



BRINGING
MINERALS
TO LIFE...



Supplier Name: Macco Organiquae, s.r.o. Supplier Address: Zahradní 46c, 792 01 Bruntál, Czech Republic	Date Form Filled Out: 12.9.2018 Signature:
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Directions: Identify elemental impurities in (Material Name) that are likely to be present. If likely to be present, identify expected concentration (or range), analytical method used and limit of detection, if known. Please note if any metals catalysts or reagents are intentionally used in the manufacturing process in the Comments column.

Please complete a separate form for each material

Material Name Sodium hydrogen carbonate
 Source/Type of Excipient: ___ Mineral ___ Mineral derived ___ Plant ___ Plant derived ___ Synthetic ___ Fermentation derived
 Other (explain):

Elemental Impurity	Class	Likely to be Present			If Known, Please Identify the Expected Concentration /Units (or Range)	Analytical Method Used (and Limit of Detection if Available)	Comments regarding source of information (i.e.; frequency of testing, process understanding, etc.)
		Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>			
Arsenic (inorganic)	1	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	<0.5 mg/kg	Limited method	Specification limit NMT 2 ppm
Cadmium	1	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	<0.2 mg/kg	ICP-MS	
Mercury (inorganic)	1	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	<0.02 mg/kg	AAS	
Lead	1	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	<0.5 ppm	Limited method	Heavy metals as Pb Specification limit NMT 10 ppm
Cobalt	2A	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input checked="" type="checkbox"/>			
Nickel	2A	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input checked="" type="checkbox"/>			
Vanadium	2A	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input checked="" type="checkbox"/>			



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		Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input checked="" type="checkbox"/>			
Silver	2B	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input checked="" type="checkbox"/>			
Gold	2B	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input checked="" type="checkbox"/>			
Iridium	2B	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input checked="" type="checkbox"/>			
Osmium	2B	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input checked="" type="checkbox"/>			
Palladium	2B	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input checked="" type="checkbox"/>			
Platinum	2B	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>			
Rhodium	2B	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input checked="" type="checkbox"/>			
Ruthenium	2B	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input checked="" type="checkbox"/>			
Selenium	2B	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input checked="" type="checkbox"/>			
Thallium	2B	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input checked="" type="checkbox"/>			
Barium	3	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input checked="" type="checkbox"/>			
Chromium	3	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input checked="" type="checkbox"/>			
Copper	3	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input checked="" type="checkbox"/>			
Lithium	3	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input checked="" type="checkbox"/>			
Molybdenum	3	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input checked="" type="checkbox"/>			
Antimony	3	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input checked="" type="checkbox"/>			
Tin	3	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input checked="" type="checkbox"/>			

Reference: ICH Q3D Guideline for Elemental Impurities, Step 4 version, September 2014