



To Whom It May Concern:

Your request for a Material Safety Data Sheet (MSDS) for Durasphere® Injectable Bulking Agent has been received. United States (US) federal and state Occupational Safety and Health Administration (OSHA) laws require that employees are given information regarding hazardous substances. The written information on hazards is provided on forms called Material Safety Data Sheets (MSDS).

Durasphere® Injectable Bulking Agent is a US Food and Drug Administration (FDA) class III medical device. This device was approved for commercialization by the FDA through the pre-market approval (PMA) process and as such does not fit the OSHA definition of a hazardous substance.

A requirement of the PMA process is that safety data be provided in the product labeling. If you have any further questions regarding the product, please refer to the labeling and instructions for use that accompanies the product.

Sincerely,

A handwritten signature in blue ink, appearing to read "Andrew Adams", is written over a horizontal line.

Andrew Adams

Director – Regulatory Affairs & Quality Assurance
Carbon Medical Technologies, Inc.