



RE: Elemental Impurities - White Wax, Pastilles, NF (Cat# W1122)

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	< 0.10
Lead	Pb	1	< 0.1
Arsenic	As	1	< 0.1
Mercury	Hg	1	< 0.05
Cobalt	Co	2A	< 0.10
Vanadium	V	2A	< 0.20
Nickel	Ni	2A	< .040
Thallium	Tl	2B	< 0.10
Gold	Au	2B	< 0.75
Palladium	Pd	2B	< 0.42
Iridium	Ir	2B	< 0.42
Osmium	Os	2B	< 0.38
Rhodium	Rh	2B	< 0.42
Ruthenium	Ru	2B	< 0.42
Selenium	Se	2B	< 0.10
Silver	Ag	2B	< 0.10
Platinum	Pt	2B	< 0.42
Lithium	Li	3	< 2.30
Antimony	Sb	3	< 0.10
Barium	Ba	3	< 5.8
Molybdenum	Mo	3	< 0.10
Copper	Cu	3	0.13
Tin	Sn	3	< 0.20
Chromium	Cr	3	0.53

Elements indicated as "Not tested" are not intentionally added to the manufacturing process.

* Lead is present below the limit of 10 ppm under the specification Lead as required by the USP monograph.

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



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.

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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