



**RE: Elemental Impurities - Lactose, Monohydrate, USP/NF, EP, JP, ChP
bioCERTIFIED™ (Cat# L9010)**

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. The following elemental impurities are likely to be present:

| Elemental Impurity | | Class | Expected Concentration |
|--------------------|----|-------|------------------------|
| Cadmium | Cd | 1 | < 0.5 ppm |
| Lead | Pb | 1 | < 0.5 ppm |
| Arsenic | As | 1 | < 1.5 ppm |
| Mercury | Hg | 1 | < 3 ppm |
| Cobalt | Co | 2A | < 5.0 ppm |
| Vanadium | V | 2A | < 10 ppm |
| Nickel | Ni | 2A | < 20 ppm |
| Selenium | Se | 2B | < 15 ppm |
| Lithium | Li | 3 | < 55 ppm |
| Antimony | Sb | 3 | < 120 ppm |
| Barium | Ba | 3 | < 140 ppm |
| Molybdenum | Mo | 3 | < 300 ppm |
| Copper | Cu | 3 | < 300 ppm |
| Tin | Sn | 3 | < 600 ppm |
| Chromium | Cr | 3 | < 1100 ppm |

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.

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.

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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,

Technical Services
Spectrum Chemical Mfg. Corp.

This document has been produced electronically and is valid without a signature.

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