

March 5, 2021

RE: Elemental Impurities – Calcium Saccharate, Tetrahydrate, USP (Cat# C1830)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. Per the current supply chain, the following elemental impurities are likely to be present:

Elemental Impurity		Class	Expected Concentration
Cadmium	Cd	1	Unknown
Lead	Pb	1	< 3 ppm
Arsenic	As	1	< 3 ppm
Mercury	Hg	1	Unknown
Cobalt	Co	2A	Unknown
Vanadium	V	2A	Unknown
Nickel	Ni	2A	Unknown
Thallium	Tl	2B	Unknown
Gold	Au	2B	Unknown
Palladium	Pd	2B	Unknown
Iridium	Ir	2B	Unknown
Osmium	Os	2B	Unknown
Rhodium	Rh	2B	Unknown
Ruthenium	Ru	2B	Unknown
Selenium	Se	2B	Unknown
Silver	Ag	2B	Unknown
Platinum	Pt	2B	Unknown
Lithium	Li	3	Unknown
Antimony	Sb	3	Unknown
Barium	Ba	3	Unknown
Molybdenum	Mo	3	Unknown
Copper	Cu	3	Unknown
Tin	Sn	3	Unknown
Chromium	Cr	3	Unknown

Unknown elemental impurities showed poor recovery during analysis. Further information regarding expected concentration is unavailable at this time

Other elemental impurities considered by USP <232>, <233> and ICH Q3D which are not addressed in the above mentioned table are not likely to be present. These substances are not used in the production process, are not intentionally added or known to be present in the above mentioned material.

CORPORATE HEADQUARTERS

769 Jersey Avenue
 New Brunswick, NJ 08901
 PHONE 732.214.1300
 FAX 732.246.7132

WEST COAST FACILITY

14422 South San Pedro Street
 Gardena, California 90248
 PHONE 310.516.8000
 FAX 310.516.9843



This information is subject to change and is intended for risk assessment only. It is responsibility of the end user to evaluate suitability of any chemical for the intended use as well as to assess compound-specific limits of daily intake of metal impurities. For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at TechServices@spectrumchemical.com.

Sincerely,

A handwritten signature in black ink that reads "Rebekah J. White". The signature is written in a cursive style.

Rebekah J. White
Technical Service Representative
Spectrum Chemical Mfg. Corp.

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