dihydrated**
 INCI name: **zinc PCA**
 CAS: **15454-75-8**
 EC: **239-473-5**



PRODUCT ORIGIN

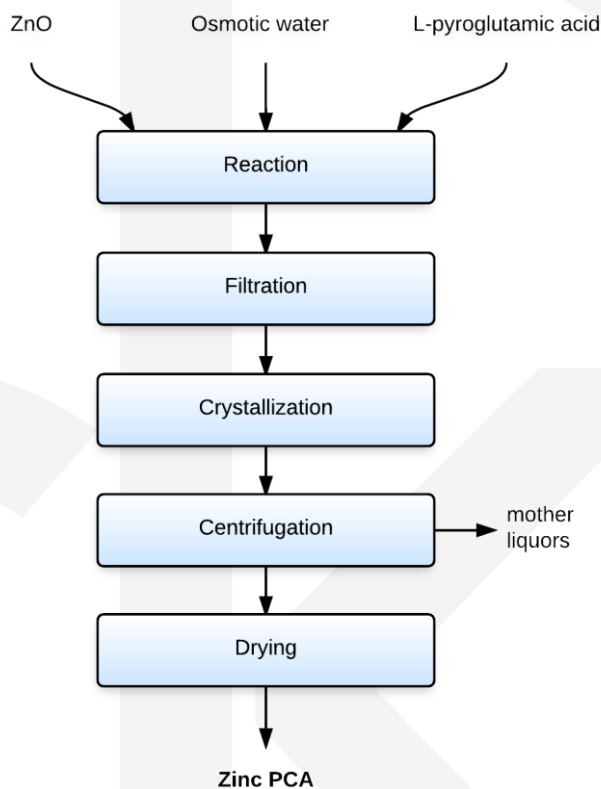
QRD.00480.02.(02)

Country of origin

The product **ZINC PCA** is manufactured in ITALY in the plant of EURO-KEMICAL SRL located in via Sabbioncelli, snc - COVO (BG).

FLOW CHART

QRD.00480.01.(01)





SVHC SUBSTANCES

QRD.00480.27.(01)

ZINC PCA is not a SVHC substance and at the current state of our knowledge and according to current information, on the basis of raw materials used and the production process, we exclude the possibility that impurities (if any) contained in the product **ZINC PCA** are *substances of very high concern*, (reference to the definition given in Article 57 of EC Regulation 1907/2006 REACH, and the list of Annex XIV of the REACH Regulation).

Art.57 Reg. EC 1907/2006: [...

(a) substances meeting the criteria for classification in the hazard class carcinogenicity category 1A or 1B in accordance with section 3.6 of Annex I to Regulation (EC) No 1272/2008;

(b) substances meeting the criteria for classification in the hazard class germ cell mutagenicity category 1A or 1B in accordance with section 3.5 of Annex I to Regulation (EC) No 1272/2008;

(c) substances meeting the criteria for classification in the hazard class reproductive toxicity category 1A or 1B, adverse effects on sexual function and fertility or on development in accordance with section 3.7 of Annex I to Regulation (EC) No 1272/2008;

(d) substances which are persistent, bioaccumulative and toxic in accordance with the criteria set out in Annex XIII of this Regulation;

(e) substances which are very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII of this Regulation;

(f) substances — such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of points (d) or (e) — for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) and which are identified on a case-by-case basis in accordance with the procedure set out in Article 59. ...]

CMR

QRD.00480.16.(02)

At the current state of knowledge and according to the current information, the **ZINC PCA** is not a carcinogenic, mutagenic or toxic for reproduction substance and it cannot be classified as such, as expressed by EC Regulation 1272/2008.

Therefore, this substance is in accordance with Art.15 of REGULATION CE 1223/2009.

NANOMATERIALS

QRD.00480.23.(01)

No nanomaterials, according to the definition provided by the Regulation EC 1223/2009 (Chapter 1, Article 2, paragraph 1, point *k*), are contained in the product **ZINC PCA**, or are used during the manufacturing process by EURO-KEMICAL SRL.

**PROHIBITED SUBSTANCES (as per Reg. EC 1223/2009)**

QRD.00480.32.(03)

The product **ZINC PCA** is not a prohibited substance listed in *ANNEX II* and *ANNEX III* of *REG. EC 1223/2009*.

IMPURITIES DETAILS:

The product Zinc PCA has a degree of purity more than 98% as shown in the table 1.

Substance	Content [%]
Zinc PCA dihydrated	> 98 %
Humidity	< 2 %
Impurities	≤ 0,5 %

table 1 - composition

VOC – RESIDUAL SOLVENTS

QRD.00480.06.(01)

The substance **ZINC PCA** does not contain organic solvents residues or VOC, in compliance with European Directive 2009/32/CE and related amendments.

ANIMAL TESTING

QRD.00480.22.(01)

According to Art.18 Regulation EC 1223/2009, EURO-KEMICAL S.R.L has not carried out animal testing on product **ZINC PCA**, in order to meet the requirements of International Regulations.

HEAVY METALS

QRD.00480.36.(01)

The table 2 shows the analytical results obtained from the research of heavy metals in the product.

Substance	Concentration [mg/kg]
Antimony	< 0,01
Silver	n.r.
Arsenic	< 0,01
Cobalt	< 0,02
Chromium	< 0,05
Mercury	< 0,01
Nickel	< 0,02
Lead	< 0,10

table 2 - Heavy metals

* This document cancels and replaces all previous issues.

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