



## MACCO ORGANIQUES INC.

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THE MANUFACTURING PROCESS OF THE PRODUCTS BELOW ARE COVERED BY A REGISTERED ISO-9001 QUALITY SYSTEM AND A FSSC-22000 FOOD SAFETY SYSTEM

Date: February 06<sup>th</sup>, 2015

Supersedes: August 8<sup>th</sup>, 2012

Official Statement

Ref # : **OVI-RS E -1**

## ***OVI & Residual Solvents / Official Statement***

### **MACCO ORGANIQUES INC' PRODUCTS**

Macco's products, including *calcium acetate*, *calcium propionate*, *potassium acetate*, *potassium benzoate*, *sodium acetates*, *sodium benzoate*, *sodium diacetate* and *sodium propionate*, manufactured at its Valleyfield facility, are free from the ***Residual Organic Solvents*** and meet the ***OVI & Residual Solvents*** requirements as outlined in the USP, EP and CPMP\*/ICH/ 283/95-ICH Q3C (R4) Guidelines.

*\*Note: CPMP, Committee for Proprietary Medicinal Products, now CHMP Committee for Medicinal Products for Human Use, is responsible for preparing the opinions on all questions concerning medicinal products for human use for the European Medicines Agency [EMA](#).*

Based on our knowledge of the manufacturing process and on controlled handling, shipping and storage of the material, there is no potential for organic solvents to be present because the only solvent used in our inorganic synthesis process, is potable water.

Macco's manufacturing facility is a FDA bioterrorism, FSMA and C-TPAT registered facility that operates under an ISO 9001 Quality System, an FSSC 22000 ISO Food Safety System (GFSI approved) and in compliance with food GMP. Macco's facility is audited yearly.