

ADM Quality Center of Excellence

4666 Faries Parkway Decatur, IL 62526 217.424.5200 | CPTechService@adm.com

Citric Acid Anhydrous Elemental Impurities Statement

As part of our continued effort to provide customers with assurance of compliance to USP-NF monograph specifications, we have tested representative samples of ADM Citric Acid Anhydrous for the Elemental Impurities listed in USP <232>, following AOAC 2013.06 methodology. Results are presented in the table below, including elements that may be present in our product and the average concentration observed. None of the listed elemental impurities are intentionally added during the production of Citric Acid Anhydrous. ADM will conduct testing on a periodic basis in support of compliance with USP <232>.

Elemental Impurity	Sym	Class	Likely to be Present			Permitted Inhalation Concentrations USP <232> Table 3*	Expected Concentration /Units (or Range)*
Arsenic (inorganic)			Yes ⊠	No 🗆	Unknown □	0.2 μg/g	3.5 μg/kg
Cadmium	Cd	1	Yes 🗆	No ⊠	Unknown □	0.2 μg/g	
Mercury (inorganic)	Hg	1	Yes □	No ⊠	Unknown □	0.1 μg/g	
Lead	Pb	1	Yes □	No ⊠	Unknown □	0.5 μg/g	
Cobalt	Со	2A	Yes □	No ⊠	Unknown □	0.3 μg/g	
Nickel	Ni	2A	Yes ⊠	No 🗆	Unknown □	0.5 μg/g	15 μg/kg
Vanadium	V	2A	Yes □	No ⊠	Unknown □	0.1 μg/g	
Silver	Ag	2B	Yes □	No ⊠	Unknown □	0.7 μg/g	
Gold	Au	2B	Yes □	No ⊠	Unknown □	0.1 μg/g	
Iridium	Ir	2B	Yes □	No ⊠	Unknown □	0.1 μg/g	
Osmium	Os	2B	Yes □	No ⊠	Unknown □	0.1 μg/g	
Palladium	Pd	2B	Yes □	No ⊠	Unknown □	0.1 μg/g	
Platinum	Pt	2B	Yes □	No ⊠	Unknown □	0.1 μg/g	
Rhodium	Rh	2B	Yes □	No ⊠	Unknown □	0.1 μg/g	
Ruthenium	Ru	2B	Yes 🗆	No ⊠	Unknown □	0.1 μg/g	
Selenium	Se	2B	Yes □	No ⊠	Unknown □	13 μg/g	
Thallium	T1	2B	Yes □	No ⊠	Unknown □	0.8 µg/g	
Barium	Ва	3	Yes ⊠	No □	Unknown □	30 μg/g	1000 μg/kg
Chromium	Cr	3	Yes ⊠	No □	Unknown □	0.3 μg/g	20 μg/kg
Copper	Cu	3	Yes ⊠	No 🗆	Unknown □	3.0 µg/g	15 μg/kg
Lithium	Li	3	Yes □	No ⊠	Unknown □	2.5 μg/g	
Molybdenum	Mo	3	Yes □	No ⊠	Unknown □	1.0 μg/g	
Antimony	Sb	3	Yes □	No ⊠	Unknown □	2.0 μg/g	
Tin	Sn	3	Yes □	No ⊠	Unknown □	6.0 μg/g	

^{*}Please note that the Permitted Inhalation concentrations are given in parts per million (μ g/g) values and the known/expected concentrations are given in parts per billion (μ g/kg) values. Table 3 in USP 41 lists the permitted concentrations in oral, parenteral and inhalation applications. The lowest permitted concentration given in USP <232> Table 3 is in the Inhalation category.