

## Identification of Potential Elemental Impurities Statement

<b>Manufacturer Names &amp; Addresses:</b>  <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <b>ISP Technologies Inc.</b>  <b>4501 Attwater Ave.</b>  <b>Texas City, TX 77590 USA</b> </div> <div style="width: 45%;"> <b>ISP Chemicals LLC</b>  <b>455 North Main Street</b>  <b>Calvert City, KY 42029</b> </div> </div>	<b>Contact Phone Number: 302-995-3400</b>  <b>Contact Email Address: pszawislak@ashland.com</b>  <b>Date Form Filled Out: April 6, 2015</b>
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Material Name \_\_\_\_\_ Plasdone™ povidone \_\_\_\_\_

Source/Type of Excipient:   \_\_\_Mineral   \_\_\_Mineral derived   \_\_\_Plant   \_\_\_Plant derived    \_X\_\_\_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.)
Arsenic (inorganic)	As	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.5 ppm	ICP-MS (detection limit is 0.5 ppm for ALL elements)	Test every lot
Cadmium	Cd	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.5 ppm	ICP-MS	Test every lot
Mercury (inorganic)	Hg	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.5 ppm	ICP-MS	Test every lot
Lead	Pb	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.5 ppm	ICP-MS	Test every lot
Cobalt	Co	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.5 ppm	ICP-MS	Test every lot
Nickel	Ni	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.5 ppm	ICP-MS	Test every lot
Vanadium	V	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.5 ppm	ICP-OES (limit of detection is 0.5 ppm for ALL elements unless otherwise noted)	16 samples
Silver	Ag	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.5 ppm	ICP-MS	Test every lot
Gold	Au	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.5 ppm	ICP-OES	16 samples

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Iridium	Ir	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.5 ppm	ICP-OES	16 samples
Osmium	Os	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.5 ppm	ICP-OES	16 samples
Palladium	Pd	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.5 ppm	ICP-OES	16 samples
Platinum	Pt	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.5 ppm	ICP-OES	16 samples
Rhodium	Rh	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.5 ppm	ICP-OES	16 samples
Ruthenium	Ru	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.5 ppm	ICP-OES	16 samples
Selenium	Se	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<1.3 ppm	ICP-OES (limit of detection 1.3 ppm)	16 samples
Thallium	Tl	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.5 ppm	ICP-OES	16 samples
Barium	Ba	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.5 ppm	ICP-OES	16 samples
Chromium	Cr	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.5 ppm	ICP-MS	Test every lot
Copper	Cu	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.5 ppm	ICP-MS	Test every lot
Lithium	Li	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.5 ppm	ICP-OES	16 samples
Molybdenum	Mo	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.5 ppm	ICP-MS	Test every lot
Antimony	Sb	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.5 ppm	ICP-MS	Test every lot
Tin	Sn	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.5 ppm	ICP-MS	Test every lot

Reference: ICH Q3D Guideline for Elemental Impurities, Dec 2014