LevGo® smartSpatula® Multipurpose Disposable Laboratory Spatula **Regulatory Status Statement 2024**

Statement of Intended Use – LevGo Disposable Laboratory Spatulas (Cat. Nos. 17211, 17221, 17231, 17241, 17251, 17261, and 17271) are intended for **Research Use Only** and are **Not** medical devices.

Food Contact Status – Randomly selected representative samples of each base model (17211, 17221, 17231, 17241, and 17261) are SGS tested to assure that they meet US and EU food contact standards: FDA 21CFR Part 177 subpart B: Substances for Use as Basic Components of Single and Repeated Use Food Contact Surfaces, part 177.1520 and Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004, (EU) No 10/2011 and its amendment (EU)2020/1245 (Overall migration, Sensorial examination odor and taste test, Specific Migration of Primary Aromatic Amine (Total) . All models passed these tests. Sterile spatulas are not re-tested as they are comprised of catalog no 17221 that has been repackaged and EtO Sterilized in the USA.

Nitrosamines – Only food contact grade materials, processing and packaging are specified in the manufacture of the LevGo Spatulas. Specific Migration of Primary Aromatic Amine (Total) testing is performed on random samples annually. See Food Contact Status statement above for details.

RoHS – RoHs refers to EU rules restricting the use of hazardous substances in electrical and electronic equipment. RoHS does not apply to LevGo spatulas.

REAch SVCH – Substances of Very High Concern. No substances of very high concern are specified in the manufacture of LevGo spatulas, nor are they expected to be present.

Toxics in Packaging Clearinghouse (TPCH) – Lead, mercury, cadmium, and hexavalent chromium were not intentionally added to any package or packaging component of LevGo spatulas during the manufacturing process.

Dodd-Frank Conflict Minerals – No minerals (conflict or otherwise) are specified in the manufacture of LevGo spatulas.

Heavy Metals – LevGo spatulas are not intentionally formulated with heavy metals, and none are expected to be present. SGS Testing per Regulation (EC) No 1935/2004 of the European Parliament and the Council of 27 October 2004, (EU) No 10/2011 and its amendment (EU) 2020/1445 Regulation – Specific Migration of Heavy Metals is performed annually on random samples. These samples all passed the test.

Lacey Act – No wildlife, fish or plants are specified in the manufacture of LevGo spatulas. The antistatic micro spatula (17231) does contain an FDA food contact compliant internal antistatic agent (~0.04%) that is formulated with animal derived substances. See BSE/TSE statements below.

California Proposition 65 - LevGo spatulas do not contain any substances requiring labelling according to the Safe Drinking Water and Toxic Enforcement Act.

Allergens - LevGo spatulas are not formulated with known allergens, such as: peanuts, tree nuts, refined or unrefined oils, milk or milk products, eggs, wheat, and soy.

Latex - LevGo spatulas are not formulated with latex or natural rubber latex.

Melamine - LevGo spatulas are not formulated with melamine.

Animal Derived, TSE & BSE Statement - Cat Nos 17211, 17221, 17241, 17251, 17261 and 17271. No raw materials that contain, or are derived from, animals are specified in the manufacture of these LevGo spatula catalog numbers.

Animal Derived, TSE & BSE Statement - Cat No 17231. The LevGo Micro Antistatic spatulas are made of 96% PP and 4% AMPACET 40390 Hostat 10 BOPP Masterbatch, an internal anti-static agent additive, which is made of 90% food grade PP and 10% active ingredient. The net effect is that the 17231 Micro Antistatic spatulas contain ~0.4% of the active ingredient. The following statements in italicized text have been excerpted in their entirety from the Ampacet Regulatory Status document for 40390 Hostat 10 BOPP Masterbatch and relate only to the Ampacet additive that is used to give the Micro Antistatic spatulas the desired level of surface resistivity:

> *"One or more of the raw materials used in the manufacture of this product originated in whole or in part from animal sources. The animal sourced raw material(s) have been chemically altered from of their original structure and have undergone significant chemical processing. Because of these processing conditions this material is expected to meet or exceed the human and veterinary medicine guidance requirements for minimizing the risk of transmitting animal spongiform encephalopathy agents as of the effective date of this regulatory status document." Ampacet Regulatory Status document dated June 2016*