



## MACCO ORGANIQUES INC.

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THE MANUFACTURING PROCESS OF THE PRODUCTS BELOW ARE COVERED BY A FSSC 22000 FOOD SAFETY SYSTEM

Date: February 15, 2023	Supersedes: September 01, 2022	Official Statement	Ref # : <b>NNitA E-1</b>
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### ***No Nitrosamines and amines / Official Statement***

Following US FDA'S Guidance for the control of Nitrosamine Impurities in Human Drugs, European Medicines Agency guidance under Regulation (EC) No 726/2004 Article 5(3) (CHMP's Article 5 (3) opinion EMEA-H-A5(3)-1490) and in accordance with the Hazard Assessment as per ICH Q7M (R1), no potential mutagenic and carcinogenic impurities were identified in any of Macco's products.

**Macco Organiques Inc.**'s products, including *calcium acetate, calcium propionate, potassium acetate, potassium benzoate, potassium chloride, sodium acetate, sodium benzoate, sodium diacetate* and *sodium propionate*, manufactured at its Salaberry-de-Valleyfield plant, are the result of a chemical synthesis which do not make use of *Nitrosamines, Nitrosamines* generating substances such as *Nitrites, Nitrates, Amines (primary, secondary or tertiary), Proteins* and use of any other *Nitrosamines, Amines or Nitrosating agents* containing raw materials, including its food grade packaging. There is no usage of recovered solvents or reagents in the manufacturing process of the products that can lead to the formation of *Nitrosamines* impurities and there is no potential for cross-contamination with *Nitrosamines*.

Hence, based on the knowledge & controls of our incoming raw materials, based on the knowledge & controlled manufacturing processes and based on the controlled handling, storage and shipping of our products, there is no potential for *Nitrosamines or Amines* to be present in all of the Macco's Products.

Macco's manufacturing facility is a FDA bioterrorism, FSMA and C-TPAT registered facility that operates under an ISO Food Safety System FSSC 22000 (GFSI approved) and in compliance with food GMP. Pharmaceutical grade products are manufactured according to cGMPs. Macco's facility is audited yearly.