



To: Compliance

Subject: REACH, RoHS, MDR Declaration Statement

May 2, 2023

Dear Valued Customer,

The products that are manufactured by Pelham Plastics Inc are done so in our facility in Pelham, New Hampshire. Please note that Pelham Plastics does not test products for compliance analysis. The information provided is based upon information from raw material and component suppliers, product composition, and Pelham Plastics Inc. manufacturing process knowledge.

**REACH Declaration**

In accordance with Article 59 of the European Union Regulation 1907/2006 on Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH), the European Chemicals Agency periodically publishes lists identifying Substances of Very High Concern, or SVHCs. The SVHC list was updated on January 17, 2023, increasing the number of substances. The products manufactured by Pelham Plastics do not have any of these SVHCs intentionally added, and therefore we believe are not contained above 0.1% by weight.

**RoHS 2 Declaration**

RoHS is defined in Directive 2011/65/EU, and the RoHS Amendment (EU) 2015/863 sets restrictions on the use of certain hazardous substances in electric and electronic equipment. RoHS specifically restricts the concentration of the following materials: lead, mercury, hexavalent chromium, polybrominated biphenyls (PBB), polybrominated diphenyl ethers (PBDE), and other polybrominated compounds to a level equal to or less than 0.1% by weight. It further restricts the use of cadmium to equal to or less than 0.01% by weight. The products manufactured by Pelham Plastics do not contain any of the RoHS-listed chemicals and are compliant with both RoHS Directives and Amendments.

**Medical Devices Regulation**

The EU Medical Devices Regulation, MDR 2017/745, sets high standards of quality and safety for medical devices in order to meet common safety concerns regarding such products. The regulation specifically restricts certain carcinogenic, mutagenic, and reproductive toxins (CMR) and endocrine-disrupting chemicals (EDC). CMR's and EDC's must be limited to a concentration below 0.1% by weight unless justification for their use can be provided. The products manufactured by Pelham Plastics do not contain any of the restricted substances listed in the MDR regulation.

The above statements are based on information available at this point in time and are believed to be accurate. Please consider this information confidential and privileged. Pelham Plastics Inc. will keep track of any relevant changes regarding this compliance certificate and keep customers informed of any updated information. These statements do not bind Pelham Plastics Inc. to any legal obligations. Pelham Plastics Inc is providing these statements in good faith, but no warranties are made, and no liability is accepted.

Sincerely,

Scott Smith  
Sales & Marketing Account Manager