

## Statements for Standard One-Shot™ Single-Use Filler Needles with Polycarbonate Hubs

(Does not apply for coated needles or check-valve needles)

<b>USP Class VI:</b>	The polycarbonate resin utilized for the manufacture of the hub component of the One-Shot™ Single-Use Filler needle is USP Class VI.
<b>Latex:</b>	Overlook Industries, Inc. does not manufacture the referenced product with any intentional use of natural or synthetic rubber latex.
<b>Melamine:</b>	Based on a statement from Overlook Industries, Inc.'s polycarbonate supplier, the supplier does not manufacture the resin with any intentional use of Melamine. Overlook Industries, Inc. does not manufacture the referenced product with any intentional use of melamine or melamine-containing materials.
<b>REACH Compliance:</b>	Overlook Industries, Inc. certifies that its One-Shot™ Single-Use Filler Needles do not contain any of the 240 REACH SVHCs as updated by ECHA on January 23, 2024, in thresholds exceeding 0.1% by weight.
<b>BPA:</b>	The fluid path for One-Shot™ Single-Use Filler Needles is made of 316L Stainless Steel and does not contain the chemical Bisphenol A. The hub is made of polycarbonate, which is known to contain BPA, but is not product contact. The polycarbonate resin used to manufacture may contain Bisphenol-A up to 100ppm or 0.1%. A final assembled One-Shot™ Single-Use brand needle, with 316L Stainless Steel tube and Polycarbonate Hub, contains Bisphenol-A at a level of <0.1%, in compliance with REACH.
<b>Phthalates:</b>	The fluid path for One-Shot™ Single-Use Filler Needles with polycarbonate hubs is made of 316L Stainless Steel and does not contain phthalates (DEHP, DBP, BBP, DINP, DIDP, DNOP, DOP). The polycarbonate raw material utilized in the One-Shot™ Single-Use hubs is not manufactured using any of the above listed phthalates.
<b>RoHS:</b>	Overlook Industries, Inc. does not manufacture electrical or electronic equipment as categorized in the Restriction of Hazardous Substances Directive. Overlook Industries, Inc. does not manufacture with any of the hazardous substances as listed in the Restriction of Hazardous Substances Directive and therefore is considered compliant.
<b>Nitrosamines</b>	Overlook Industries, Inc. confirms that its One-Shot™ Single-Use Filler Needle line listed above does not utilize raw materials that contain Nitrosamines and that the manufacturing process of the final product onsite does not add Nitrosamines.
<b>Allergens:</b>	Overlook Industries, Inc. does not manufacture the above-listed product line with any intentional use of raw materials that contain allergens.
<b>GMO:</b>	Overlook Industries, Inc. does not manufacture the above-listed product line with any intentional use of raw materials that come from GMO sources.
<b>TSE/BSE:</b>	To the best of Overlook Industries, Inc. knowledge, the products at Overlook Industries, Inc. pose a negligible risk of Transmissible Spongiform Encephalopathies (TSE)/Bovine Spongiform Encephalopathy (BSE) transmission due to being either free of Animal Derived Ingredients (ADI) or inactivation with chemical/heat/pressure treatments.
<b>GAMMA Compatibility /Shelf Life:</b>	Overlook Industries, Inc. One-Shot™ Single-Use Filler Needles with polycarbonate hubs have been validated to hold a 5-year shelf life from the date of manufacture and are GAMMA Compatible up to 40kGy.

Please note that analysis of the raw materials and/or finished products for the presence of the materials listed above is not conducted by Overlook Industries, Inc. and therefore it shall not be construed as any warranty, expressed, or implied.

The statements above are based on our current level of knowledge and covers the referenced product as supplied by Overlook Industries at the date of issue of this document.

Signed,



Kim DiManno  
Quality Manager